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**THE HUMAN RIGHT TO MEDICINES  
IN SUB-SAHARAN AFRICA**

**L. Niada**

**PhD  
2010**

**THE HUMAN RIGHT TO MEDICINES  
IN SUB-SAHARAN AFRICA**

**Laura Niada**

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requirements of the University of Westminster  
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## ABSTRACT

The sub-Saharan African people experience the greatest burden of disease in the world although medicines exist that can treat the majority of the illnesses afflicting them. In fact, many essential medicines are not accessible for most of the people in the region. While the lack of resources is apparently a major impediment for access to medicines, man-made deliberations are also consequential, and can to some extent be influenced by regulation. The research question of this thesis therefore is: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. In effect, in the last decade the notion of an international human right to medicines has started to develop in the human rights law and literature, prescribing that ultimately all individuals shall have access to medicines. This work contributes to the international human rights law doctrine by studying this area of the law, which is still largely uncharted.

The thesis, furthermore, moves from a descriptive analysis of the law and undertakes a critical normative enquiry, underscoring the challenges of utilising human rights law to guide and redress access to medicines in sub-Saharan Africa. In effect, the contingencies of access to medicines within complex health systems make it practically difficult to identify the appropriate arrangement of access to medicines in a country. Moreover, policies and regulation for access to medicines can be morally questionable if conflicting with individuals’ legitimate rights, interests, needs and liberties. The relevance and merits of my arguments are grounded on different instances of critical-analytical research. I will use in particular interdisciplinary and empirical research on access to medicines, including a two-month field work in Tanzania, as well as the theoretical insights drawn from Luhmann’s social systems theory and Foucault’s theory of biopower. Therefore the thesis provides an ethical analysis of the potential operationalisation and implementation of the human right to medicines in sub-Saharan Africa. This analysis is also a case-study intervention to the debates concerning more generally health care, public health, development and human rights in the region. Moreover, the thesis contributes to socio-legal studies identifying the phenomena of autopoiesis, contingency, power and the limits of steering affecting human rights, law and politics.

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Make everything as simple as possible, but not simpler.

Albert Einstein

In order to know anything it is necessary to know everything, but in order to talk about anything it is necessary to neglect a great deal.

John Robertson

The best and most beautiful things in the world cannot be seen or even touched. They must be felt with the heart.

Helen Keller

## CHAPTER 1: INTRODUCTION

### 1.1 Introduction

This introductory chapter presents my research question relating to the human right to medicines in sub-Saharan Africa: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. The chapter first illustrates the current events which have predominantly galvanised attention to the theme of access to medicines worldwide, in particular with regard to the situation of sub-Saharan Africa. It then frames my research question with respect to the existing scholarly debates regarding the human right to medicines. Consequently, the chapter presents the arguments defended by the thesis relating to the challenges of utilising human rights law to guide and redress access to medicines in sub-Saharan Africa. The relevance and merits of my arguments are grounded on different instances of critical-analytical research, which are considered in dialectic between them. Namely, these features are: the legal study of the human right to medicines *de jure*; interdisciplinary and empirical research on the realisation of the right *de facto*; and theoretical insights from socio-legal studies, in particular drawn from Luhmann’s social systems theory and Foucault’s theory of biopower. The chapter consequently delineates my methodology, states the contribution to knowledge I seek and provides the outline of the thesis.

### 1.2 Access to medicines and current events

The theme of access to medicines has gained attention in contemporary debates due to the coincidence of some momentous events that occurred throughout the last three decades.<sup>1</sup> Some of those events specifically relate to sub-Saharan Africa.<sup>2</sup> A non-exhaustive list counts, first, the diffusion of the HIV/AIDS pandemic from the 1980s onwards which has attracted discussion about access to treatment across the world [Leach et al 2005: 23]. Second, the establishment of international arrangements on

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<sup>1</sup> On the emergence of the theme of access to medicines *see generally* WHO, How to Develop and Implement a National Drug Policy [2001: vii]; Lewis-Lettington and Munyi [2004]; Leach et al [2005]; and Klug [2005].

<sup>2</sup> For the definition of sub-Saharan Africa *see* Chapter 2 section 2.1.

intellectual property have conveyed attention to access to medicines as they can curtail access to cheaper generic medicines, especially to poorer countries. In particular, in 1995 the Trade-Related Intellectual Property (TRIPS) Agreement has entered into force. The Agreement sets out duties, enforceable at the World Trade Organisation (WTO), to protect a minimum standard of intellectual property rights, including patents on medicines [Lewis-Lettington and Munyi 2004: 9]. Third, old, widely-marketed medicines, such as those used in developing countries for the treatment of AIDS, malaria and tuberculosis, have encountered resistance and had to be replaced by innovative products which are patentable and often more expensive, raising again the issue of access to patented medicines [Lewis-Lettington and Munyi 2004: 9]. Fourth, since the 1980s many countries have undertaken structural adjustment of the public sector and health-care reform which have imposed a critical reconsideration of the provision of health services by the public health sector, including the provision of medicines. Fifth, health has increasingly been recognised as an instrument and a goal of international development. For example, three out of eight Millennium Development Goals (MDGs) are related to health and entail access to medicines.<sup>3</sup> Sixth, the problem of priorities in health care is subject to intense public debate in ‘developed’ countries where the state provides health assistance. For example, in the United Kingdom (UK) the advice on treatment based on cost-effectiveness undertaken by the National Institute for Health and Clinical Excellence (NICE) often raises fierce criticism with regard to the failure to recommend certain cancer therapies at the national level [Rawlins and Culyer 2004]. The public eye has also been alerted worldwide about the rationing of vaccines and treatments for the last treacherous outbreaks of influenza pandemics, such as the recent 2009 ‘swine flu’ pandemic.<sup>4</sup> Seventh, in effect, civil society has become increasingly vocal in advocating for access to medicines [Klug 2005]. With regard to sub-Saharan Africa, it can be recalled that civil society groups campaigning worldwide obtained the withdrawal of the Pharmaceutical Manufacturers Association from the notorious case it presented at the South African Constitutional Court [Klug 2008: 222-3]. In this case, the Pharmaceutical Manufacturers Association argued that the provisions in the South Africa’s Patent Act favouring parallel importation and compulsory licenses were unconstitutional [South Africa, *PMA v. South Africa*, 2001]. Those pieces of law can in effect be used in South Africa to procure cheaper generic medicines [South Africa, *PMA v. South Africa*, 2001;

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<sup>3</sup> See Chapter 4 section 4.3.1 and Chapter 6 section 6.4.1.

<sup>4</sup> See, e.g., the article tellingly titled on the Wall Street Journal: “If We Must Ration Vaccines for a Flu, Who Calls the Shots” [Begley 2006].

Klug 2008: 222-3]. Always in South Africa, the South African non-governmental organisation Treatment Action Campaign set up and won a legal case against the government for the provision of nevirapine – an antiretroviral medicine which helps preventing mother to child transmission of HIV – in public health facilities [South Africa, *Ministry of Health v. TAC*, 2002; Klug 2008].<sup>5</sup> The case was decided considering inter alia the government's constitutional obligations with regard to the human right to health [*id.*]. In sum, as Lewis-Lettington and Munyi put it:

Within the health care sector, access to medicines has traditionally been considered within the context of broader issues of health care provision. However, the resurgence of, and emergence of drug resistance in historically problematic public health problems, particularly tuberculosis (TB) and malaria, together with the emergence of the HIV/AIDS pandemic over the last 20 years, has increasingly focused attention on the cost and supply of medicines. These questions have become particularly sensitive with the increasing enforcement of intellectual property rights since... the entry into force of the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995. [Lewis-Lettington and Munyi 2004: 9]

In particular, my study focuses on access to medicines in sub-Saharan Africa, where medicines are particularly needed but access to medicines is particularly poor. The sub-Saharan African people are afflicted by poorest health conditions. These allegations are discussed in Chapter 2 but it is mentioned here that the level of mortality is by far higher than that in other regions, as life expectancy at birth is on average 46 years [Adetunji and Bos 2006: 12]. Also, the measurement of disability adjusted life years (DALYs) lost to disease suggests that sub-Saharan Africa accounts for 25% of the world burden of disease, the largest share [WHO, *The World Health Report*, 2003: 120]. Yet most of the burden is engendered by preventable, treatable and contagious diseases: some medicines exist which can contribute to cure or alleviate the conditions affecting the people of the region. However, reportedly, basic medicines are not accessible – *ie* available and affordable – to approximately one half of the people living in sub-Saharan Africa [WHO, *The World Medicines Situation*, 2004: 62].<sup>6</sup> Only India fares worse in terms of percentage of WHO regional population without access [*id.*].

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<sup>5</sup> See Chapter 5 section 5.4.3

<sup>6</sup> See generally Chapter 2.

### 1.3 The human right to medicines: my research question

The problem of access to medicines in sub-Saharan Africa, in principle, could be countered by the international human right to medicines. The notion of a human right to medicines has started to develop in the human rights discourse and prescribes that ultimately all individuals shall have access to medicines. In the last decade, for example, the Committee on Economic, Social and Cultural Rights (CESCR), which monitors the implementation of the United Nations-sanctioned International Covenant on Economic, Social and Cultural Rights (ICESCR), has identified the provision of essential medicines as a duty that the signatories to the ICESCR shall realise immediately [CESCR 2000: para. 17]. The African Commission on Human and Peoples' Rights (hereinafter African Commission) has recently issued a resolution recognising that "access to needed medicines is a fundamental component of the human right to health" [AC Res. 141 (2008): preambular para. 5]. The United Nations (UN) Special Rapporteur on the human right to health has expressly reported to the UN General Assembly on the human right to medicines [Hunt 2006]. At the domestic level the human right to medicines is not generally explicitly declared *de jure*. However, access to essential medicines has been successfully claimed – although sporadically – in court cases with reference to the human right to health, or to applicable human rights treaties.<sup>7</sup> The human right to health or the human right to health care is in effect recognised in at least 115 constitutions (at least six other constitutions set out duties in relation to health, such as the duty on the State to develop health services or to allocate a specific budget to them) [UNOHCHR and WHO 2008: 10]. Among the 48 sub-Saharan African countries I could count the human right to health or health care as enshrined in 31 countries [Kinney and Clark 2004]. In the doctrine, some scholars have started investigating a human right to medicines. The scholarly literature on the human right to medicines is however still scarcely developed, and this thesis also aims at overcoming this gap. Among the rare examples, Hestermeyer and Yamin have written articles, respectively, on "Access to Medication as a Human Right" [Hestermeyer 2004], and "Not Just a Tragedy: Access to Medications as a Right

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<sup>7</sup> Hogerzeil and colleagues for example have identified and analysed 71 completed court cases from 12 low-income and middle-income countries in which individuals or groups had claimed access to essential medicines with reference to the right to health in general, or to specific human rights treaties ratified by the government. They found that in 59 cases access to essential medicines as part of the fulfilment of the right to health could indeed be enforced through the courts. Most cases came from Central and Latin America, with South Africa being the only African case identified [Hogerzeil et al 2006: 305]. See *generally* Chapters 3 and 5.

under International Law” [Yamin 2003]. Non-governmental organisations and the WHO also see access to medicines (or ‘essential’ medicines) as a human right [Oxfam 2007: 31; South Centre 2001; WHO, WHO Medicines Strategy 2004-2007: 32].

Thus my research question is: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?” By asking ‘can’, the question is two-fold. First, I intend a *descriptive* enquiry of the law asking whether access to medicines can be framed in international human rights law as a human right to medicines. If so, I ask what duties the human right to medicines imposes, on what actors, and how the right can be enforced. Second, I intend a *normative* enquiry asking if the problem of access to medicines in sub-Saharan Africa *ought to* be solved by utilising the hypothetical human right to medicines. From a normative point of view, a human right to medicines presents, in principle, two interesting features for access to medicines in sub-Saharan Africa. First, a human right could give to access to medicines supremacy to overrule ordinary law and government policies. Secondly, the international human right to medicines could provide a regulatory and policy framework for a comprehensive approach to access to medicines, at the national and international level. Indeed, as it will be shown, access to medicines involves a variety of interwoven factors and actors. In effect, however, interventions on access to medicines are problematic. Given the contingencies of access to medicines within complex health systems it may be difficult to identify the appropriate arrangements for access to medicines in a country. Moreover, policies and regulation for access to medicines can conflict with legitimate needs, interests and rights in society. Therefore, the normative question cannot but be answered by enquiring about *how* the right is to be operationalised (*ie* provided with a precise content through the identification of good practices and policies) and implemented.<sup>8</sup>

Some problematic issues relating to the operationalisation and implementation of a human right to medicines are mentioned here by way of illustration. Certain important instances of international human rights law oblige home states to provide ‘essential’ medicines [CESCR 2000; Yamin 2003; Hestermeyer 2004; Hunt 2006; AC Res. 141 (2008)]. However health needs are virtually infinite while financial resources are scarce. Therefore, the government has to make choices as to which treatment and medicines are

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<sup>8</sup> Operationalisation is here defined as the attribution of precise content to a concept, in this case the human right to medicines, through the identification of good practices and policies. This definition has been used by the UN Human Rights Council [Human Right Council, Res. 29 (2007): para. 2(c)].

‘essential’. This prioritisation poses questions of medical ethics. ‘Essential’ medicines and essential care, in effect, are not necessarily identified as those for mortal or common diseases. Rather the identification of essential treatment can be informed by different criteria such as how diffused the condition is, what effects it has on society, who is principally affected by it, how debilitating it is on the individual, how cost-effective it is to treat it [Brock 2002; Daniels 1981, 1983, 1985, 2002, 2008; Gruskin and Daniels 2008; Hope et al 2002; Kamm 2002; McKie and Richardson 2003; Menzel 1990; Menzel 2002; Ozar 1983; Sheaff 1996; Stell 2002]. Furthermore, if more resources are to be raised, how much burden can be justified? In operational terms, choices have to be made on the proportion of primary (first point of consultation), secondary (specialist) and tertiary (specialised on referral) care to be provided or if favouring horizontal (which regard the health-care system at once, for instance through primary health care) or vertical (disease-oriented) interventions [*id.*]. Next, it has to be considered that the state is not necessarily efficient and effective when operating the health-care system and providing medicines [Lush 2002, 2004; Leach et al 2005: 80-81].<sup>9</sup>

With regard to intellectual property, the UN Special Rapporteur on the human right to health and the African Commission both demand the government to utilise the so-called TRIPS flexibilities (*e.g.* parallel trading, compulsory licensing) and at the same time to stimulate innovation and/or intellectual property [Hunt 2006: para. 47; AC Res. 141 (2008): para. 2(b)]. Some authors in political science instead argue that international obligations on intellectual property and intellectual property rights protection in developing countries should be avoided [Drahos and Braithwaite 2002; May 2000; Sell 2003; Pugatch 2004]. They point out that intellectual property policy has been determined by the lobbying of private economic interests, rather than by a rational account of the good for the society (social utility) and its access to medicines. Such ‘distortion’ occurs at the national level, and all the more at the international level, through the coercion of developing countries by developed ones [*id.*]. However, intellectual property rights foster the development of new pharmaceutical products, encourage local pharmaceutical sector, foster economic development and can be morally warranted in terms of reward for the effort undertaken by the inventor [Burns 2005;

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<sup>9</sup> On the problems of provision of treatment at the state level *see* Chapter 5. On the problems of provision of treatment through the initiative of foreign states and non-state actors *see* Chapter 6.

Grabowski 2002; IFPMA 1997; Maskus 2000; Royal Society 2003; Scherer 2001].<sup>10</sup> Also, it is often argued that pharmaceutical companies have some human rights – or moral – obligations to facilitate access to medicines to the worse-off, for instance through differential pricing (discounts for the lower-income countries) [Bluestone et al 2002; Hunt 2007]. Some pharmaceutical companies do already engage in differential pricing, also as a fruit of self-regulation and corporate social responsibility. However, these initiatives are voluntary, ad hoc policies, lacking predictability. Some authors in fact propose internationally regulated differential prices schemes for essential medicines. Such initiatives yet are difficult to configure in the detail and to implement. In fact, mandatory schemes can be economically unsustainable and morally questionable in selecting what products should be included, identifying what countries and peoples should benefit from them, and in distorting the private initiative.<sup>11</sup>

Furthermore, access to medicines is sometimes seen in light of ‘development’. ‘Underdevelopment’ affects or impairs access to medicines and access to medicines can prop up development.<sup>12</sup> Access to medicines is also an indicator of development, as per the Millennium Development Goals.<sup>13</sup> When relating about the human right to medicines, the UN Special Rapporteur on the human right to health for instance refers to the Millennium Development Goals (MDGs) [Hunt 2006: para. 39]. Health has been categorised as a development issue also by WHO (the role of WHO in formulating public health programmes is recommended by the CESCR in its ‘General Comment’ on the realisation of the human right to health [CESCR 2000: paras. 1, 63]).<sup>14</sup> Access to medicines policies are often pledged and adopted as components of objectives such as development [Abuja Declaration 2000: preambular para. 3; Abuja Declaration 2001: paras 13, 15, 23; Abuja Call 2006: para. 8]. Reference to development can however be problematic when it focuses on the economic output of a health intervention (*e.g.*, work days saved, productivity, reduction of burden of disability) [Preker 2004]. It is questionable in fact, under the perspective of medical ethics, to conceive priorities in health as subordinated to the concept of development, or to assume that special principles should be followed for the national design of health systems and the prioritisation of

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<sup>10</sup> See Chapters 5 and 6.

<sup>11</sup> See, generally, the articles collected in Granville [2002] and Attaran and Granville [2004]. See Chapter 6.

<sup>12</sup> See Preker [Preker 2004] on the reciprocal influence between health and economics.

<sup>13</sup> See also Chapter 6 section 6.4.1.

<sup>14</sup> See, *e.g.*, the WHO Commission on Macroeconomics and Health report [CMH 2001].

health intervention in developing countries. If considerations of burden of disease and cost-effectiveness are heeded, for example, the principle of aggregate status of a population may take unwarranted pre-eminence over the attention to the individual medical needs, a cornerstone principle of medical ethics [Brock and Wikler 2006; Kumaranayake and Walker 2002]. Finally, foreign aid can also be problematic, for instance distorting local health systems being volatile and not responding to local needs [Hanefeld et al 2007; Horton 2006; Jones 2003; Navarro 2000].<sup>15</sup>

#### **1.4 Theoretical framework**

As illustrated in section 1.3, regulation and policies relating to access to medicines have to face practical complexities and ethical dilemmas. Ought a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa? Ought a human right to medicines overrule the current settings of access to medicines in sub-Saharan Africa? In order to analyse these questions I utilise a variety of research tools, namely: legal analysis, interdisciplinary studies, empirical work, and socio-legal theories. This section presents my use of socio-legal studies, while the other tools will be discussed in *infra* section 1.5 on methodology. The thesis draws from different contributions such as: critical approaches to law and human rights [*e.g.*, Arendt 1958, 1986; Douzinas 2000; Kennedy 2004; Luhmann 2004; 2002/1965]; theories of rights [Steiner 1994; Sumner 1987] discourse analysis [*e.g.*, Foucault 1990/1976]; sociology and critique of ‘modernity’ [*e.g.*, Bauman 1993; Luhmann 1995, 1998], positivism and quantification in science and public life [*e.g.*, Marcuse 1964; Porter 1995]; critical approaches to development [*e.g.*, Escobar 1991, 1992, 1997; W. Sachs 1992]; public health and medical ethics [*e.g.*, Kumaranayake and Damian Walker 2000; Navarro 1977, 2000; Sheaff 1996]; social systems theory [*e.g.* Luhmann 1995; 2004; Paterson 1996, 2010; Philippopolous-Mihalopoulos 2010] critique of biopolitics and biopower [*e.g.*, Agamben 1998, Fassin 2000, 2007; Foucault 2001/1976-1988; Pandolfi 2001, 2003, 2003]. These theoretical approaches are not used as exhaustive, all-encompassing grand theories. Rather, they are utilised as critical-analytical devices (*see infra* section 1.5 Methodology). I make more extensive use, nonetheless, of Luhmann’s

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<sup>15</sup> See Chapter 6.

social systems theory, enriched by the concept of biopolitics and biopower pioneered by Foucault and further elaborated in sociology, socio-legal studies and critical theories.

With regard to Luhmann's theory of social systems, I will utilise in particular the analysis of 'autopoiesis', 'contingency', 'structural coupling' and 'steering' in law and politics.<sup>16</sup> Furthermore, I will refer to Luhmann's critique of human rights. With regard to autopoiesis (literally, self-creation), according to Luhmann systems exist by differentiating themselves self-referentially – through autopoiesis – from what is residually identified as the 'environment' [Luhmann 1995: 9]. As Luhmann stated:

... systems can differentiate only by self-reference... only insofar as systems refer to themselves in constituting their elements and their elemental operations. To make this possible, systems must create and employ a description of themselves; they must at least be able to use the difference between system and environment within themselves, for orientation and as a principle for creating information [*id.*].

Social systems, in particular, are constituted by communications [Luhmann 1995: 59].<sup>17</sup> Among social systems there are 'subsystems', *ie* functional systems which focus on a specific problem of society [Luhmann 2004: 93]. The autopoiesis and differentiation of the subsystems occurs along communications coded in binary opposites [*id.*]. For example, the subsystem of law is construed on the opposite legal (the system)/illegal (the environment), the subsystem of politics on the opposite power (the system)/not power (the environment), the subsystem of economics on the opposite payment (the system)/not payment (the environment), the subsystem of science on the opposite truth (the system)/not truth (the environment) [Luhmann 1995: 425-6; 2004: 162, 390]. Indeed, Luhmann sees modern society as characterised by differentiation – the specialisation of functional subsystems (functions).<sup>18</sup> Such differentiation occurs, however, through generalisation and simplification of complex, contingent, multidimensional problems [Luhmann 2002/1965: 70].

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<sup>16</sup> In this introduction I briefly present the aspects of Luhmann's social systems theory and of the concept of biopower which are more salient for my thesis. An apt exegesis of Luhmann's work is instead undertaken, *e.g.*, by Philippopoulos-Mihalopoulos [2010].

<sup>17</sup> Social systems are one type of systems. Other types are machines, organisms and psychic systems [Luhmann 1995: 2].

<sup>18</sup> According to Luhmann, "... civilization and its consequences are a result of the differentiation of human communicative performances from their natural conditions" [Luhmann 1990: 31]. Rationalism, division of labour and other controlling features of 'modernity' can have unfortunate consequences. *See, e.g.*, Bauman [1993] arguing that the holocaust itself has ultimately been a product of modernity.

Luhmann gives further insight on the autopoiesis of social systems in his analysis of the role of ‘contingency’. Recalling Aristotle, Luhmann defines as contingent something which “is neither necessary nor impossible; it is just what it is (or was or will be), though it could also be otherwise” [Luhmann 1995: 115].<sup>19</sup> Contingency can be seen as the disorder in the environment, and the raw material of the system. Luhmann notably maintains that social systems operate in a “*paradoxical world*, the paradox being the *necessity of contingency*” [Luhmann 1985: 7 *emph. orig.*]. Thus contingency is a threat to stability but the concealment of contingency through generalisation permits the self-referential expansion of subsystems in the ‘erratic’, ‘unruly’ environment – still bearing in mind that the operation of each system can only connect with other communications from the same system: each system must construct its environment for itself [Luhmann 2004: 357]. The expansion occurs through thematization of complexity. The environment is always more complex than the system and it therefore presents a constant pressure to develop and refine strategies for the reduction of complexity [Luhmann 1990: 11-12]. In effect, the autopoietic generalisations and simplifications exercised through the binary coding adopt and conceal the environment’s contingency. Such contingency therefore re-enters the social systems in the form of indeterminacy.<sup>20</sup>

To note, social subsystems do not *interact* with ‘reality’. They can however ‘irritate’ their environments for example by ‘structurally coupling’ to other subsystems (which are part of their environments), ‘programming’ and ‘steering’. Structural couplings occur when subsystem need events to occur within their environment that they cannot achieve through their own operations [Luhmann 2004: 382]. Nevertheless, mechanisms of structural coupling must be self-referentially compatible with the separation of these systems and their respective operative closures [*id.*: 391]. As Luhmann remarked: “[w]hat [structural coupling] includes (couples with) is as important as what it excludes. Accordingly the forms of a structural coupling *reduce* and *so facilitate* influences of the environment on the system” [*id.*: 382, *emph. orig.*]. In effect, in structural coupling, systems refer to each other as environments, *ie* generalising and simplifying according to their binary communications, thereby concealing contingencies. ‘Programming’ can be used by subsystems for external interventions but programmes are always framed within the subsystem code [Luhmann 1997: 53]. If a subsystem is to influence a social sphere outside its competence it has to solicit the self-steering of

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<sup>19</sup> See also Luhmann [1995: 25].

<sup>20</sup> See Luhmann [1995: 23-28].

another subsystem [*id.*]. ‘Steering’ is more specifically a difference-minimising programme (for example, the reduction of health inequality). To note, within system theory, “[w]hat is seen in the steering process as input is only information constructed in the system itself and this construction is nothing else than a component of the distinction of which difference the system tries to minimize” [Luhmann 1997: 46].

These notions are relevant for our analysis of law and politics. For example laws can conceal their indeterminacy through a vague, general and abstract language. But there are no general and abstract realities; the legal subsystem is autopoietic in its distinction legal/illegal, forcing contingency within its communications. With regard to the steering of law, “law does not necessarily solve the original conflicts but only those that it can construct on its own terms” [Luhmann 2004: 169]. The function of politics, the subsystem differentiated through communications power/non power, is to take binding decisions and indeed it is eased by generalising and simplifying the environment and its contingencies. Therefore, it avoids complexity and systemic, multidimensional ethical problems [Luhmann 2002/1965: 55, 58].<sup>21</sup> With regard to the steering of politics, “politics too can only steer itself, and if the steering refers to the environment then it is only *its* environment” [Luhmann 1997: 46]. Therefore, the (self-)steering of the political system encounters three typical practical problems: 1) the unexpected and/or undesired side-effects 2) the so-called ‘deficits of execution’ and 3) the so-called ‘self-fulfilling’ or ‘self-defeating prophecies’ (obtain the opposite of what sought) [*id.*: 44]. Notably, the legal and political subsystems structurally couple between themselves: “[i]n order for law to be enforced it needs politics, and without the prospect of enforcement there is no stability to norms that are credible to (or which are expected by) everybody. Conversely, politics uses law to diversify access to politically concentrated power” [Luhmann 2004: 162]. Law and politics also structurally couple to other subsystems, for example science or morality. However, structural coupling does not overcome the functional and cognitive limits of a subsystem in dealing with its environment; rather it introduces foreign uncertainty. In effect, as Philippopoulos-Mihalopoulos sharply pointed out, structural coupling is ultimately ‘environmental coupling’ [Philippopoulos-Mihalopoulos 2010: 129-136].

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<sup>21</sup> Luhmann sees the modern state as a specific political organisation of society, *ie* as the particular social system with the function of taking binding decision [Luhmann 2002/1965: 63].

Luhmann also presents an important critique of human rights. A ‘human rights subsystem’ can be identified – even though Luhmann does not explicitly name it – as coded on the binary opposites humanity (the system)/non humanity (the environment) [Luhmann 2004: 135, 468]. Human rights are distinct from law: they are in the environment of law, they can actually conflict with the law [Luhmann 2002/1965: 45: 2004: 468-9; 483].<sup>22</sup> Or, they can be positivised by the legal subsystem. Indeed the subsystem of human rights can be seen as ‘meta-positive’ law [Luhmann 2004: 483]. In sum, as Luhmann wrote, “this form of normative expectation of normative expectations lies largely beyond the established juridical world of forms and is also directed against the law. Legal or illegal – what counts is humanity” [*id.*: 469]. A substantially similar view is, to note, shared by the international law and international relations literatures. For example, Armstrong et al analyse international human rights as rules of positive law, principles and discourse [Armstrong et al 2007: 152-157].

The presumption of human rights (that is, what the system says of itself) is that they are the ultimate utopia, the programme of ‘humanity’ [Luhmann 1997(b): 992-3]. Luhmann however cautions against a ‘fundamentalist’ use of human rights.<sup>23</sup> To begin with, human rights are justified as indisputable values. But there are as many values as stars in heaven and they can actually collide between each other [Luhmann 2008: 28, 29]. To note, collisions of fundamental values are resolved in a contingent manner, with ad hoc decisions:

Values are necessary in order to give decisions recourse to indisputability. Decisions however bring this necessity into the form of contingency. The necessity of adhering to values becomes for its part a contingent evaluation – when it comes to deciding – which can turn out differently depending on value constellations, the site of decision, and influences on the course of decision. [Luhmann 2008: 30].

The thesis will therefore explore the problems and paradoxes of the positivisation of a human right to medicines in the legal subsystem, and of the utilisation of human rights as political programmes. For example, the positivisation of human rights – and their contingencies – can result in a positive law which lacks of clarity [Luhmann 2004: 483]. Furthermore, human rights are utilised to include individual human beings in the

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<sup>22</sup> Cf. Philippopoulos-Mihalopoulos’s reading of Luhmann as placing fundamental rights “on the very boundary between system and environment, which means in no particular system or, to put it more abstractly, always on the other side of the systemic boundary” [Philippopoulos-Mihalopoulos 2010: 154].

<sup>23</sup> Luhmann [1997(b): 1022] translated in Moeller [2008: 139].

legal system [*id.*: 414]. The paradox is, however, that subjective rights are legally valid only as objective rights, that which entails forgoing the unity and uniqueness of the individual:

Human rights are always generalized; I cannot claim them simply ‘as myself’, but only, for instance, as a woman, as a worker, or as a member of a racial minority. In that way, one has actually to disavow one’s unique individuality in order to be able to rely on human rights. A subject can only claim them ‘objectively’ in the form ‘as X’.<sup>24</sup>

Moreover, human rights have a complex relationship with politics. Such relationship will be further explored in the thesis but it can be mentioned that human rights, in their utopian communication, are meant to control the assault of the state. As Luhmann notes, in fact, by maintaining the functional differentiation (and autopoiesis) of politics from other social subsystems in society (*e.g.*, the legal, moral, economic subsystems) human rights also serve the autopoiesis of the political subsystem [Luhmann 2002/1965: 60-61]. Without human rights the other social subsystems would collapse into the absolute power of politics – and politics itself would no longer be ‘politics’ [*id.*]. Furthermore, it is underlined that in order to realise their utopia human rights attribute roles and powers to the very actors which bear human-rights duties (states as well as, in some cases, non-state actors). Therefore, it will be observed, the human right to medicines can legitimise power and biopower to take decisions relating to sensitive, morally problematic issues.

The concepts of power and biopower need further theoretical definition. As Lukes aptly put it, indeed, the notion of power is problematic:

... for instance Bertrand Russell defines power as ‘the production of intended effects’. But is power the actual *production* of such effects or the *capacity* to produce them? ... And is it *necessary* that the effects be intended? ... And is it *sufficient* that the results be intended? ... And which effects are going to count? Surely not all intended effects? Am I powerful (as opposed to you) if the effects I intentionally produce are produced because you have threatened or induced me, or if I produce them because I know they are the effects you want me to produce? And am I powerful if I can only produce such effects at enormous cost, say by sacrificing my life or what gives it value, or if I produce nothing but trivial and unimportant effects (and how do we decide what is and what is not important)? [Lukes 1986: 1-2, *emph. orig.*]

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<sup>24</sup> Luhmann [1995(b): 231] translated in Moeller [2008: 131].

The concept of power adopted in this thesis builds on the theories of Foucault and his followers. Foucault writes from a different sociological perspective but his view is to some extent compatible with that of Luhmann, as some scholars have argumentatively maintained [Borch 2005; Pottage 1988].<sup>25</sup> Thus, when referring to power, I will draw from both Luhmann and Foucault considering that power: is the capacity to determine behaviour, not the actual production of effects; can derive from multiple sources, therefore it is not confined to juridico-political concept [Foucault 1980; Luhmann 1979: 168];<sup>26</sup> is ontologically a nominal entity [Foucault 1990/1976: 93; Luhmann 1990: 157]; is fostered by autopoietic, contingent decision-making [Luhmann 1979: 139] and the entrenchment of regimes of truth and right, also through disciplinary power [Foucault 1980]. More narrowly, as Foucault also does, I will be concerned with the ‘external visage’ of power, *ie* the relationship with the object rather than the intents of the power-holder [Foucault 1980].<sup>27</sup> In effect, I am interested in the moral problems of power. Two main problems can be identified: first, by definition, power is a reduction of liberty for the individual subject to power. The second problem is that power can impose morally undesirable policies and actions impairing legitimate interests, rights, needs and liberties in society. Such features are not merely pathological of a ruthless use of power; power is in fact inherently eased by simplifying complexity, generalising and avoiding ethical problems [Luhmann 1979: 116].

With regard to biopower, in particular, Foucault identifies the birth of biopolitics in the 18<sup>th</sup> century, with the rationalisation of the problems posed to the public governance by the phenomena deriving from a population, such as health, hygiene, nativity, longevity, and races [Foucault 2001/1976-1988: 818]. Biopower is distinguished

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<sup>25</sup> Borch remarks that a major difference between the approach of Luhmann and Foucault is that Luhmann investigates general and very abstractly formulated sociology whereas Foucault studies non-sociological genealogies of concrete historical phenomena [Borch 2005: 155]. Yet I note that also Luhmann indulges in historical considerations (for example with regard to the increasing scope of power in the evolution and differentiation of society) and Foucault in sociological generalisations, for example with regard to power [Foucault 1990/1976; Luhmann 1979: 116].

<sup>26</sup> However, Luhmann does recognise the action of the rule of law so that “[t]he political system of the society takes over the creation, administration, and control of power for the society” [Luhmann 1979: 139].

<sup>27</sup> Therefore, I avoid the question (posed by Lukes, above) whether A’s power on B is constitutively identified as an influence exerted *against B’s interest* (and therefore the identification of the authentic B’s interest). *Cf.* Luhmann, on the usefulness of power in societal development [Luhmann 1979: 163] and Parsons’ identification of power as authority exercised for the collective interest [Lukes 1974: 28].

from traditional sovereignty as while the latter entails the ‘right to *take* life or *let* live’ (*de faire mourir ou de laisser vivre*), the former is the ‘power to *foster* life or *disallow* it to the point of death’ (*faire vivre ou rejeter dans la mort*) [Foucault 1976: 138]. As Foucault identified it, power is not addressed anymore at ‘deduction’ [prélèvement] but is exerted positively on life, aiming at managing, growing, multiplying it and exerting precise controls and regulations on it [*id.*: 136]. Biopower is therefore problematic in as much as it informs *vital* issues. In effect, power is likely to endorse a particular approach to the human right to health, as we shall see, focussed on the aggregate status of the population rather than on the health of the individual.

Foucault’s notion of ‘security’ further sensitises on the potential problems of the exercise of biopower [Foucault 1990/1976; 2007]. According to Foucault, security is a form of power based on the growth and production of a population [Foucault 2007].<sup>28</sup> Under the security approach, ‘population’ is not conceived of as a collection of individual juridical subjects but as “a set of elements in which we can note constants and regularities even in accidents... and with regard to which we can identify a number of modifiable variables on which it depends” [*id.*: 74]. Moreover, the security paradigm follows ‘normalisation’ rather than ‘normation’. While according to normation, “there is an originally prescriptive character of the norm and the determination and the identification of the normal and the abnormal becomes possible in relation to this posited norm” [*id.*: 57], according to normalisation different immanent normalities are observed within the population as a whole and a norm is fixed on the basis of these normalities: “[t]he norm is an interplay of differential normalities. The normal comes first and the norm is deduced from it” [*id.*: 63]. To note, Foucault’s concept of normalisation in effect recalls Luhmann’s analysis of steering, as difference-minimising programmes [Luhmann 1997]. For example, in the case of an epidemic, the security approach manages the interplay of the different normalities in order to act on the sections of the population that fall without such ‘normality’ [*id.*: 63]. This may involve, for example, specifically tailored interventions to arrest the spread of disease in certain areas, as well as leaving other areas or groups untreated [*id.*].<sup>29</sup> Thus, the health of a ‘population’ is ultimately instrumental to security and translates into more biopower.

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<sup>28</sup> To be precise, I see security as both an end of biopower and a means of biopower to perpetuate itself.

<sup>29</sup> See also Golder who provides a stimulating account of the pastoral power in Foucault [Golder 2007].

Foucault's concepts of biopower and biopolitics have subsequently been utilised by Agamben, who analyses biopolitics in connection with human rights [Agamben 1998]. Agamben identifies in certain sociological phenomena the creation of the *bios*, the bare life, as opposed to *zoe*, the political life [*id.*: 10]. *Bios* is subject to the sovereign whom Schmitt depicted as s/he who can claim the state of exception. Agamben sees human rights most properly as rights of citizenship, and pessimistically remarks that

... the very rights of man that once made sense as the presupposition of the rights of the citizen are now progressively separated from and used outside the context of citizenship, for the sake of the supposed representation and protection of bare life that is more and more driven to the margins of the nation-states... [*id.*: 132].<sup>30</sup>

Agamben interestingly expands the argument to certain trends occurring in emergency international humanitarian interventions, noting that “[t]he separation between humanitarianism and politics that we are experiencing today is the extreme phase of the separation of the rights of man from the rights of the citizen” [*id.*: 133]. Building on Agamben's ideas Pandolfi subsequently asks what can be more an exception than humanitarianism, and what can be more a bare life, a *homo sacer*, than one whose life depends on the humanitarians [Pandolfi 2002]. Pandolfi also underscores the fugacity of aid, as emergency ends somewhere and bursts elsewhere [*id.*]. The perverse sovereign-subject relationship of biopower is fostered by the non-territorial accountability of the decision-makers for such health interventions. In sum there is a risk that both at the national and international level the human right to medicines serve unwarranted biopower, rather than emancipate.

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<sup>30</sup> Cf. Foucault: “[f]or millennia, man remained what he was for Aristotle: a living animal with the additional capacity for a political existence; modern man is an animal whose politics places his existence as a living being in question” [Foucault 1976: 143].

## 1.5 Methodology

The methodology comprises legal analysis of the international human right to medicines *de jure*, a broad study of the literature concerning access to medicines, empirical work, and theoretical insights from socio-legal studies. With regard to the critical analysis of the right *de jure*, I focus on international law, where human rights obligations with regard to access to medicines are arguably consolidating. The right is nonetheless to be applied at the national as well as the international level. Indeed international and national law intertwine, and are both analysed.<sup>31</sup> For the study of international law, I have researched the sources of international law as recognised by the Statute of the International Court of Justice (ICJ) – *ie* primarily treaties, international custom, general principles of law and, as subsidiary means, judicial decisions and the opinions of authoritative publicists [ICJ Statute art. 38]. It is highlighted here that in addition to treaty law, the identification of the international customary law on the human right to medicines is potentially important for access to medicines as, among other reasons, it is legally binding on all states. However, it has proved to be particularly problematic and not thoroughly investigated in the literature. Thus, I have undertaken an original investigation in the state practice and *opinio juris* relating to the human right to medicines. Very experimental has also been the research with regard to the obligations relating to the human right to medicines borne in treaty as well as customary law by extra-governmental actors, *ie* the actors other than home states (the traditional recipients of human right obligations), which therefore include foreign states and non-state actors. I have furthermore investigated the sources of law which do not strictly qualify as international law according to the ICJ statute such as international soft law, the ‘*jure ferenda*’ and instances of regulation which relate to access to medicines concerning extra-governmental actors. Such non-binding formulations of the human right to medicines can in effect be seen as communications of the ‘human rights subsystem’. The legal value of those instances is critically analysed in the thesis.

With regard to the literature concerning the realisation of access to medicines, I have researched other fields of law and a variety of disciplines including public health, medicine, ethics, medical ethics, development studies, economics, political economy, political science. Sources of such material have been academic books and articles in specialised journals as well as data and reports circulated by governments, international

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<sup>31</sup> See Chapter 3 section 3.1.

organisations, NGOs and other advocacy groups. All material is utilised with a critical view and the approach is *interdisciplinary* rather than *multidisciplinary*.<sup>32</sup> This means that my aim is not to study the disciplines in their self-referential isolation, but to utilise their insights in order to critically investigate the different dimensions of the problem of access to medicines. In particular I utilise ethics, as I normatively research if the human right to medicines *ought to* be utilised to solve the problem of access to medicines in sub-Saharan Africa. To be clear, ‘ethics’ is distinguished from ‘morality’. Ethics is “concerned with what is morally good and bad, right and wrong. The term is also applied to any system or theory of moral values or principles” [Singer 1985]. The term “morality”, instead, can be used “either 1. descriptively to refer to a code of conduct put forward by a society or, a. some other group, such as a religion, or b. accepted by an individual for her own behavior or 2. normatively to refer to a code of conduct that, given specified conditions, would be put forward by all rational persons” [Gert 2008]. Thus ethics is “the field of study, or branch of inquiry, that has morality as its subject matter” [Singer 1985].

Another main standing regarding my methodology is the critical view of aggregative measures and quantitative data. Quantitative data are supposed to represent precisely and objectively certain situations. Thus they are often utilised by the literature and advocacy concerning access to medicines as premises for their arguments. I will use such data too but they have to be considered prudently. For example, the collection in sub-Saharan Africa of, among the others, economic and health data is practically taxing due to the scarcity of official, regular recording. In fact, statistics often ultimately rest on estimates and subjective assumptions. Furthermore, I found considerable amount of discrepancies within the literature utilising quantitative data.<sup>33</sup> Importantly, the value of quantitative studies is arguably limited, as they are inherently aggregative, overlooking the personal situations of individuals.<sup>34</sup> The use of quantitative data for justifying public policies is therefore questionable.<sup>35</sup> Qualitative studies and empirical work are used to complement quantitative approaches, even though they also suffer from limited objectivity.

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<sup>32</sup> On the potential and challenges of ‘interdisciplinarity’ as a method of research in socio-legal studies *see* Banakar and Travers [2005: 4-6].

<sup>33</sup> *See* Chapter 2 section 2.1.

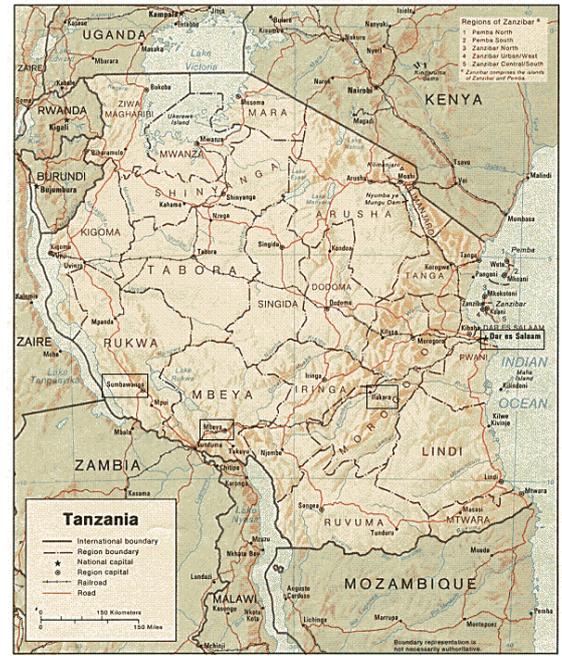
<sup>34</sup> The ethical and legal limitations of aggregative considerations with regard to the realisation of the human right to medicines is discussed in chapters 5 and 6.

<sup>35</sup> *See also* Porter [1995].

With regard to my empirical work, to begin with, I have undertaken field research in Tanzania.<sup>36</sup> The field research has encompassed background study of access to medicines in Tanzania and a two-month visit to the country. The visit to Tanzania took place in July-August 2009. I spent approximately five weeks in Dar es Salaam (where most institutions are based) and three weeks travelling up-country to see first-hand the situation of access to medicines in more remote areas (namely Sumbawanga, Mbeya, Mikumi and Ifakara. *See* map at page 31), visiting public health facilities and interviewing the competent authorities. Overall, I conducted more than 50 relevant interviews about access to medicines, healthcare, human rights, with officials from the Tanzanian government (central and local), international organisations, non-governmental organisations, foreign aid, medical practitioners, health facilities personnel and others (*see* Annexe A). The method of my interviews has been semi-structured interviews, therefore based on a set of themes and topics to form questions in the course of conversation [Burgess 1984: 102], but also including specific questions. I prepared my themes, topics and questions specifically for every interviewee. I generally started my interviews by asking the interlocutor to talk about his career and present position. I would consequently ask the substantial questions, which could be very technical, as I intended to learn the practicalities of health, medicine and access to medicines in Tanzania. Finally, I would always ask to freely comment on the idea of access to medicines as a human right. I recorded approximately half of my interviews, and I always collected the informed consent form. In order to safeguard the privacy of the interviewees, throughout the thesis I generally refer to them anonymously by their professional role and position.

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<sup>36</sup> The term ‘field research’ is utilised broadly, as in Burgess, who intends it to cover “what is colloquially known as participant observation, unstructured interviews and documentary methods” [Burgess 1984: 4].



Maps' sources: map on the left: Katie Fortuna, website. Map on the rights, US Central Intelligence Agency (CIA) [University of Texas 2010]. I have marked in this map (in the squares) the biggest towns I have visited during my empirical work (Dar es Salaam, Ifakara, Mbeya, Sumbawanga).

I managed to organise this empirical work through a long background preparation preceding the journey and through the logistic and technical support of the Tanzania Food and Drug Authority (TFDA) during my stay in Tanzania. With regard to the background preparation, I have undertaken considerable reading which has spanned books, journals, newspapers, reports written on health care and access to medicines in Tanzania. I have furthermore participated to meetings and conferences on this matter in London. Both the readings and the meetings have not only provided familiarity on the subject but also contacts for the interviews. By far, I must acknowledge, the most important connection has been Emmanuel Alphonse who introduced me to TFDA. I interviewed him several times in the UK (both in Leeds where he was undertaking his MSc in Public Health and in London). In Tanzania, he provided me with indispensable support, indications and suggestions notwithstanding his work overload as manager at TFDA. With regard to the role of TFDA, the institution has provided me with a desk, logistic support during my travelling and has formally presented me to governmental authorities. I am immensely grateful for this help.

With regard to the merits of my empirical work in Tanzania, I firstly focussed on a case study, the Duka la Dawa Muhimu, known internationally as Accredited Drugs Dispensing Outlets (ADDOs). ADDOs are meant to increase access to quality medicines

in underserved areas. The project aims at training the shopkeepers of over-the-counter (OTCs) shops so that they can sell a few ‘necessary’ (‘muhimu’) products which are otherwise supposed to be sold under prescription in Tanzania. This arrangement is important for instance for malaria, considering that reportedly up to 70 percent of fevers are managed in the private sector [Lynch et al 2006: 20; *See also* Kachur et al 2006]. OTC shops are a favoured option for access to medicines in remote areas because they are more diffused and less expensive than pharmacies, but the first-line antimalarial in Tanzania (artemether-lumefantrine) is a prescription medicine [*id.*].<sup>37</sup> As opposed to other OTC shops, ADDOs are authorised to sell artemether-lumefantrine. The ADDO project also offers an interesting hook for observing the operation of extra-governmental actors on access to medicines in sub-Saharan Africa as, while the TFDA is the main implementer of the programme, ADDOs are an international public private partnership (PPP) which involves foreign NGOs (*e.g.* Management Science for Health), bilateral aid (*e.g.* the US President’s Malaria Initiative), and international aid (*e.g.*, the Global Fund to Fight AIDS, Tuberculosis and Malaria).<sup>38</sup> Thus I conducted interviews on the subject and visited ADDOs.<sup>39</sup> However, since ADDOs are just one component of access to medicines, I have also enquired on the other elements of access to medicines such as the supply chain of distribution (for example interviewing the state’s Medical Stores Department as well as private suppliers), the role of the public health facilities (key note has been joining the council team of Sumbawanga in its periodic inspection of tens of dispensaries), the role of foreign aid (for example by meeting with USAID officials, implementing NGOs and the local coordinators of the Global Fund for AIDS, Tuberculosis and Malaria), medical research in Tanzania (visiting the Ifakara Health Institute that is supported among the others by the Tanzanian government, the Swiss Tropical Institute and the Novartis Foundation for Sustainable Development), the work on quality and safety of medicines by TFDA. With regard to the disease focus I have definitely learnt a lot about malaria (especially thanks to Molteni from the National

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<sup>37</sup> *See* Chapter 2 section 2.4.

<sup>38</sup> PPPs are commonly defined as voluntary and collaborative relationships between various parties, both state and nonstate, in which all participants agree to work together to achieve a common purpose or undertake a specific task and to share risks, responsibilities, resources, competencies, and benefits [UN Secretary General, *Enhanced Cooperation between the United Nations and All Relevant Partners, in Particular the Private Sector*, 2003].

<sup>39</sup> More details on the ADDOs can be found in Chapters 2, 5 and 6.

Malaria Control Program and to the researchers at the Ifakara Health Institute and at the KEMRI-Wellcome Trust in Kenya, which I also visited).

I furthermore consider as empirical experience the innumerable conferences, debates, interviews and discussions that I have attended during my research in the UK. These events saw the participation of, among the others, governmental and intergovernmental officials, pharmaceutical industry and business people, lawyers working on access to medicines in Africa, people from implementing NGOs, medical researchers and practitioners on health care in Africa. In these occasions I had the chance not only to learn the practicalities of access to medicines but also to interact proactively and network with the people influent in the sector. Important empirical experience has also been my one-week visit to Dr James Berkley in Kilifi, Kenya. Dr Berkley is a paediatrician active in research at the Kenya Medical Research Institute (KEMRI)-Wellcome Trust Collaborative Programme Centre for Geographic Medicine Research. I got in touch with him as he is the son of Jean and Barrie Berkley, who set up the Alistair Berkley Charitable Trust which has also funded my PhD studies. It had been extremely interesting to exchange views and insights with Dr Berkley and his colleagues at the research centre. I finally travelled to Nairobi, Kenya, where I met other researchers on the topic of access to medicines in developing countries. Lastly, I could mention some empirical experience in Africa which I had lived before engaging in this thesis but is, I reckon, still relevant. Namely, in 2005 I undertook a three-month internship at the Italian Embassy in Eritrea, which gave me great insight of problems of one of the poorest African country and about the work of foreign cooperation, international aid, NGOs and other non-state actors. Finally, with regard to the empirical work, I acknowledge that such research can raise a few issues of academic independence considering especially my work in close contact with the Tanzania Food and Drug Authority or my meeting with Jean, Barrie and James Berkley. With regard to the former, I am happy to acknowledge that TFDA gave me indispensable support but I have conducted most of the networking and enquiring on my own without interference. With regard to the acquaintance with the Berkley family, again, I received a lot of expert and passionate knowledge on medicine in Africa but no pressure on the merits of my thesis. Finally, I must note that due to the vast amount of material that is dealt with in this thesis, the field work receives less explicit reference than it probably should. The empirical experience nonetheless often upholds my remarks without being specifically mentioned.

With regard to the theoretical enquiry, I have undertaken a wide exploration but I have chosen the systems theory elaborated by Luhmann and his followers, among whom in particular Philippopoulos-Mihalopoulos, as the driving framework. I have mentioned above the reasons of such selection. As far as the methodology is concerned, I use the contribution of Luhmann and of the other authors as critical-analytical, heuristic tools which can guide and explain the findings, not as a deductive grand theory. Such methodology is for example supported by Ziegert who argues that “Luhmann’s concepts are, contrary to widely held opinion, an excellent mapping device in the methodological framework of qualitative empirical research” [Ziegert 2005: 51].<sup>40</sup> Other theoretical insights, such as Foucault’s theory of power and biopower, are also considered as suggestions rather than deductive guidelines. Indeed complexity and contingency impede a match between reality and abstract formulations of it in all but generalised and simplified formulations. Therefore I am not interested in uncovering general laws concerning society, pretending to describe and predict its trends with certainty. Instead, I am interested in pointing out the ‘logic’, the possible outcomes and the scenarios relating to the realisation of the human right to medicines in sub-Saharan Africa.

Thus theory, interdisciplinary study on access to medicines and empirical work have operated in a triadic exchange with regard to the human right to medicines. I chose Luhmann’s social systems theory because of a certain perception of reality which was developed through academic research as well as life and experience of sub-Saharan Africa. My approach to the theory yet has pre-existed the 2009 field-work in Tanzania and Kenya, and has helped me as a critical-analytical tool in appreciating the empirical findings. The empirical work, consequently, has contributed to build on the theory. Moreover, the theory has functioned as a critical-analytical tool with regard to the law and the other literature on access to medicines. In sum, the triadic exchange is aimed at deconstructing the social systems and subsystems relating to access to essential

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<sup>40</sup> In his essay Ziegert compares grounded theory and system theory, even stating that “[t]he fundamental difference between the systems theory approach and grounded theory approaches is *the much more serious reflection of the human condition* in the theoretical (conceptual) groundwork of the systems theory approach. This provides a clear sense of theoretical direction and gives researchers a head start through the case-specific and area specific dense conceptual groundwork already done and stimulated by systems theory” [Ziegert 2005: 59]. The human condition is intended “in the sense of evolutionary conditions for the possibility of social systems” [*id.*] (*Cf.* Flood proposing ethnography as an interpretivist approach to socio-legal research [Flood 2005]). I detach, however, from Ziegert’s focus on sociology, as my research is, rather, interdisciplinary and ultimately informed by an ethical – rather than sociological – enquiry.

medicines revealing the contingencies, realities and subjectivities which are often demoted by the standardised communications of access to medicines in Africa or human rights. In the thesis I critically analyse and elaborate such insights, problematising the international human right to medicines.

## **1.6 Contributions to knowledge**

I envisage four main contributions originating from the investigation of the research questions. The first contribution concerns international human rights law. The thesis offers a thorough identification and analysis of the obligations concerning access to medicines in international human rights law applicable *de jure* in African countries. Very limited scholarly literature exists so far on that matter. In particular, the literature is poor with regard to the obligations originating from international customary law and soft law. With regard to the range of duty-bearers, very scarce thorough research exists on the obligations of extra-governmental actors and non-state actors. The second contribution regards the ethical analysis of policies for operationalising and implementing the human right to medicines in sub-Saharan Africa. Such analysis is also a case-study intervention to the debates concerning health care, public health, development and human rights in the region. The practical and ethical problems of access to medicines, as well as health care more generally, are critically analysed through an interdisciplinary study drawing from an array of disciplines (which include public health, medical ethics, economics, law) and empirical work which includes a two-month field work in Tanzania. Therefore I will identify the limits of steering and the possible conflicts between legitimate rights, interests and needs that policies for access to medicines can engender. This approach, incidentally, challenges a previous work of mine on the human right to food wherein I maintained that human rights law identify a framework for action which should be immediately used by states in order to design policies for realising the right [Niada 2006].<sup>41</sup> It is acknowledged at this point that a dissertation on the access to medicines in sub-Saharan Africa may be questionable for instance as its scope is too broad or, as it is produced outside the region, it cannot but be ‘alien’ to certain realities. Nevertheless, I find that the thesis is still relevant as it provides an original view to the problems of that area from an external perspective. Moreover, it problematises the existing contributions

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<sup>41</sup> See also the work on the “Right to Food Guidelines” published by FAO [FAO 2006].

on this matter that foreigners export to Africa, for example through development studies and interventions.

Thirdly, the thesis contributes to the socio-legal studies identifying the phenomena of autopoiesis, contingency, and limits of steering affecting human rights, law and politics. Such framework is also utilised in order to analyse the exercise of power and biopower to control issues of life in a population through the use of law (including the human right to medicines) and politics. The fourth contribution is the answer to the research question: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. As explained in section 1.3 above this question is two-fold asking if – descriptively – the right has the capacity and if – normatively – it ought to be applied to solve the problem of access to medicines in sub-Saharan Africa.

## **1.7 Outline**

Chapter 1 is the ‘introduction’ and presents the research question, its justification and the methodology for answering it. Chapter 2 illustrates the problem of access to medicines in sub-Saharan Africa. It first outlines the health status of sub-Saharan African countries underlining the severe burden of disease and the relevance of medicines to overcome several health conditions. It subsequently provides an overview of the economic and regulatory features of the supply chain that brings medicines from the manufacturers to the people. It finally describes the situation of access to medicines in Tanzania, which I studied with my empirical work. Chapters 3 and 4 investigate the prescriptions of a human right to medicines in international law. They demonstrate that certain instances of international law enshrine human rights obligations in relation to access to medicines, especially as part of the human right to health, which are applicable *de jure* to the situation of access to medicines in sub-Saharan Africa. However, these chapters also illustrate that the international human rights law often does not give clear indications about what the duty-bearers are expected to do in order to comply with their obligations. The law is to great extent characterised by paradoxes and contingencies. In particular, Chapter 3 analyses the duties held by home states and Chapter 4 analyses the duties of ‘extra-governmental’ actors, that is, foreign states and non-state actors (international organisations, NGOs, pharmaceutical companies).

Chapters 5, on home states, and 6, on extra-governmental actors, investigate how the duties identified in Chapters 3 and 4 can and ought to be operationalised, implemented and enforced. Both chapters are structured following the tripartite division of duties to respect, protect and fulfil the human right to medicines. The operationalisation of the obligations is examined through a critical approach considering the conflicts that can possibly originate between legitimate interests, needs and rights. Empirical and interdisciplinary perspectives, mainly drawing from public health, medical ethics and economics help identifying the challenges of the operationalisation of the human right to medicines. Luhmann's theory of social systems and ideas from other socio-legal theories are utilised to identify contingency, autopoiesis, biopower and thereby the weight of taking decisions relative to complex, sensitive and morally challenging issues of access to medicines. Chapter 7 provides the conclusion to the thesis, reporting about the 'contributions to knowledge' sought.

### **1.8 Note on language and references**

The term 'medicine' is used as a synonym of 'drug'. The term 'medicine' is being replaced in the public health literature as the term drug can denote an 'illicit drug'.

The term 'human right to medicines' will be generally used as a short-hand expression for "fundamental component of the human right to health regarding access to medicines". Therefore it does not denote, unless otherwise specified, a self-standing human right.

With regard to the style of referencing, I use the Harvard system. However, for the sake of clarity, I report in the brackets also the titles of the works of certain authors and institutions (for example, courts or international institutions), if they have published several pieces in the same year. When the reference is a website, I indicate in the brackets the name of the webpage.

## **1.9 Conclusion**

Chapter 1 has presented the research questions of the thesis: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?” The question is two-fold: first I intend a descriptive enquiry of the law and its practice as they are. Secondly, I intend a normative enquiry of the law and its practice as they ought to be. This research inserts in the context of increasing attention to access to medicines in current affairs and of the emerging notion of a human right to medicines in international and national human rights law. However, the consequences of this right are not appreciated in the literature. Generally, policies for access to medicines can conflict with legitimate needs, interests and rights in society. In particular, legal and political decisions regarding medicines can constrain the freedom of individuals concerning their health, thereby sanctioning biopower. I therefore approach this topic reserving a critical approach with regard to the idea that the operationalisation, implementation and enforcement of access to medicines shall be channelled through a ‘human right to medicines’ in sub-Saharan Africa. The relevance and merits of my arguments are grounded on legal, socio-legal, interdisciplinary and empirical critical analyses, which are considered in dialectic between them.

## CHAPTER 2: THE PROBLEM OF ACCESS TO MEDICINES IN SUB-SAHARAN AFRICA. THE CASE-STUDY ON TANZANIA

### 2.1 Introduction

This chapter aims at presenting the circumstances, problems and relevance of access to medicines in sub-Saharan Africa. The chapter is divided into three parts: section 2.2 outlines the health status of sub-Saharan African countries illustrating the severe burden of disease and the possibilities offered by medicines to overcome health problems. Section 2.3 deals with the economic and regulatory features of the supply chain that brings medicines from the manufacturers to the end-consumers. Section 2.4 presents the situation of access to medicines in Tanzania that I studied with my empirical work. A conclusion is finally provided in section 2.5 arguing that access to medicines is to some extent arbitrary, dependent on man-made deliberations. Therefore, there is scope for a human right to medicines to intervene regulating such actions and policies. However, the chapter also shows the complexities and contingencies of access to medicines in the sub-Saharan African health systems. Those complexities, as it will be shown in Chapters 5 and 6, can represent challenges to the identification of ideal regulatory and policy frameworks to operationalise the human right to medicines.

Some limitations have to be preliminarily disclosed with regard to the account provided in this chapter. To begin with, the object of study, sub-Saharan Africa, is not an entirely homogenous entity. The region is constituted by 48 countries which are fully located south of the Sahara.<sup>42</sup> At a general level, sub-Saharan African countries share history, culture, economy and health situations.<sup>43</sup> The distinction between sub-Saharan Africa and North Africa is generally adopted by international organisations such as the UN or the World Bank [WHO AFRO 2006: xxv]. However, other institutions do not divide Africa along those lines. The WHO AFRO region, for instance, excludes Djibouti, Somalia and Sudan but includes Algeria [WHO AFRO 2006: xxv]. The African Union,

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<sup>42</sup> See Chabal and Daloz [1999: xxi] and The Economist, The Power of the Angry Voter [2010]. Sub-Saharan Africa is often simply referred to as 'Africa' [Chabal and Daloz 1999: xxi].

<sup>43</sup> See Stock in "Africa South of the Sahara: A Geographical Interpretation" [2004: 6, 7]. For history, culture and politics see, e.g., Chabal and Daloz [1999], Herbst [2000], Hyden [2006], Mamdani [1996]. For the economics see Barratt-Brown [1995]; for the epidemiology of sub-Saharan Africa see, e.g., Jamison et al [2006] and *infra* section 2.2.

in fact, includes 53 continental African countries except Morocco [African Union, website, Member States, last accessed 17 February 2010]. Indeed, on a closer look, the countries within the region can be quite diverse. The contexts and situations with regard to disease and access to medicines vary. Nevertheless, there are some features that make sub-Saharan Africa quite homogenous with respect to the rest of the world.<sup>44</sup> The relevance of national contexts is analysed in Chapters 5 and 6.

Another caveat is expressed with regard to the value of the quantitative data, such as those relating to health systems and economics, presented in the chapter. Quantitative data are presumed to represent precisely and objectively the general characters of the health systems and access to medicines in sub-Saharan Africa. Thus they are often utilised by the literature and advocacy concerning access to medicines as premises for their arguments.<sup>45</sup> However, they have to be assessed critically, as discussed throughout this chapter. The data offered by the literature often present discrepancies or are out-of-date.<sup>46</sup> Primary data themselves suffer from scarcity of official, systematic recording. In fact statistics often ultimately rest on estimates and hypotheses. Moreover, the significance of quantitative studies is arguably limited as they are inherently aggregative, overlooking the personal situations of individuals.<sup>47</sup> Qualitative studies and empirical work are used to complement quantitative approaches, even though they also suffer from limited objectivity. Furthermore, it is noted that the medical theories on disease and treatment which are presented in the chapter may not be definitive, as they are often drawn from studies that are ‘in progress’, still based on restricted samples of the population, and that are always subject to scientific falsification.

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<sup>44</sup> With regard to health, *see generally* WHO AFRO [2006]. *See infra* in this chapter.

<sup>45</sup> For examples of the use of quantitative studies in the scholarly literature on the human right to medicines *see* Hestermayer [2004: 103], Yamin [2003: 102-103]. For the scholarly literature on access to medicines *see, e.g.*, Tetteh [2008: 569-570]; for WHO’s literature *see* WHO, “How to Develop and Implement a National Drug Policy” [2001], “The World Medicines Situation” [2004], WHO AFRO [2006]. For UN literature on access to medicines as part of the Millennium Development Goals (MDGs) *see* Leach et al [2005: 1-4]. For advocacy literature *see* Médecins Sans Frontières (MSF), “A guide to the post-2005 world: TRIPS, R&D and Access to Medicines” [2005], Oxfam’s “Patents Versus Patients” [2006].

<sup>46</sup> For example, with regard to the cases of death caused each year by malaria in Tanzania, the US President’s Malaria Initiative reported between 100,000 and 125,000 lives per year while the WHO reported 38,730 for 2006 [US President’s Malaria Initiative 2005: 12; WHO, World Malaria Report 2008: 142].

<sup>47</sup> The ethical and legal limitations of aggregative considerations with regard to the realisation of the human right to medicines is discussed in Chapters 5 and 6.

## 2.2 The state of health in sub-Saharan Africa

### 2.2.1 Epidemiological overview of sub-Saharan Africa: mortality, morbidity, burden of disease

This section presents the diffusion of health problems in sub-Saharan Africa. It illustrates the proportion with which the most prevalent diseases affect the region as well as the interconnectedness between the health conditions. The method mainly utilised for this purpose is the study of mortality and morbidity rates.<sup>48</sup> Mortality and morbidity rates are often used in epidemiological studies as a proxy of the ‘burden of disease’. Other indexes can be used for the burden of disease, such as the disability-adjusted life years (DALYs).<sup>49</sup> DALYs are a summary measure, also ultimately founded on mortality and morbidity, and will also be referred to in the thesis.<sup>50</sup> Some important limitations to the rendition given here have to be mentioned. First, the account provided in this section only relates to approximately *two thirds* of the health problems causing death in sub-Saharan Africa. Another third of deaths is due to other causes, as shown in Annexe B. The factors of morbidity in sub-Saharan Africa are even *more* numerous, as shown in Annexe C. Second, I realised during my research that the accuracy and value of

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<sup>48</sup> Morbidity is defined as the prevalence of illness in the community. Mortality is defined as causes of death and rates of death [Last 1983 in Phillips 1990: 31].

<sup>49</sup> In its study “The Global Burden of Disease and Risk Factors”, the World Bank defines the global burden of disease as a “[a] comprehensive demographic and epidemiological framework to estimate health gaps... for an extensive set of disease and injury causes, and for major risk factors, using all available mortality and health data and methods to ensure internal consistency and comparability of estimates” [World Bank, The Global Burden of Disease and Risk Factors, 2006: 3]. As a proxy for the global burden of disease, the authors utilise disability-adjusted life years (DALYs) [*id.*]. However, other estimates can be chosen. The study of mortality and morbidity has been adopted, for example, by the Tanzanian Ministry of Health in “Burden of Disease 2001- The Morogoro District” and by the World Bank in the study “Disease and Mortality in Sub-Saharan Africa”, which will be extensively utilised in this section [Tanzania Ministry of Health, Burden of Disease 2001 – The Morogoro District, 2001; Adetunji and Bos 2006]. See, in particular, Rao et al [2006].

<sup>50</sup> DALYs are defined as “a measure of the future stream of healthy life (years expected to be lived in full health) lost as a result of the incidence of specific diseases and injuries”, *ie* a sum of “both premature mortality (years of life lost because of premature mortality or YLL) and disability (years of healthy life lost as a result of disability or YLD, weighted by the severity of the disability)” [World Bank, The Global Burden of Disease and Risk Factors, 2006: 3].

epidemiological studies on burden of disease in sub-Saharan Africa are doubtful.<sup>51</sup> To begin with, the causes of morbidity and death are often multiple and correlated. Therefore it may be difficult to identify a single health problem as the cause of death or bad health. Moreover, since the production of health statistics in the region does not occur on a regular basis, the data used in the literature are generally several years old. Next, due to the scarcity of official, systematic recording, statistics often ultimately rest on estimates and subjective assumptions.<sup>52</sup> Furthermore, there are variations between – and within – countries in the burden of disease. A major distinguishing factor across African countries is, reportedly, the HIV infection rate (see below) [WHO, World Health Report 2003: 233; Rao et al 2006: 55]. Lastly, the data that will be presented often come from the very same global health policy-makers and policy-advocates, which include UN agencies (WHO, UNAIDS, World Bank) and NGOs. The conflict of interests can impair the objectivity of such studies.<sup>53</sup>

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<sup>51</sup> Epidemiology has at its core “the use of quantitative methods to study diseases in human populations so that they might be prevented and controlled” [Beaglehole and Bonita 2004: 107].

<sup>52</sup> For instance, good vital records – necessary as denominators for estimating the overall mortality of cause-specific rates – are absent in almost all sub-Saharan Africa countries. See Baingana and Bos discussing the efforts for health data collection in the World Bank study on “Disease and Mortality in Sub-Saharan Africa” [2006]. In World Bank’s “Disease and Mortality in Sub-Saharan Africa”, from which I draw substantively in this section, the authors endeavour to complement the records by utilising sources such as household surveys, including demographic and health surveys, the UNICEF Multiple Indicator Cluster Surveys, the World Bank’s Living Standards Measurement Surveys and other surveys conducted by WHO, as well as country statistical offices [Baingana and Bos, 2006: 8]. Antenatal clinics have been used for assessing AIDS prevalence [*id.*].

<sup>53</sup> On the WHO see Scruton [2000: 44]. See Navarro pointing out the manipulation of statistical data by Frenk and Murray in the “World Health Report 2000: Health Systems: Improving Performance” [Navarro 2006; Murray and Frenk, World Health Report 2000: Health Systems: Improving Performance, 2000]. Reportedly, Professor Philip Musgrove, the technical director of the study supervised and directed by Frenk and Murray, tried to prevent the publication of such data. Unsuccessful, Musgrove later publicly denounced their manipulation thereby supporting the accusations pronounced by Navarro and others. The story has been object of a *querelle* in medical including the Lancet and the American Journal of Public Health [Murray and Frank, World Health Report 2000, 2000; Murray and Frank World Health Report 2000: A Step Towards Evidence Based Health Policy, 2000; Navarro, Assessment of the World Health Report 2000, 2000; Navarro, World Health Report 2000: Responses to Murray and Frenk, 2000; Musgrove 2006]. A recent (November 2007) scandal on the worldwide diffusion of the AIDS has stimulated a flurry of speculation about the good faith of the WHO in gathering data that constitute the factual basis of its action and therefore funding. UNAIDS, the joint UN programme on HIV/AIDS, to which WHO is a main participant, has in effect admitted with a 2007 report that “as a result of alternative methods and fresh information, especially from

Overall, WHO proclaims Sub-Saharan Africa to be the region in the world cursed by the highest burden of disease, accounting for 25% of the global burden [WHO 2003, The World Health Report: 120].<sup>54</sup> The level of mortality in the region is the highest by far: life expectancy at birth is 46 years whereas in Asia, which endures the second lowest life expectancy, it amounts to 67 [Adetunji and Bos 2006: 12]. WHO reckons that adult mortality in Africa has reversed since 1990, shifting from a state of steady decline into a situation characterized by rapidly increasing mortality rate which “exceed[s] the levels of three decades ago” [WHO, The World Health Report 2003: 16]. The literature on health and development often expresses alarm on the current situation in sub-Saharan Africa. For example Madavo, the former Vice-President Africa Region of the World Bank has remarked that:

... the sobering reality is that life expectancy has decreased by almost five years for the continent as a whole since the 1991 publication, and by much more in some countries... children under five are dying at unacceptably high rates from causes for which effective interventions exist, and adult mortality from infectious diseases has risen to extraordinary levels. HIV/AIDS has spread from eastern Africa to the rest of the continent, affecting southern African countries the most. Malaria mortality of children increased during the 1990s, and TB has reemerged as a leading cause of death for adults, largely due to the spread of AIDS. Not surprisingly, at this time Sub-Saharan Africa is not on track to reach any of the health Millennium Development Goals. [Jamison 2006: xiii]<sup>55</sup>

Analysing the burden for each disease, HIV/AIDS is deemed to be the leading cause of death in the region, being responsible for approximately 20% of total deaths [Rao, Lopez and Hemed 2005]. Nearly 80% of the almost three million global deaths from HIV/AIDS in 2002 occurred in sub-Saharan Africa [WHO, The World Health Report 2003, 2003: 18]. UNAIDS and WHO have estimated, in 2005, that 25.8 million

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India, it was reducing its 2006 figures from 39.5m to 32.7m infected people” [Jack, UN lowers estimate of people with Aids to 33m, 2007]. Caldwell reports some polemic accounts by Chin (infectious-disease epidemiologist at Berkeley), and Epstein (molecular biologist and author): “Dr Chin describes UNAids’ epidemiology with the Horatian expression *splendide mendax* – meaning untruthful to a noble end. It sought ‘to avoid further stigmatisation’ of infected groups, Dr Chin believes, and fostered a climate in which the public remained ‘fearful about HIV infections ‘jumping out’ from these foci of infection to spread into the ‘general population’”. This was an unlikely outcome, in Dr Chin’s view, but such worries kept vigilance and fundraising high. Helen Epstein... also said this week that the old numbers had ‘fitted perhaps a certain fundraising agenda’” [Caldwell 2007].

<sup>54</sup> The burden of disease is here approximated in DALYs.

<sup>55</sup> The statement can however be seen as slightly alarmist, for instance indicating tuberculosis as a leading cause of death on adults. *See infra* this section.

people are currently infected, representing 64% of the world HIV positive population [UNAIDS and WHO 2005]. In Swaziland, Botswana and parts of South Africa women antenatal clinics reveal a shocking 30% seropositivity rate [Craddock 2004: 1]. Women are disproportionately affected, as they account for approximately 60% of estimated HIV infections in sub-Saharan Africa [UNAIDS 2009: 22]. The reasons are both greater physiological susceptibility and the social, legal and economic disadvantages they often confront [*id.*].<sup>56</sup> HIV/AIDS is also worsening the trends of many communicable diseases such as tuberculosis, malaria and lower respiratory tract infections.<sup>57</sup> With regard to noncommunicable diseases, HIV positive children are more prone to developmental disabilities [Baingana and Bos 2006: 3]. Maternal HIV seropositivity compromises the provision of care and undermines global cognitive development [Baingana, Thomas, and Comblain 2005]. The Kaposi's sarcoma is now the leading cancer in children where there is high HIV prevalence [Baingana and Bos 2006: 4].<sup>58</sup> Finally, 30% of HIV positive individuals show some evidence of cardiac involvement [Mbewu and Mbanya 2006: 312]. To note, there are conspicuous variations in the incidence and mortality due to AIDS within Africa.<sup>59</sup>

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<sup>56</sup> See also section 2.2.2 below.

<sup>57</sup> Baingana and Bos report that the caseload of tuberculosis has increased by a factor of five or more in the regions of eastern and southern Africa most affected by HIV [Baingana and Bos 2006: 3]. HIV positive individuals are also more vulnerable to malaria, suffering from higher density of parasitemia and more severe symptoms of malaria in adults. HIV seropositivity approximately doubles the risk of malaria parasitemia and clinical malaria in nonpregnant adults. Consequently HIV infection increases incidence and severity of clinical malaria in adults [Snow and Omumbo 2006: 205]. 45% of the children hospitalised for lower respiratory tract infections are HIV positive. The HIV positive patients represent 80% of the deaths among the children hospitalised for the respiratory condition.

<sup>58</sup> Noteworthy, before the HIV epidemic, the Kaposi's sarcoma was a rare condition, which has now increased 20-fold [Baingana and Bos 2006: 4].

<sup>59</sup> The sub-Saharan African countries most affected by the AIDS epidemic endure a particularly high rate of morbidity and mortality and, to mean, are the only countries classified by WHO in its mortality strata as subgroup 'E', characterised by 'high child, very high adult mortality'. The other African countries classify as 'D', implying 'high child, high adult mortality'. Even in 'D' countries, AIDS represents the leading cause of death for individuals aged 15-59 [Roa et al 2006: 55]. In AFR D countries 25.8% of deaths at 15-59 are due to HIV/AIDS. In AFR E countries, the quota arises to 54.1% [Roa et al 2006: 55]. The WHO's regional subgroup AFR E countries are: Botswana, Burundi, Central African Republic, Côte d'Ivoire, Democratic Republic of Congo, Eritrea, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, the Republic of Congo, Rwanda, South Africa, Swaziland, Uganda, Tanzania, Zambia, Zimbabwe. WHO's classification is utilised in other epidemiological studies such as the those by the

Malaria is the second leading cause of mortality in sub-Saharan Africa, accounting for 10% of deaths [Rao, Lopez and Hemed 2006]. It is the main killer for the 0-14 years old youths, causing 20% of deaths [*id.*: 53]. In the last 20 years children mortality due to malaria in sub-Saharan Africa has reportedly risen [Snow and Omumbo 2006: 205]. Moreover, besides the deaths occurring as a direct result of the infection by *P. falciparum*, malaria also causes consequential and indirect mortality which, according to Snow and Omumbo, increase the amount of deaths due to this disease by 10%.<sup>60</sup> Also, it seems that high density of exposure to malaria infections may increase the rate of progression of HIV in Africa.<sup>61</sup> The third killer in sub-Saharan Africa is again related to an infection. The acute respiratory infections, a category of lung infections including the particularly severe lower respiratory tract infections such as pneumonia and bronchiolitis, are responsible for 9.8% of deaths in sub-Saharan Africa each year [Rao, Lopez and Hemed 2006: 53]. The burden of lower respiratory tract infections doubles where HIV is more virulent [Madhi and Klugman 2006: 151]. HIV-infected children are up to 40 times more likely to get a pneumococcal disease [The Economist, New Vaccines for Old Killers, 2007]. Sub-Saharan Africa is suspected to have the world's highest incidence of acute respiratory infections. The death toll is particularly heavy for children under five years of age, for which acute respiratory infections represent the leading cause of death.

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World Bank (*see infra*) [Roa et al 2006: 55]. AFR D countries are: Algeria, Angola, Benin, Burkina Faso, Cameroon, Cape Verde, Chad, Comoros, Equatorial Guinea, Gabon, The Gambia, Ghana, Guinea-Bissau, Liberia, Madagascar, Mali, Mauritania, Mauritius, Niger, Nigeria, São Tomé and Príncipe, Senegal, Seychelles, Sierra Leone, Togo [Roa et al 2006]. The WHO estimates that without HIV/AIDS, life expectancy at birth in the African region would have been almost 6.1 years higher in 2002. In effect, the reduction in life expectancy varies significantly across the African region. The greatest impact has been in Botswana, Lesotho, Swaziland and Zimbabwe, where HIV/AIDS has reduced male and female life expectancies by more than 20 years [WHO, The World Health Report 2003, 2003: 204].

<sup>60</sup> With regard to consequential mortality, death can occur as a consequence of certain situations caused by malaria such as antimalarial adverse drug reaction, anaemia, HIV infection through transfusion, neurological disability associated with severe malaria [Snow and Omumbo 2006: 203]. With regard to indirect mortality, malaria: can also increase mortality both for the child and the mother during pregnancy; is a major contributor of anaemia in children; is concomitant to undernutrition, even though the precise causal relationship is difficult to quantify (probably, the two conditions enjoy a synergic relationship rather than a unilateral causality); and can facilitate the severity of HIV in an individual [Snow and Omumbo 2006: 203].

<sup>61</sup> According to a study in Malawi reported by the authors, HIV blood viral levels were found to be seven times higher in HIV positive adults with acute, uncomplicated malaria than in HIV positive blood donors without malaria. Importantly, the increased HIV viral burden was reversed by effective malaria therapy [Snow and Omumbo 2006: 206]. Note, this interaction also occurs with other acute infections [Snow and Omumbo 2006].

Estimates indicate that, in 2000, 70% of the worldwide 1.9 million children deaths due to acute respiratory infections occurred in Africa and Southeast Asia [Williams et al 2002].

Diarrhoeal diseases are the next major cause of mortality in sub-Saharan Africa. They are responsible for 6.5% of total deaths and are particularly harsh on children, accounting for 12.7% of the deaths in the age group 0-14 [Rao, Lopez and Hemed 2006: 55].<sup>62</sup> Sub-Saharan Africa, again, holds a sad worldwide record relating to an epidemiological phenomenon. As Bryce et al reckon, of the estimated total 10.6 million deaths among children younger than five years of age worldwide, 42 percent occur in the WHO African region.<sup>63</sup> HIV/AIDS contributes also to the incidence of this condition [Boschi-Pinto, Lanata, Mendoza, Habte 2006: 107]. Leading to 3% of all deaths in sub-Saharan Africa, tuberculosis (TB) is gaining ground in the region as its incidence rate is increasing at 3% per year [Dye et al 2006: 183]. WHO notes that while the largest number of new tuberculosis cases in 2004 occurred in WHO's South-East Asia Region, the estimated incidence per capita in sub-Saharan Africa is nearly twice that of the South-East Asia Region, at nearly 400 cases per 100,000 population, the highest in the world. Both the highest number of deaths and the highest mortality per capita take place in the WHO Africa region [WHO, website, Tuberculosis, 2006]. The mortality rate is increasing. The main responsible for this situation is the diffusion of HIV, which not only facilitates the infection, but also undermines the possibilities of recovery from tuberculosis [Dye et al 2005: 187].<sup>64</sup> In return, tuberculosis is a leading cause of death among HIV-positive people, accounting for about 13% of AIDS deaths worldwide [WHO, website, Tuberculosis, 2006]. In 2000, sub-Saharan Africa was aggrieved by the 70% of world HIV-TB co-infections, affecting 17 million people [Dye et al 2006: 183]. A last mention can be made to the recent emergence of drug resistance to the standard tuberculosis treatment in sub-Saharan Africa, where it has been traditionally low.<sup>65</sup>

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<sup>62</sup> The major causes of diarrhoea are enteropathogens such as rotavirus, entero-adherent *Escherichia coli*, enterotoxigenic *Escherichia coli* and *Giardia lamblia* [Boschi-Pinto, Lanata, Mendoza, Habte 2005].

<sup>63</sup> The study is quoted in Boschi-Pinto, Lanata, Mendoza, Habte [2006: 107].

<sup>64</sup> Up to 15% of tuberculin-positive, HIV-positive adults will develop tuberculosis each year [WHO 1999 in Dye et al 2005: 188], while the lifetime risk is 50% or higher [Dye et al 2005: 182]. Without HIV coinfection, the average lifetime risk of infected individuals developing tuberculosis is 5 to 10% [Dye et al 2005: 181]. The interval between HIV infection and the onset of tuberculosis is four to six years [Dye et al 2005: 188].

<sup>65</sup> Beside MDR-TB, cases of XDR-TB, practically incurable, are occurring in South Africa. See BBC News, "Virtually Untreatable TB Found" [2006].

Sub-Saharan Africa also bears the greatest burden of vaccine-preventable diseases. This region accounts for 59% of all measles deaths, 41% of tetanus deaths, 80% of yellow fever deaths, and 58% of pertussis (whooping cough) deaths [Disease Control Priority Project, online, 2006]. It is estimated that the African continent suffers as much as 59% of all global cases of measles [US Coalition for Child Survival, website, 2007]. Measles alone accounts for 4% of total deaths in sub-Saharan Africa, 8.75% for children under 14 [Rao, Lopez and Hemed 2006: 55]. Finally, sub-Saharan Africa is not spared from the chronic diseases that mostly affect richer regions in the world. In fact, if circulatory system (ischemic heart diseases and hypertensive diseases) and cerebrovascular diseases are lumped together as cardiovascular diseases, they account for 11% of total deaths in sub-Saharan Africa amounting to the second most common cause of adult deaths [Mbewu and Mbanya 2005: 305].<sup>66</sup> Interestingly, half of cardiovascular diseases deaths occur among people 30 to 69 years of age, which is ten or more years younger than in more developed countries [Baingana and Bos 2005: 2,3].

### **2.2.2 Determinants of health and public health**

The epidemiological situation described above is due to a multiplicity of contingent factors, some of them human and some natural, which together constitute the sub-Saharan African ‘health systems’. Namely these factors include geography, climate, infrastructures (*e.g.*, access to drinking water and sanitation), nourishment, knowledge about health issues and hygiene, culture, mores, attitudes, behaviours and the health care systems.<sup>67</sup> The role of the health-care systems will be analysed in the following sections

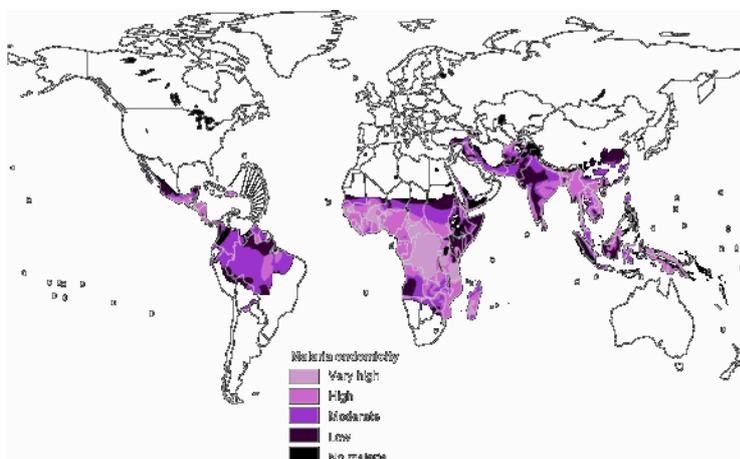
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<sup>66</sup> Cardiovascular diseases encompass a wide array of disorders, including diseases of the cardiac muscle and of the vascular system supplying the heart, brain, and other vital organs. Ischemic heart disease, stroke, congestive heart failure account for at least 80% of the burden of cardiovascular diseases in all income regions. A fourth manifestation, rheumatic heart disease accounts for three percent of all DALYs lost as a result of cardiovascular diseases, does not contribute significantly to the overall global burden of cardiovascular diseases [Gaziano et al 2006: 645].

<sup>67</sup> The WHO “World Health Report – Health Systems: Improving Performance” defines health system “to include all the activities whose primary purpose is to promote, restore or maintain health” [WHO, World Health Report 2000, 2000: 5]. According to Sheaff, “[a] health system... includes a healthcare system plus methods for influencing health determinants in other sectors” [Sheaff 1996: 173].

with particular regard to access to medicines. This section presents the role of other aspects of health systems and public health.<sup>68</sup>

With regard to environmental risks, WHO AFRO reports that hundreds of thousands of Africans, particularly children, die every year from diseases caused by micro-organisms, certain chemicals in the water supply, or diseases caused by poor sanitation. Poor water and sanitation also bring with them a host of non-fatal but debilitating diseases as well as severe problems of environmental degradation that have a further impact on health. Without safe water for drinking and for use in food preparation, populations are vulnerable to an array of waterborne diseases including cholera, typhoid and other diarrhoeal infections as well as to parasites, such as guinea worm and schistosomes [WHO AFRO 2006: 86]. The UNICEF/WHO Joint Monitoring Programme for Water and Sanitation found that in 2002 the percentage of the population of sub-Saharan Africa with access to a safe water supply was 58%. Just 36% of African individuals have access to adequate sanitation facilities [WHO/UNICEF 2005]. Deadly malaria parasites are particularly diffused in the equatorial and tropical areas of Africa, as shown in the following map representing the global distribution of malaria transmission risk in 2003 [World Malaria Report 2005].<sup>69</sup>

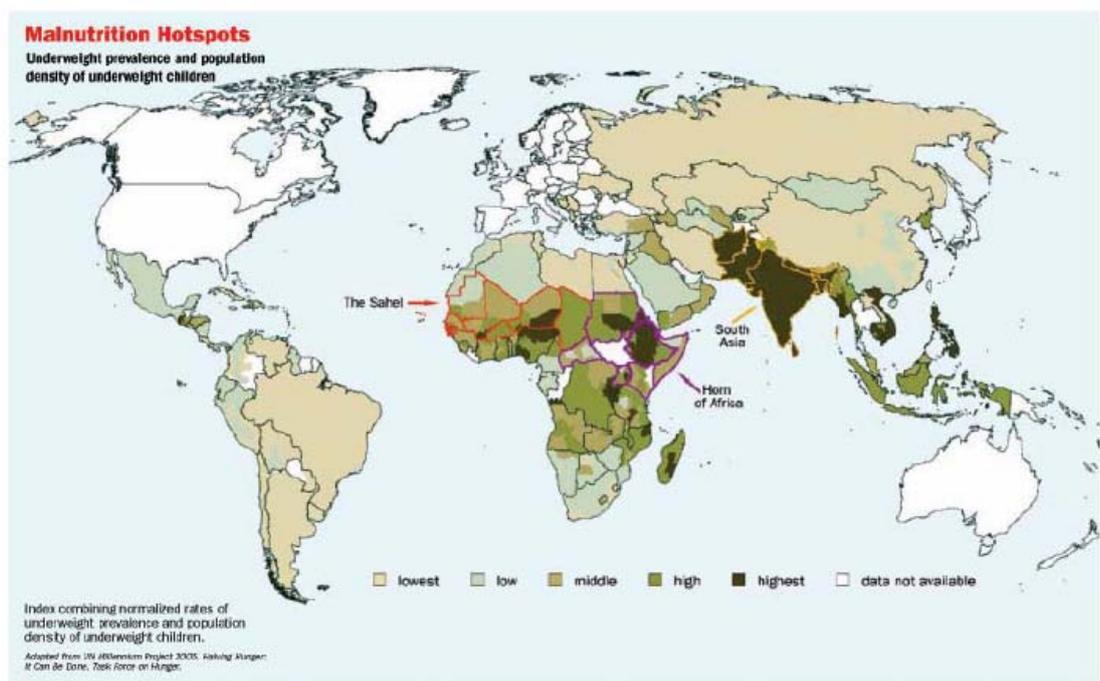


Global distribution of malaria transmission risk, 2003. The burden of Africa is apparent. Source: World Malaria Report 2005 [Roll Back Malaria website, last accessed February 2010]

<sup>68</sup> Beaglehole and Bonita in their “Public Health at the Crossroad” normatively define public health as the “collective action for sustained population-wide health improvement” [Beaglehole and Bonita 2004: 174]. The notion of public health is normatively controversial. *See* Chapter 4 section 4.4.4.

<sup>69</sup> The 2005 World Malaria Report is the last available [Roll Back Malaria, website, World Malaria Report 2005].

Undernourishment can originate both from insufficient calories intake and from inadequate micronutrients blend [Gale Encyclopedia of Medicine 2002]. The latter is particularly crucial for infants, young children, teenagers, pregnant or breastfeeding women. Deficiencies in essential vitamins (etymologically ‘the amines of life’) such as vitamin A, and minerals, such as iron, folic acid and iodine, can have life-long dire consequences. Moreover, undernourishment readily crosses generations through a phenomenon called biological programming. The infants of undernourished women begin their own lives malnourished, and face increased risk of early death, childhood disease and life-long impairments. Undernourished women are more likely to die in childbirth, or to suffer debilitating complications of pregnancy and childbirth [FAO 2002]. More generally, undernourishment is the major risk factor for over 28% of all deaths in Africa – some 2.9 million deaths annually [Benson and Shekar 2006: 87]. An estimated 200 million people in Africa are undernourished [FAO 2003]. Sub-Saharan Africa is the only region in the world where famines are endemic [Deveraux 2000].



Underweight prevalence and population density of underweight children. Sub-Saharan Africa is severely affected by this condition [Shepherd 2008; UN Millennium Project, *Halving Hunger, It Can Be Done*, 2005]

Lack of knowledge about hygiene and health-relevant information may result in people not getting the full health gain from inputs that are available to them. It is sometimes claimed that one of the most effective interventions against diarrhoea is hand-washing [Wagstaff and Claeson 2004: 137]. Many women do not know that piped water

often requires further purification [*id.*: 78]. It has been estimated that secondary education can exert a significant effect on infant mortality. The use of almost all child health interventions is higher in households with better-educated mothers [Wagstaff and Claeson 2004: 40]. In sub-Saharan Africa an average of only 30% of each age cohort completes junior secondary education and 12% senior secondary education [World Bank, Secondary Education and Training in Africa]. According to Gaziano et al, high blood pressure, high cholesterol, extensive tobacco and alcohol use, and low vegetable and fruit consumption are already among top (behavioural) risk factors for disease in Sub-Saharan Africa [Gaziano et al 2006: 659].

With specific regard to AIDS, a flourishing literature researches the characters of the AIDS pandemic ‘beyond epidemiology’, to borrow the expression used by Kalipeni et al, focusing on the behavioural and social contexts of AIDS contagions [Chin 2007; Craddock 2004; Barnett and Whiteside 2002/2006; Epstein 2007; Kalipeni et al 2004; Pisani 2008]. Craddock emphasises some socio-economic features underpinning the AIDS problem such as children abandonment and women exploitation [Craddock 2004]. Gender can in effect be made a ‘risk factor’. Women are often unable to protect themselves from unprotected intercourse and sexual violence makes them more vulnerable to HIV infection [Craddock 2004; McCoy 2003: 9]. Such weakness also contributes to the diffusion of ‘unsafe sexual practices’ and enhances the burden of sexually-transmitted diseases in sub-Saharan Africa. Indeed, WHO reckons that more than 99% of the HIV infections prevalent in Africa in 2001 are attributable to unsafe sex [WHO, World Health Report 2002: 62]. Globally, about 2.9 million deaths (5.2% of total) are attributable to unsafe sex [*id.*: 63]. The vast majority of this burden results from HIV/AIDS infections occurring in the African region [*id.*]. Furthermore, Barnett and Whiteside in effect identify different causes for the epidemics depending on the context of each region.<sup>70</sup> Epstein, moreover, finds a strong correlation between the sexual lifestyle that she dubs ‘concurrency’ of long-term sexual relationships – as opposed to serial monogamy – and the diffusion of HIV/AIDS in sub-Saharan Africa [Epstein 2007]. Therefore, preventive interventions of social campaigning can modify those behaviours

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<sup>70</sup> Barnett and Whiteside argue for example that in Uganda and Democratic Republic of Congo the AIDS epidemic originated from the scourge of corrupt governments and war; in Tanzania AIDS diffused within gradual economic and social changes; in South Africa, the epidemic originated from the legacy of apartheid, and especially the utilisation of migrant black workers at mines which were separated from the families and turned to local prostitutes for sex [Barnett and Whiteside 2002].

and/or the risks associated with them: Epstein for instance appeals to social mobilisation on the issue, taking inspiration from what has happened in San Francisco (US) and Uganda [*id.*].

### **2.2.3 The possibilities offered by medical prevention and treatment**

This section illustrates the bio-medical approaches which can prevent, alleviate or cure the health problems affecting the people in sub-Saharan Africa. Curative (as opposed to preventive) bio-medical interventions in particular act on the identifiable patient, seeking to heal or alleviate the condition she suffers from. Bio-medical approaches generally use pharmaceutical products. It has always to be considered, nonetheless, that bio-medical treatment often is not sufficient on its own to cure diseases – let alone to deliver health; its success generally depends on the patient's conditions and on the quality of the health assistance accessible to her. Again, extensive reference is made in the following paragraphs to medical studies often supported or compiled by UN agencies.

With regard to HIV, as of today it is not possible to eliminate the virus after it settles in a body.<sup>71</sup> In the absence of a therapy, after a median of between nine to ten years of latency, HIV progresses to the acquired immunodeficiency syndrome (AIDS), after which the remaining median survival time is 9.2 months [Morgan et al 2002]. Yet, the highly active antiretroviral therapy (HAART) can increase the life expectancy of a HIV positive person to 32 years from the time of infection if treatment is started when the CD4 count is 350/ $\mu$ L [Schackman et al 2006]. The effectiveness of the treatment can vary according to the patient's viral load, medication tolerance and environment, also including the availability of medical care such as monitoring of the progress of the treatment and care of side effects. A major determinant of treatment effectiveness, though, is adherence, *ie* the continuous utilisation of the prescribed medicines, which has to be maintained at 98% [Department of Health and Human Services 2006]. Encouragingly, studies conducted in several African countries indicate high degree of success and patients demonstrated a strong commitment to adhere to the prescribed

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<sup>71</sup> Some cases have been reported where HIV prevalence became so low that it could not be detected [Levy 2009].

regimen of drugs [Mboup et al 2005: 244].<sup>72</sup> As in most developing countries, the standard regimen is now a three-drug combination that includes two nucleoside analogue reverse transcriptase inhibitors (NRTIs) and one nonnucleoside transcriptase inhibitor (NNRTI) [Mboup et al 2005: 243].<sup>73</sup> However, in 2005, only 17% of the people in need of treatment in the African Region were receiving it (*ie* 810,000 people out of 4.7 million).<sup>74</sup> One major problem, moreover, is that the antiretroviral therapy requires regular and nutritious food intake, which is often a problem for people in sub-Saharan Africa, as seen in section 2.2.2.<sup>75</sup>

Malaria used to be treated with chloroquine and sulfadoxine–pyrimethamine (SP), but in recent years *plasmodium falciparum* has developed resistance to such remedies in most of the African continent [WHO AFRO 2006: 53]. So far, combination treatments based on artemisinin do not encounter resistance, and many African countries are shifting to this as first-line treatment. However, while a total of 33 out of the 42 malaria-endemic countries in the African Region have adopted artemisinin combinations as first-line treatment, only nine of these are currently implementing such treatment policies [*id.*: 55].<sup>76</sup> It is reported that the number of people receiving effective antimalarial medicines within 24 hours of onset of symptoms remains low [*id.*].

If left untreated, 50–80% of patients with smear-positive tuberculosis will die of their disease.<sup>77</sup> In contrast, death rates in directly observed therapy, short-course (DOTS)

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<sup>72</sup> As Mboup et al report, these include survival rates of 85% or higher, and escalation of CD4 cell counts of 150 CD4+ cells per cubic millimetre or more by a year after drug initiation. Moreover, surprisingly positive responses also came from patients who began drug therapy at cell counts below 50 CD4+ cells per cubic millimetre, most of whom would have probably died within a year if left untreated [Mboup et al 2005: 244]. These results are important, as scepticism originally abounded on the possibility of maintaining the required adherence in the African health setting.

<sup>73</sup> Common reverse transcriptase inhibitors are for example zidovudine (AZT) and lamivudine (3TC); a common nonnucleoside transcriptase inhibitor is nevirapine (NVP).

<sup>74</sup> From WHO [Report on the State of the Global AIDS Pandemic, 2006]. *See also* Losse et al holding that “[i]n 2001, in high-income countries, 500,000 patients took antiretrovirals and fewer than 25,000 died; in sub-Saharan Africa, fewer than 30,000 patients took antiretrovirals and 2.2 million died” [Losse et al 2007:1].

<sup>75</sup> *See* WHO, 2006 Report on the Global AIDS Epidemic [2006: 171]. The World Food Programme is intervening by collaborating with the WHO/UNAIDS 3 by 5 programme [*id.*]. On the 3 by 5 programme *see also* Chapter 6 section 6.4.1.

<sup>76</sup> *See also* MSF, Malaria still kills needlessly in Africa – Effective Drugs are not Reaching Patients [2006].

<sup>77</sup> For the majority of countries, pulmonary TB (PTB) is diagnosed by sputum smear microscopy, the only tool available despite a widely variable sensitivity of 22–80%.

programmes throughout the world are generally less than 5% [Frieden 2002: 895]. DOTS consists of a combination of antibiotics, usually rifampicin and isoniazid, and takes around 6 to 12 months to entirely eliminate the mycobacteria from the body [American Lung Association 2005: 7]. However, in a poorly implemented tuberculosis programme, as many as 30% of patients with smear-positive tuberculosis die [Frieden 2002: 895]. In fact, as WHO reports, the “treatment success in the 2003 DOTS cohort of 1.7 million patients was 82% on average” [WHO 2006, Tuberculosis, Fact Sheet N°104, Revised March 2006]. As for Africa, the proportion of success amounted to 72% [Dye et al 2005: 187].<sup>78</sup> It should be observed, though, that the estimated case detection rate under DOTS was 48%.<sup>79</sup> Treatment of HIV positive tuberculosis patients is particularly problematic as they are more likely to develop adverse reaction to anti-TB medicines and their immune status is compromised. Accordingly, Dye et al state that antiretroviral therapy could greatly extend the lives of HIV-infected patients [Dye et al 2005: 189]. A preventive treatment for tuberculosis is also possible, which reduces the short-term risk of developing the active disease.<sup>80</sup> It is particularly indicated for tuberculin positive, HIV positive individuals, for whom isoniazid preventive treatment reduces tuberculosis prevalence by about 60% [Corbett et al 2006: 933]. However, as Corbett et al note, this low-cost intervention has been little used in Africa, with only Botswana attempting widespread implementation [Corbett et al 2006: 933].

Lower respiratory tract infections are due to a variety of pathogen agents. The dominant pathogens in sub-Saharan Africa are the respiratory syncytial virus and two bacteria: *Streptococcus pneumoniae* and *Haemophilus influenzae*, which can be defied with antibiotics. Drawing conclusion from the evaluation of a programme in Malawi,

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Although smear-negative PTB cases are less infectious than smear-positive cases, a significant proportion of secondary cases have been traced to exposure to smear-negative patients. In HIV/AIDS patients, an increase in the proportion of smear-negative PTB has been observed. HIV-infected smear-negative PTB cases have also been shown to have a poor prognosis compared to smear-positive PTB patients. Therefore, the Stop TB Strategy emphasizes the need for timely diagnosis and treatment of all tuberculosis cases, including smear-negative PTB. Worryingly, in the presence of HIV infection, altered clinical and radiological presentations make the diagnosis of tuberculosis difficult. In HIV-infected patients, PTB with normal chest X-rays and without clinical symptoms has been documented frequently, furthering the need for high-quality microscopic and microbiologic examinations [Tamahane et al 2009: 347].

<sup>78</sup> The HIV coinfection increases the death rate in some countries [Dye et al 2005: 187].

<sup>79</sup> The global average is 53% [Dye et al 2005: 186].

<sup>80</sup> The protection has a limited duration, approximately 2.5 years where transmission rate of *M. tuberculosis* high [Dye et al 2005: 188].

Madhi and Klugman state that “standard inpatient case management of severe and very severe pneumonia by trained staff with a regular supply of antibiotics produced a striking impact on the number of deaths occurring after 24 hours of hospital admission, even in the adverse conditions of Malawi, where the prevalence of HIV infection is high, malnutrition is rife, the level of maternal literacy is low, and an efficient transport system from peripheral to district hospitals is lacking” [Madhi and Klugman 2005: 155-6]. Indeed the overall success of treating lower respiratory tract infections improved from 55% at the time of the start of the programme to 82%, 26 months later [Madhi and Klugman 2005: 155-6]. The risk of developing lower respiratory tract infections can be preventively reduced through the administration of vaccines such as the measles vaccine,<sup>81</sup> the Hib conjugate vaccine<sup>82</sup> and the *S. Pneumoniae* conjugate vaccine.<sup>83</sup> The heavy burden of lower respiratory tract infections notwithstanding, the latter two vaccines are not but exceptionally routinely adopted in sub-Saharan Africa.<sup>84</sup>

Diarrhoea is a symptom that, as pneumonia, can be caused by different pathogens. The most relevant pathogens in terms of morbidity and mortality in sub-Saharan Africa are enteropathogens such as rotavirus, entero-adherent pathogenic *Escherichia Coli*, enterotoxigenic *Escherichia Coli* and *Shigella*. Effective medical interventions for the treatment of diarrhoea include oral rehydration therapy and antimicrobials. These latter are especially necessary for bloody diarrhoea, and their prescription has to be accurate considering the increasing occurrence of drug resistance by the pathogens involved [Keusch et al 2006: 378]. According to Jones et al the

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<sup>81</sup> Under-five children immunised with the measles vaccine had a mortality rate due to lower respiratory-tract infections two-fold less common [Madhi and Klugman 2005: 155].

<sup>82</sup> In The Gambia the Hib conjugate vaccine reduced the incidence of radiologically confirmed pneumonia by 21% [Mulholland et al 1993 in Madhi and Klugman 2005: 156].

<sup>83</sup> Among South African children, the *S. Pneumoniae* conjugate vaccine was shown to reduce culture-confirmed invasive pneumococcal disease by 83% and radiologically confirmed pneumonia, irrespective of microbiological diagnosis, by 20% [Klugman et al 2003 in Madhi and Klugman 2005: 157]. In The Gambia it was also found to reduce all-cause hospitalisation by 15% and all-cause mortality by 16% [Cutts et al 2005 in Madhi and Klugman 2005: 158].

<sup>84</sup> Despite Hib conjugate vaccines being available since the late 1980s, the only sub-Saharan African country to have introduced it in its routine immunisation programme was South Africa (since 1999) [Madhi and Klugman 2005: 156]. In 2000, fewer than 1% children living in the 42 countries with 90% of worldwide child deaths (which roughly represent sub-Saharan Africa) received the vaccine [Jones et al 2003: 67, referring to UNICEF, State of the World’s Children 2003, 2003].

utilisation of oral rehydration therapy and antibiotics could save 15% and 3% respectively of all under-5 deaths in the 42 countries with 90% of worldwide child deaths in 2000 [Jones et al 2003: 67]. Yet, the coverage estimates for these child survival interventions is respectively 20% and 10% [Jones et al 2003: 67, referring to UNICEF, State of the World's Children 2003, 2003].

According to Yusuf et al, up to 22% of premature all-cause mortality by cardiovascular diseases and 45% of stroke mortality can be reduced by appropriate detection and treatment [Mbewu and Mbanya 2005: 321 referring to Yusuf et al 2004]. Gaziano et al report some medical interventions which they consider cost-effective in developing countries because they “result in large reductions in cardiovascular diseases events, are inexpensive, or the prevalence or incidence of the diseases to which they are directed is significant” [Gaziano et al 2006].<sup>85</sup> For instance, with regard to ischemic heart disease,<sup>86</sup> the treatment of acute myocardial infarction uses beta-blockers, aspirin or thrombolytics or an invasive intervention with cardiac catheterization and angioplasty, while the long-term medical management of existing vascular disease involves pharmacotherapy and can use invasive techniques.<sup>87</sup> Congestive heart failure<sup>88</sup> is to be treated with diuretics, angiotensin-converting enzyme inhibitors,<sup>89</sup> and beta-blockers.

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<sup>85</sup> See also Mbewu and Mbanya stating that cheap, effective therapy for cardiovascular diseases is available [Mbewu and Mbanya 2005: 321].

<sup>86</sup> Ischemic heart disease is the clinical manifestation of the coronary heart disease. Two leading manifestations of ischemic heart disease are acute myocardial infarction and angina pectoris [Mbewu and Mbanya 2005: 310; Gaziano et al 2006: 645].

<sup>87</sup> Beta-blockers reduce myocardial oxygen demand and fatal arrhythmias. Aspirin restores blood flow by inhibiting platelet aggregation. Thrombolytics dissolve the thrombus occluding the arterial lumen [Gaziano et al 2006: 650-53]. The pharmacological interventions either prevent thrombosis, as does aspirin, or target the individual risk factors, as do the antihypertensives (diuretics, beta-blockers, and angiotensin-converting enzyme inhibitors) or statins targeting cholesterol. Furthermore, these agents may possibly have additional properties of reducing the risk of fatal arrhythmias, improving repair after AMI (remodeling), or stabilizing the atherosclerotic plaque. Invasive techniques are angioplasty or percutaneous coronary intervention [Gaziano et al 2006: 650-53].

<sup>88</sup> Congestive heart failure is the end stage of many heart diseases. Ischemic heart disease and hypertension-related heart disease are the most common etiologies [Gaziano et al 2006: 646].

<sup>89</sup> Angiotensin-converting enzyme inhibitors reduce risks related to a variety of endpoints, including mortality, hospitalization, major coronary events, deterioration of symptoms, and progression from asymptomatic to symptomatic left ventricular dysfunction, by 25 to 33%. Angiotensin-converting enzyme inhibitors has proved to be highly cost-effective in developed countries [Gaziano et al 2006: 650-53].

With regard to the rheumatic heart disease,<sup>90</sup> antistreptococcal treatment (such as penicillin) manages clinical manifestations. Secondary prophylaxis to prevent colonization of the upper respiratory tract consists of penicillin or sulfadiazine for the first five years. Tertiary treatment entails surgery for valve replacement or valvuloplasty [Gaziano et al 2006: 650-53]. However, Mbewu and Mbanya note that “[c]ardiovascular disorders currently receive little or no attention in most African countries” [Mbewu and Mbanya 2005: 322]. Lastly, supplementary and therapeutic foods can be administered to overcome undernourishment and malnourishment. Fortified peanut butter-like pastes have proved to be particularly effective for malnourished children [Enserink 2008].

## **2.3 Access to medicines in sub-Saharan Africa**

### **2.3.1 Estimate and dimensions of access to medicines in sub-Saharan Africa**

The account provided in the previous section maintains that some medical interventions which would improve the health of the people in sub-Saharan Africa are technically feasible but are seldom put into practice. One of the necessary components for treatment lacking in sub-Saharan Africa is access to medicines.<sup>91</sup> A precise quantification of access to medicines overall is difficult, but the WHO has estimated that 47% of the people in Africa lack access to ‘essential’ medicines [WHO, The World Medicines Situation, 2004: 62].<sup>92</sup> To note, the identification and selection of ‘essential’ medicines is ethically, medically, economically and legally problematic, as it will be discussed in Chapters 5 and 6.<sup>93</sup> In fact, the approximation utilised by WHO in this study relates to a mere minimum list of 20 essential medicines; the list most probably does not include the latest artemisinin-based combination therapy adopted since 2004 by African countries in their drug policies [WHO AFRO 2006: 54] or antiretrovirals, which have

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<sup>90</sup> Rheumatic heart disease is the consequence of an acute rheumatic fever. It can entail several complications which may lead to sudden cardiac deaths [Gaziano et al 2006: 647].

<sup>91</sup> See Sheaff on the elements of health-care systems [Sheaff 1996: 172].

<sup>92</sup> WHO estimate for 1999. In 37 out of the 45 countries in the African Region the percentage of people with regular access to essential medicines was inferior to 50%, accordingly defined ‘very low’ [WHO 2004: 62].

<sup>93</sup> In particular see Chapter 5 section 5.4.1.

been recommended for the first time in WHO model essential drug lists (EDLs)<sup>94</sup> only in 2002 [Laing 2004: 1724].<sup>95</sup> More analytical are the surveys on medicine prices and availability undertaken by some African countries within the ‘Medicines Prices’ project.<sup>96</sup> The surveys revealed a diversity in prices and availability of medicines between geographical areas (and most evidently between urban and rural areas), as well as between the public, private and non-profit sectors.<sup>97</sup> Moreover they underscore the discrepancies between the procurement prices and the private retail prices, also comparing those to the international reference price. Again, to be noted, these studies are indicative, focussing on a restricted sample of products which provide comparable data (30 common core medicines to which other supplementary products can be added by each country).<sup>98</sup>

These studies highlight that access to medicines is an elaborate concept, which has to be operationalised. The WHO has produced a seminal definition and a framework for access to medicines which are also referred to by the Committee on Economic, Social and Cultural Rights (the treaty-body which oversees the International Covenant on Economic, Social and Cultural Rights) and the African Commission on Human and Peoples’ Rights (the treaty-body which oversees the African Charter on Human and Peoples’ Rights) when they prescribe access to medicines as a human right [CESCR 2000: para. 43(d); AC Res. 141 (2008): para. 2(3)(a)]. WHO defines ‘access’ to essential medicines as having essential medicines “continuously available and affordable at public or private health facilities or drug outlets that are within one hour walk of the population”

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<sup>94</sup> WHO’s essential drug lists (EDLs) are meant to recommend which medicines should be available to a population, thereby indicating what priority WHO gives to certain medicines. *See more* in Chapter 6 section 6.2.1.1.

<sup>95</sup> Indeed, the data presented in “The World Medicines Situation” refer to a 1999 survey. I was unable to find out which medicines were included in the survey. My letters written in July 2008 to several WHO email addresses have not been replied.

<sup>96</sup> The ‘Medicine Prices’ project originates in a collaboration between WHO and Health Action International. It provides a framework and encouragement for governments to undertake medicine price and availability surveys. So far, in sub-Saharan Africa, Cameroon, Chad, Congo, Ethiopia, Ghana, Kenya, Malawi, Mali, Mauritius, Nigeria, South Africa Gauteng province, South Africa Kwa Zulu Natal state, Sudan, Tanzania, Uganda and Zambia have participated [HAI, website, last accessed February 2010].

<sup>97</sup> *See, e.g.*, Candau and Guimier on Senegal [2001]; Chweya et al on Kenya [2003]; the Kenya Ministry of Health’s “Medicine Prices in Kenya” [2004]; The Ghanaian Ministry of Health’s “Pharmaceutical Sector Baseline” [2004] and the Ghanaian Ministry of Health’s “Medicines Prices in Ghana” [2004].

<sup>98</sup> *See* WHO and HAI [website, Medicine Prices: A New Approach to Measurement, last accessed 9 February 2010].

[WHO, The World Medicines Situation, 1999]. Access, therefore entails two main components: availability and affordability. Availability implies the physical presence of medicines, while affordability relates to the individuals' entitlements to acquire medicines. The notion of 'essential' medicines has also been worked out by the WHO and will be discussed in Chapters 5 and 6.<sup>99</sup>

### **2.3.2 Medicines manufacturing and sale: the pharmaceutical and retail sector**

The section above has anticipated that access to medicines is a multidimensional matter, not limited to the cost of medicines. Sections 2.3.2 and 2.3.3 present the economics and regulation that mainly affect access to medicines in sub-Saharan African countries. They illustrate how the actions of the business, non-profit and public sector can and do influence access to medicines. Some of these conducts can be influenced by different policies and regulations – and this provides the room of manoeuvre for the prescriptions of a human right to medicines. In particular, section 2.3.2 reviews the role of pharmaceutical companies, retailers and the state in the supply of medicines. Section 2.3.3 will present the main alternative arrangements for medicines distribution and financing.

Many pharmaceutical products utilise cheap raw material and greatly benefit from economies of scale.<sup>100</sup> However, the availability and affordability of medicines is weakly

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<sup>99</sup> In particular *see* Chapter 5 section 5.4.1.

<sup>100</sup> Since the internal costing of pharmaceuticals production is notoriously secretive, such allegation has to be actually inferred from a series of evidence. Economists Mossialos and Dukes offer some insights, suggesting to look at the following signs: “(a) [t]he proven ability of numerous ‘generic’ producers to supply products of high quality at a small fraction of their original cost once patents have expired or where they do not apply. For example: in India, where the originator company has sold a 500 mg dose of ciprofloxacin for US\$ 4.40, the Indian company Cipla is able to make and sell an identical product profitably for \$ 0.12, a 36-fold difference in price... [F]luconazole in Thailand costs \$ 14.00 per treatment day in branded form, whereas, a generic Thai version of the same drug is available at a price corresponding to \$ 0.75 per treatment day... (b) The fact that in a series of negotiated agreements on minimum-level pricing major manufacturers have reduced their asking prices for specific markets to as little as 1% of their original levels. There is no evidence that in doing so they have sold these products at a loss...(c) The experience of those independent investigators who have in the past occupied senior posts within industry. (d) Estimates by international organisations. WHO has estimated that most patented medicines are sold at 20-100 times their marginal costs” [Mossialos and Dukes 2001: 6-7].

related to the cost of production. With regard to the role of pharmaceutical companies, they often operate in regimes of non-perfect competition. Therefore, in order to maximise their profits, they may be able to charge the maximum price that consumers are willing to pay instead of a price close to the marginal cost of production, as it should be expected in regimes of perfect competition.<sup>101</sup> Competition can be restricted by natural and legal barriers [Gwartney et al 2006: 508], and both types of barriers can take place in the pharmaceutical sector. With regard to natural barriers to competition, the pharmaceutical market is ‘dynamic’. As Evans and Padilla note, “in dynamic industries, where typically fixed costs are high and incremental costs are low, the ‘competitive price’ is not given by marginal costs. Rather, it is efficient to charge prices according to customers’ willingness to pay so as to cover costs in the least output restricting way” [Evans and Padilla 2005: 101]. Oligopolies are *naturally* created because the production of pharmaceuticals requires high fixed and sunk costs, that which creates natural barrier to the entry in the market [Burns 2005]. It is remarked that the pharmaceutical industry is strongly concentrated. In 2002 the ten largest firms accounted for almost 50 percent of sales [Oberholzer-Gee and Inamdar 2004: 2147].<sup>102</sup> However, as Klimek and Peters underline, it is especially the concentration in specific markets/products that determines the nature of competition [Klimek & Peters 1995: 74]. Namely, some authors have identified a ‘rule-of-fives’ according to which the lowest prices are achieved when at least five therapeutic alternatives produced by five competing firms are present in the market [WHO and WTO Secretariats 2001: 16]. However, competition can be regulated and controlled by states. For example, competition law can redress abuses of dominance in a market. This has occurred, for instance, in 2002 in South Africa, when accusation of excessive pricing had been upheld by the South Africa Competition Commission in 2002.<sup>103</sup> States can also impose price controls, as for example Greece, Belgium and France do [Danzon et al 2005]. African countries however do not implement price controls policies [Tetteh 2008: 571]. The implementation of price controls is indeed problematic as it can reduce the availability of medicines.<sup>104</sup> On the other hand,

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<sup>101</sup> According to the microeconomics tenet, firms have a stimulus to enter competitive markets and compete on the price until the market price allows for some profit. *See, e.g.,* Katz and Rosen [1997].

<sup>102</sup> The trend is one of increasing concentration: in 1987, the 10 largest companies represented approximately 12 percent of worldwide sales [Oberholzer-Gee and Inamdar 2004: 2147].

<sup>103</sup> *See* Chapter 5 section 5.3.2.

<sup>104</sup> *See* Chapter 5 section 5.3.2.

regulation can provide legal barriers to the entry of potential competitors in a market, thereby constituting legal monopolies. Market power can be *legally* entrenched through the protection of intellectual property rights for pharmaceutical innovations which confers time-limited legal monopolies [Gwartney et al 2006: 508]. Such legal artifice is diffused and relevant in African countries. In Africa, only Angola and Eritrea do not currently protect patents on pharmaceuticals [Grace 2003: 53; CIPR: 46, 27; Thorpe 2002]. The consequences of the implementation of intellectual property law on access to medicines in Africa can be enormous, for instance with regard to the newest antiretrovirals and malaria treatments.<sup>105</sup>

Imperfect competition, however, does not necessarily imply that firms will adopt inconsiderate prices. Beside the distortion of imperfect competition, the price offered by the manufacturer can differ from the producing cost, for example, if the firm adopts differential pricing, which means that it charges different prices according to the different willingness to pay of the consumers. The segmentation of consumers generally occurs at the country level, in favour of poorer countries. This pricing policy is theoretically advantageous to firms, as it permits to get revenues from the worse-off purchasers. Furthermore, differential pricing can be based on equity pricing, namely the consideration that developing countries should not be asked to pay for medicine development cost, marketing, and shareholder returns [Leach et al 2005: 156].<sup>106</sup> The reluctance that pharmaceutical corporations have often demonstrated in adopting differential pricing is sometimes due to the technical difficulty of market segmentation and the ensuing problem of price and product leakages [Grace 2003]. Again, states can intervene supporting such schemes by impeding the re-exportation of concessionally-priced merchandise to other states.<sup>107</sup> Furthermore, pharmaceutical companies can implement other policies with explicit concern to access to medicines such as medicines donations, voluntary licenses of patented medicines, and not to patent medicines in some

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<sup>105</sup> New treatments are necessary to overcome the resistance to treatment that the human immunodeficiency virus and the malaria parasite develop by mutating throughout time. On the problem of patents on new treatments *see* Drahos and Braithwaite [2002: 11]; MSF's "A guide to the post-2005 world: TRIPS, R&D and Access to Medicines" [2005], Oxfam's "Patents Versus Patients" [2006], WHO's "Globalisation and Access to Drugs" [1999: 41]. On intellectual property *see* Chapter 5 section 5.2.1 and Chapter 6 section 6.2.1.

<sup>106</sup> *See also* Chapter 6 section 6.2.1.2.

<sup>107</sup> Purchasers in these third countries would otherwise take advantage from the so-called parallel importation, *ie* the importation in parallel to, and competing with, the official agent appointed by the manufacturer in a country [Rietveld and Haaijer- Ruskamp 2002].

countries. Often, pharmaceutical companies enter into agreements with other private and with public parties to provide medicines offering favourable conditions. Examples of such initiatives abound, with regard to Africa. For instance, pharmaceutical companies collaborate sometimes with the Accelerating Access Initiative, the Global Fund for AIDS, Tuberculosis and Malaria, the Roll Back Malaria, the Global Alliance to Eliminate Leprosy, The Global Program to Eliminate Lymphatic Filariasis, the Global Polio Eradication Initiative, as it will be seen in Chapters 4 and 6 [WHO Programmes and Projects; IFPMA partnerships].

Moreover, the availability and affordability of quality medicines depend on the retail of medicines. The retail price can more than double the manufacturer's price because of the addition of 'hidden costs', *ie*, "costs for transportation, storage, import tariffs and taxes, wholesale and retail markups, staff salaries, stock losses and procurement practices" [Levison and Laing 2003: 20]. States can influence the amount of hidden costs of pharmaceutical products, such as regulatory, transport and distribution costs [Madden, Balasubramaniam and Kibwage 2003: 18].<sup>108</sup> States can also directly regulate the retail prices of medicines, as it happens in Italy or France, even though retail price controls can discourage the availability of medicines and are not widely used in Africa.<sup>109</sup> With regard to the distribution of medicines, these can be provided through health centres, dispensaries, pharmacies and other outlets managed by the private for profit, non profit and the public sector. The availability of medicines in African rural areas, more sparsely populated, is particularly problematic, as highlighted by national surveys on access to medicines<sup>110</sup> and by my empirical work in Tanzania.<sup>111</sup> The modalities of financing of such forms of distribution are presented in the next section. Finally, with regard to the quality of medicines, pharmaceutical companies and the retail sector are responsible for the quality of medicines, but governments can regulate and monitor the safety, quality and efficacy of pharmaceutical products marketed in a country.

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<sup>108</sup> It has been noted that delivery costs are much higher in sub-Saharan Africa because of the low population density [Foster 1987].

<sup>109</sup> See Chapter 5 section 5.3.2.

<sup>110</sup> See, *e.g.*, the surveys of Candau and Guimier on Senegal [2001]; Chweya et al on Kenya [2003]; the Kenya Ministry of Health's "Medicine Prices in Kenya" [2004]; The Ghanaian Ministry of Health's "Pharmaceutical Sector Baseline" [2004] and the Ghanaian Ministry of Health's "Medicines Prices in Ghana" [2004]. For Tanzania see *infra* section 2.4. See also, generally, Leach et al [2005: 80].

<sup>111</sup> See *infra* section 2.4.

Substandard and counterfeit medicines are a common problem in Africa.<sup>112</sup> Governments can also influence the ‘rational use of medicines’, *ie* the promotion of therapeutically sound and cost-effective use of drugs by health professionals and consumers for instance by promoting generic medicines [WHO, How to Develop and Implement a National Drug Policy, 2001].<sup>113</sup>

### 2.3.3 Medicines financing

As seen in above section 2.3.2, pharmaceutical companies, retailers and regulatory institutions can influence the supply of medicines, *ie* the quality, availability and affordability of medicines. Access to medicines also depends on the characters of the demand. With regard to affordability for instance it is noted that certain most needed treatments are out of the reach of the majority of the people in sub-Saharan Africa, who have to pay out-of-pocket for their purchases, even if the prices of these treatments are reduced to the manufacturing costs. Affordability is contextual; in effect is often assessed considering the relationship between daily wage and price rather than the absolute prices.<sup>114</sup> In sub-Saharan Africa, 76% of the population lives on less than US\$ 2 a day, and 46.4% on less than US\$ 1 a day. Still, for example, the minimum cost of a first-line antiretroviral triple-combination (stavudine, lamivudine, nevirapine) is around US\$ 132 per patient per year.<sup>115</sup> US\$ 2.40 for artemether-lumefantrine,<sup>116</sup> the first-line treatment for malaria in many African countries today, are also unaffordable for many African people especially living in the rural areas, the most affected by malaria [WHO AFRO 2006: 53]. Other vital medicines as well, such as natural insulin, have prohibitively high costs [Leach et al 2005: 66].

In fact, access to medicines (affordability and availability of quality medicines) is also determined by the health-care system of a country, as operated by both the private

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<sup>112</sup> See Chapter 5 section 5.3.1.

<sup>113</sup> See Chapter 5 section 5.3.1.

<sup>114</sup> See, *e.g.*, WHO and HAI, website, Medicine Prices: A New Approach to Measurement, last accessed 9 February 2010.

<sup>115</sup> This anti-retroviral treatment is sold by Cipla, an Indian generic manufacturer, and is the cheapest version available in the world market. Notably, in 2000 the originator was selling the same product for US\$ 10,438 [MSF, Too Little for Too Few, 2006: 6].

<sup>116</sup> This is, reportedly, the price obtained by WHO for low-income malarious countries (otherwise, such therapy would cost US\$ 9.12) [Baird 2005 in Breman et al 2006: 419].

and public sectors. With regard to medicines financing and provision, medicines need not to be purchased out-of-pocket payments but can be alternatively acquired through collective financing (health insurance, public health service) and external resources (such as aid, donations).<sup>117</sup> Out-of-pocket payment are commonly utilised in sub-Saharan Africa countries. Reportedly, in some countries the individual expenditures for health are 90% out-of-pocket [WHO and WTO Secretariats 2001: 7]. Like in other developing countries, medicines constitute 50-90% of out-of-pocket spending (depending on the level of health care) [WHO, More Equitable Pricing, 2001; WHO and WTO Secretariats 2001]. Myhr (from the NGO Médecins sans Frontières), has estimated that indeed most Africans must pay 80% prescription-drug costs out-of-pocket [Myhr in Mcneil 2000]. It should be considered that, in economic jargon, consumption of medicines is sensitive to price [CIPR 2002: 33; McKinsey et al 2000; Oxfam, Generic Competition, Price and Access to Medicines, 2002; Borrell and Watal 2002]. In other words, price does determine the decision to purchase treatment. Thus, Guimier et al estimate that, in sub-Saharan Africa, paying the full out of pocket price for a complete treatment for a disease episode is out of the reach of as much as 40-70% of the population once this price is over US\$ 1 [Guimier 2004: 16].<sup>118</sup>

Collective financing, private or public, instead, promotes risk pooling. As WHO put it, “as a result of large pools, society takes advantage of economies of scale, the law of large numbers, and cross-subsidies from low-risk to high-risk individuals” [WHO, World Health Report 2000: 99]. WHO data indicate that the private prepaid plans as percentage of private expenditure on health is around 8.7% in sub-Saharan Africa.<sup>119</sup> The economic advantage of pooling in the region can in fact be less than profitable or even sustainable for non-profit organisations. States, as well, can organise insurance, or subsidise/provide medicines as part of the public health service. The public health sector has alternative avenues to collect financial resources for distributing health care and medicines. Mainly, those are cost-sharing, mandated social health insurance

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<sup>117</sup> See Huttin [2002]; Rietveld et al [2002]; WHO, World Health Report [2000: 99]. For ‘external resources’ reference is made to all grants and loans whether passing through governments or private entities for health goods and services, in cash or in kind [WHO AFRO 2006: 156].

<sup>118</sup> See also Candau [2001] for Senegal.

<sup>119</sup> I utilised the data from WHOSIS selecting WHO AFRO region subtracting Algeria and Sao Tome and Principe [WHOSIS, online, 2005]. I noticed strong variations among those data: in Namibia and South Africa the private prepaid plans as percentage of private expenditure on health amounts to 79.4 and 77.3 respectively [WHOSIS 2005].

contributions, general taxation and external resources [WHO, World Health Report 2000, 2000]. Cost-sharing can be used to finance the continuous provision of medicines at the health facilities. However, it restricts the access to treatment, exerting a direct impact on the sick's finances.<sup>120</sup> Mandated social health insurance, conversely, grants the separation between contribution and utilisation of health-care services. Such scheme is particularly uncommon in Africa, where the protection by social insurance covers less than 8% of the population [WHO and WTO Secretariats 2001: 7]. A reason can be found in the predominance of the informal sector. Diop reports that just 10% of active population are waged employees and officials and, therefore, generally eligible for social insurance [Diop 2006].

General taxation is the last method of gathering resources at the national level, *ie* without recurring to external resources. WHO statistics suggest that the central government expenditure on health as a percentage of government expenditure of the African Region countries is lower than in other higher-income less disease-burdened countries, amounting to 9.1%, as opposed to 15.8% in the UK, 12.8% in Italy, 14.7% in Argentina [WHO, website, World Health Statistics 2006, my elaboration]. Such proportion of government expenditure, however, is even lower in South East Asia, with an average of 8.36% [*id.*].<sup>121</sup> It is also noted that the percentage of contributions raised on GDP, amounting to 20%, is lower than in OECD, where it is 40% [WHO, World Health Report 2000, 2000: 98]. Commentators and experts of global public health have suggested that African states could try to raise more money through this avenue noting that low-income countries often dedicate a smaller fraction of GDP to health [Claeson and Wagstaff 2004: 145]. It is recalled, however, that sub-Saharan Africa is the poorest area in the world, with an average gross national product per capita at parity of purchasing power of US\$ 1970 [PRB 2006: 5]. This figure is lower than the per capita annual general *expenditures on health* are in OECD countries such as France (US\$ 2646), Italy (US\$ 1894), the UK (US\$ 2261), the US (US\$ 2862) [WHOSIS, website, 2005, last accessed 30 October 2009]. In effect, the per capita annual general expenditures on health in the WHO AFRO region in 2007 was purchase power parity US\$ 137 [WHOSIS, website, 2007, last accessed July 2010].

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<sup>120</sup> *See also* Chapter 6 section 6.2.1.1.

<sup>121</sup> The proportion of government expenditures in South-East Asia would be even lower, at 6.1%, if Maldives and Timor Leste, which stand out the average but are unrepresentative in terms of population, are excluded [WHO, World Health Statistics 2006, my elaboration].

Finally, sub-Saharan African countries can raise resources for health from abroad. According to WHO data, external funding amounts to 15% of total health expenditures in sub-Saharan Africa [WHO, website, World Health Statistics 2006, my elaboration]. More to the point, foreign aid for improving access to essential medicines falls within the so-called ‘development assistance for health’ (DAH). This category has been identified by the WHO Commission on Macroeconomic and Health as including: official development assistance (ODA);<sup>122</sup> nonconcessional loans provided by the World Bank and regional development banks to developing countries; and funds from private foundations and NGOs (own funds) “that contribute directly to the promotion of development and welfare in the health sector in developing countries” [CMH Working Group 6, 2002: 10]. Commitments from all external sources including foundations are rising. Reportedly, they rose from an average of US\$ 6.4 billion in 1997–1999 to about US\$ 8.1 billion in 2002 [Claeson and Wagstaff: 156], and Africa is traditionally the major beneficiary [CMH Working Group 6, 2002: 14]. Approximately US\$ 500 million of this funding goes specifically to the transfer of equipment, which includes drugs, vaccines, contraceptives, other supplies, and local institutional capacity building [*id.*: 17].<sup>123</sup>

Indeed, it is possible to observe a proliferation of initiatives for improving the access to medicines in foreign countries. Besides bilateral donors (which include the Danish International Development Agency, the UK Department for International Development, the Dutch Directorate General for Development Cooperation, the Swedish International Development Cooperation Agency, the US Agency for International Development), and multilateral governmental agencies (such as the UN WHO, UNICEF, the World Bank), also the private sector is increasingly concerned [Leach et al 2005: 41-57].<sup>124</sup> Very relevant are private foundations (most prominently, the Bill and Melinda Gates Foundation, the William J. Clinton Foundation, the Rockefeller Foundation). The

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<sup>122</sup> Official development assistance (ODA) is defined by the Development Assistance Committee (DAC) of the OECD as grants and loans to countries and territories on Part I of the DAC list of aid recipients (developing countries), which are undertaken by the official sector, with promotion of economic development and welfare as the main objective, on concessional financial terms (if a loan, with a grant element of at least 25%) [CMH, Working Group 6, 2002: 10].

<sup>123</sup> In effect, also activities categorised as disease-specific projects and programmes, systemic support to the health system, and family planning & reproductive health involve the provision of medicines [CMH, Working Group 6, 2002: 17].

<sup>124</sup> See also Ravishanker et al for an account of global health development assistance for health from 1990 to 2007 [Ravishanker et al 2009].

private also participates to public-private partnerships coordinated by multilateral (governmental and non-governmental) organisations, such as the Global Fund for AIDS, Tuberculosis and Malaria (Global Fund),<sup>125</sup> the Global Alliance for Vaccines and Immunisation (GAVI),<sup>126</sup> or the Partnership for Quality Medical Donations. This latter reports, for instance, that in 2003 the pharmaceutical corporations party thereof contributed US\$1.4 billion in medicines donated to the poor in developing countries [Leach et al 2005: 55]. Moreover, such public-private partnerships have acted as intermediaries for the grant of voluntary price-reductions by innovator pharmaceutical corporations.<sup>127</sup>

## 2.4 The context of access to medicines in Tanzania

This chapter so far illustrated the need for pharmaceutical products in sub-Saharan Africa and the technicalities relative to the provision, access and financing of medicines in the region. This section presents my case-study on Tanzania. I have considered that Tanzania can represent the emblematic problems – and possible solutions – of access to medicines in sub-Saharan Africa. Tanzania is a country heavily burdened by preventable and curable diseases; relatively poor; and with problems in access to medicines. Tanzania is a big African country, with a population of 41 million (2009 estimate) [CIA, website, Factbook, last accessed 5 February 2010]. With regard to the burden of disease, in 2009, the life expectancy at birth has been estimated to be 52 years (ranked 206<sup>th</sup> worldwide) and the under-five mortality rate 69.28/1000 deaths (the 25<sup>th</sup> highest worldwide) [*id.*]. Tanzania is the 6<sup>th</sup> country in the world for number of people living with HIV/AIDS, which has been estimated to be 1,400,000 [UNAIDS, 2008 Report on the Global AIDS Epidemic, 2008], and the 7<sup>th</sup> for HIV/AIDS annual deaths, which have been estimated to be 96,000 in 2007 [CIA, website, Factbook, Tanzania, last accessed 4 February 2010]. The rate of infections peaked 10% of the population in 2002

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<sup>125</sup> Launched in 2001, the Global Fund is a financing mechanism for country-level efforts to combat AIDS, tuberculosis, and malaria. It is an independent entity, governed by a board of directors that includes representatives from donors, the UN, civil society, and the private sector [Leach et al 2005: 44-5] (yet 98% of the funds are pledged by governments [Feachem and Sabot 2006]). *See also* Chapter 6.

<sup>126</sup> Partners include the GAVI Fund, national governments, UNICEF, WHO, The World Bank, the Bill & Melinda Gates Foundation, the vaccine industry, public health institutions and NGOs [GAVI website].

<sup>127</sup> On the contribution of foreign states and non-state actors *see generally* Chapter 6.

and has reportedly declined to 6.2 in 2007 [IRIN News 2006; UNAIDS, 2008 Report on the Global AIDS Epidemic, 2008]. HIV/AIDS is the leading cause of death and morbidity in the country. While respiratory infections are the second cause of morbidity and mortality (2004 estimates) [WHOSIS, last accessed 6 February 2010], Tanzania is heavily affected by malaria which, according to WHO estimates, in 2006 infected 11,539,867 people and killed 38,730 [WHO, World Malaria Report 2008: 142].<sup>128</sup> Cardiovascular diseases and diarrhoea are respectively the fourth and fifth causes of morbidity and mortality (2004 estimates) [WHOSIS, last accessed 6 February 2010]. With regard to tuberculosis, 54,956 new cases originated in 2008 [WHO, Global Tuberculosis Control: Epidemiology, Strategy, Financing, 2009].

Economically, Tanzania is a low-income country. Its GDP, US\$ 57.5 billion, places Tanzania at the 85<sup>th</sup> position worldwide while with a per capita GDP of US\$ 1400 the country locates at the 206<sup>th</sup> place [CIA, website, Factbook, Tanzania, last accessed 4 February 2010].<sup>129</sup> 36% of the population lives below the national poverty line [*id.*; UNDP 2005: 114].<sup>130</sup> Politically, Tanzania is a democracy, with a socialist experiment in its past and a governmental commitment to development and improvement in its present. The Tanzanian Constitution does not provide for a right to health but sanctions a role of the state against ‘disease’: “the state authority and all its agencies are obliged to direct their policies and programmes towards ensuring... (i) that the use of national resources places emphasis on the development of the people and in particular is geared towards the eradication of poverty, ignorance, and disease [...]” [Tanzanian Constitution 1995: Ch.1, Part II, art. 9(i)]. With regard to the health system, since the Arusha Declaration in 1967 the government is the major provider and financier of health services, but the private sector is now also prominent. In particular, non-profit faith-based organisations (FBOs) are reported to provide 40% of hospital care in the country.<sup>131</sup> Funding for the public

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<sup>128</sup> I found great variance among the literature, the officials and the external extra-governmental actors about the figures relating to the morbidity and mortality of malaria in Tanzania. Officials and foreign aid often rated at 16-18 million the yearly morbidity and at between 100,000 and 125,000 the yearly mortality. *See, e.g.*, US President’s Malaria Initiative [2005: 12].

<sup>129</sup> The GDP is calculated at parity of purchasing power [CIA, website, Factbook, Tanzania, last accessed 4 February 2010].

<sup>130</sup> Note that according to the UNDP 2005 report, if poverty in Tanzania was calculated using the poverty line of one international dollar a day the poverty incidence in Tanzania would be around 57.5% of the population [UNDP 2005: 114].

<sup>131</sup> *See* GFATM [website, Report on the involvement of faith-based organizations in the Global Fund] and interviews [Tanzania, July-August 2009].

sector originates from general government expenditures, including external resources, and to a smaller extent from out-of-pocket cost sharing [Tanzania MOH, 2003, National Health Policy: 27].<sup>132</sup> A National Health Insurance Fund is in place for civil servants which also sponsors private care [Tanzania MOHSW, Survey of the Medicines Prices in Tanzania, 2004: 2]. The Community Health Funds are still experimental, so far economically unsustainable.<sup>133</sup> Historically, Tanzania has been a major recipient of foreign aid. In 2002 external resources for health as percentage of total expenditure on health amounted to 26.9% [WHO, The World Health Report 2005, 2005]. The per capita government expenditure on health in 2005 was US\$ 23 [WHOSIS 2005, my elaboration]. The medicine budget for year 2003/04 was US\$ 28.5 million, *ie* US\$ 0.75 per capita.<sup>134</sup> According to an official from the Medical Stores Department (MSD), the national procurer and distributor of pharmaceutical products (*see infra*), essential medicines at Medical Stores Department are funded 85% by the government and 15% through other funding (such as sales to the non-profit sector).<sup>135</sup> The official also stated that out of the government share, 60% come from the government purse and 40% from the basket fund of donors. In particular, treatment for HIV, malaria, and tuberculosis are 90% supplied by development partners to the Medical Stores Department which re-distributes the medicines throughout the territory. Foreign agencies, international organisations and NGOs also donate in kind and provide technical assistance for access to medicines, for example by quantifying the needs for medicines and organising the logistics of medicines procurement and distribution.<sup>136</sup>

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<sup>132</sup> According to Laterveer et al [2004] user fees contribute around 4% of the total health budget.

<sup>133</sup> The idea is that rural communities would integrate their community health needs by contributing with a Tsh. 5000-10,000 per household per year. However, such amount is considerable for certain economies and is not sufficient to cover the health needs [field work, interviews].

<sup>134</sup> My elaboration from raw data in Tanzania MOHSW, "Survey of the Medicines Prices in Tanzania" [2004].

<sup>135</sup> Interview [Medical Stores Department, Dar es Salaam, 20 July 2009].

<sup>136</sup> For example, John Snow International (JSI) works on different projects: Supply Chain Management System procures and donates HIV/AIDS commodities; US Deliver works on reproductive and child health, for instance donating contraceptives; Making Medical Injections Safer (MMIS) works on blood infections prevention. The first two projects are funded by USAID, while MMIS is funded by the US Centre for Disease Control (CDC) [Interview, JSI/SCMS, Dar es Salaam, 15 July 2009]. For more information *see* Tanzania MOHSW, "Mapping of Partners and Financial Flows in the Medicines Supply System in Tanzania" [2008].

With regard to pharmaceutical regulation, the Tanzania Food and Drug Authority (TFDA) is in charge of the registration of new products and of monitoring and inspecting the quality, efficacy and safety of the medicines in the market. A Fair Competition Commission has been established in 2005 but has not been operative as of yet on matters concerning medicines such as counterfeit drugs [Tanzania, Fair Competition Act, 2005].<sup>137</sup> With regard to the rational use of medicines, the Ministry of Health and Social Welfare (MOHSW) compiles the “National Essential Medicines List for Tanzania” (NEMLIT), which lists different classes of products that should be available at the different levels of care [Tanzania MOHSW, NEMLIT, 2007]. Interviews with different health care workers and local and foreign officials working on access to medicines claim that the list is comprehensive.<sup>138</sup> The Medical Stores Department procures and distributes medicines for all the public sector and occasionally for the non-profit sector. The public health facilities order medicines through the account and the allocation that they hold with the Medical Stores Department. The private sector has to utilise other suppliers and wholesalers.<sup>139</sup> With regard to intellectual property rights on medicines, Tanzania grants patents for both processes and products, including pharmaceuticals [Tanzania’s Patents Act, 1987: Art 7(1)]. Such legislation is strict with regard to compulsory licenses, parallel importation and other exceptions to patent rights [Losse et al 2007: 8-10].<sup>140</sup> The international patent system is important to Tanzania as the country imports 70%-85% of the medicines procured by the government through the Medical Stores Department, even though the majority are not currently on-patent in Tanzania.<sup>141</sup> In fact the originator pharmaceutical companies, so far, have not patented important innovative (thence patentable) medicines such as the first-line antiretrovirals and the first-line antimalarial (the branded artemether-lumefantrine ‘Coartem’). Nevertheless the Patents Act 1987 is

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<sup>137</sup> Interview with Fair Competition Commission [Dar es Salaam, 17 August 2009].

<sup>138</sup> Interviews, Tanzania, July-August 2009. The list also includes several antiretrovirals [Tanzania MOHSW, NEMLIT, 2007].

<sup>139</sup> For comprehensive information *see* the MOHSW “In-Depth Assessment of the Medicines Supply System in Tanzania” [2008].

<sup>140</sup> *See also* Chapter 5 section 5.2.1 and Chapter 6 section 6.2.1.1.

<sup>141</sup> According to an interviewee at the Medical Stores Department, 80-85% of the medicines procured by Medical Stores Department are imported [Interview, MSD, Dar es Salaam, 20 July 2009]. According to an interviewee at the TFDA, 70% medicines circulating in the country are imported [Interview, TFDA, in Dar es Salaam, 17 August 2009]. With regard to the use of on-patent medicines, according to interviewee, 99% of the medicines used in Tanzania are generic products [*id.*].

being revised to have the TRIPS flexibilities introduced. *Inter alia*, the flexibilities are supposed to allow the importation of patented medicines.<sup>142</sup>

With regard to access to medicines in Tanzania, it is indicative to note that out of the estimated 600,000 HIV-infected Tanzanians who qualify for antiretroviral therapy, 136,700 (22.2%) were on therapy in 2007 [Tanzania NACP, National Guidelines for the Management of HIV and AIDS, 2008: 15]. With regard to tuberculosis, the case detection rate under DOTS was 47% (50% for smear-positive cases) and the treatment success rate of smear positive was 85% in 2006 [WHO, Global Tuberculosis Control: Epidemiology, Strategy, Financing, 2009: 157]. More systemic insights come from the ‘Medicine Price Monitor’, compiled by the MOHSW in collaboration with WHO and Health Action International Africa [Tanzania MOHSW, Medicine Price Monitor, June-July 2008]. The survey analyses the availability, prices and affordability of a selection of 40 essential medicines in the public, private and mission sector.<sup>143</sup> Five regions have been surveyed, namely Dar es Salaam, Mwanza, Mbeya, Morogoro and Mtwara (*see also* the map of Tanzania in Chapter 1 section 1.5). With regard to the *availability* of the 40 medicines surveyed, 26 (55%), 21 (34%), and 22 (55%) were available in up to 50% of public, private and mission health facilities, respectively; 7 (17.5%), 12 (30%) and 10 (25%) medicines were available in more than 50% to 75% of the public, private and mission health facilities, respectively; and 7 (17.5%), 7 (17.5%) and 8 (20%) medicines were available in more than 75% of the public, private and mission health facilities respectively. In particular, artemether-lumefantrine as first line treatment for malaria was found in more than 75% of the health facilities in the public sector.<sup>144</sup> Antiretrovirals were stocked in 20 out of 43 facilities in the selected public sector facilities, but the

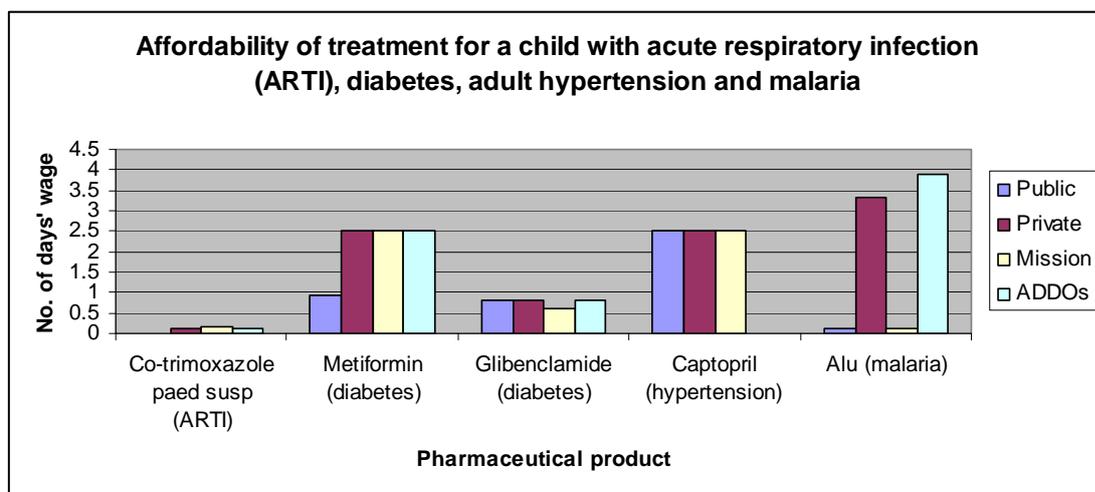
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<sup>142</sup> Interview with TFDA [Dar es Salaam, 17 August 2009]. The prospective problems of intellectual property rights for access to medicines in Tanzania are analysed in Chapter 6 section 6.2.1.1.

<sup>143</sup> The selected medicines are part to the NEMLIT [Tanzania MOHSW, Medicine Price Monitor, June-July 2008; Tanzania MOHSW, NEMLIT, 2007].

<sup>144</sup> Although, sulfadoxine–pyrimethamine is no longer the first line medicine for malaria treatment, it remains the medicine of choice for intermittent preventive treatment (IPT) for pregnant women. Its availability went down from 88% in November 2006 to 44% in July 2008 for the public sector. Since sulfadoxine–pyrimethamine is a medicine of choice for intermittent preventive treatment, the medicine should be available in all health facilities all the time. In the private sector, there was no change as sulfadoxine–pyrimethamine was at around 80% in both surveys of November 2006 and June 2007 [Tanzania MOHSW, Medicine Price Monitor, June-July 2008].

availability of treatment was deemed satisfactory.<sup>145</sup> Finally, it was noted that a medicine for asthma, the (user-friendly) beclomethasone inhaler, was not available in the health facilities but salbutamol, an alternative product for asthma, occasionally was. Oral rehydration salts, to contrast diarrhoea, were available in more than 75% health facilities including ADDOs. A medicine for diabetes, glibenlamide, was available for the first time in the public health facilities, but the price was 567% higher than that charged by the Medical Stores Department to the facilities. *Affordability* is calculated in the survey in terms of the days the lowest paid civil servant would have to work to pay for one treatment course of an acute condition or one month's treatment of a chronic condition. The daily wage of the lowest paid civil servant was Tshs. 3613.67 during the price survey. The survey reckoned that the cost of treatment of malaria with the currently introduced first-line antimalarial medicine ALu is 0.2 days wage from the public and 3.32 days from the private, 3.9 in ADDOs and 0.14 in mission hospitals. The following graph illustrates the affordability of a selection of medicines.



Affordability of treatment for a child with acute respiratory infection, diabetes, adult hypertension and malaria, in different sectors. Data from Tanzania MOHSW Medicine Price Monitor, June-July 2008 [2008: 4], my elaboration.

<sup>145</sup> Out of these facilities, 15 (75%) had stavudine/lamivudine/nervirapine (d4T/3TC/NVP) 30mg while 7 (35%) had d4T/3TC/NVP 40mg. The second product, apparently, was being withdrawn from the programme because of side-effects [Tanzania MOHSW, Medicine Price Monitor, June-July 2008: 5].

With my qualitative empirical work visiting the country and interviewing relevant people<sup>146</sup> I aimed at complementing those quantitative studies.<sup>147</sup> Early interviews with people working in the sector confirmed to me that indeed the aforementioned surveys are not conclusive. With regard to the availability of medicines in the public sector, I appraised that stock-outs are frequent.<sup>148</sup> Certain vertical programmes are better off as antiretrovirals, artemether-lumefantrine and anti-TB medicines are provided with external funds. However, there can be problems of distribution and AIDS patients may not find appropriate treatment for the opportunistic infections and conditions affecting them.<sup>149</sup> Generally I gathered six main explanations for the stock-outs. First, the estimates of the medicines needs by the health facility can be inappropriate. Among other reasons, health workers still have to adapt to the recently the ‘Integrated Logistics System (ILS)/Indent System’, which has been introduced recently.<sup>150</sup> Reportedly, the system is overly complex and is anyway based on past use of medicines rather than future needs.<sup>151</sup> However, being a ‘pull’ system, it can improve the match between the needs of the health facilities and the products actually delivered by the Medical Stores Department. Secondly, quite remarkably, the Medical Stores Department often does have the medicines in stock at the central store, but it fails to distribute them to the regional hubs and thence to the health facilities.<sup>152</sup> Third, the government allocation to the

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<sup>146</sup> I undertook more than 50 relevant interviews about access to medicines, health care, and human rights with people relevant for the matter including officials from the Tanzanian government (central and local), international organisations, non-governmental organisations, foreign aid, pharmaceutical industries, pharmaceutical traders, health workers etc. *See also* Annexe A for a list of the interviewees. With regard to the areas, I visited the health facilities (public dispensaries, health centres, hospitals and, for the private sector, ADDOs) in Sumbawanga (Rukwa region) and Ifakara (Morogoro region). *See also* Chapter 1 section 1.5.

<sup>147</sup> Together with the 2008 “Medicine Price Monitor” [Tanzania MOHSW, Medicine Price Monitor, June-July 2008], *see also* Tanzania MOHSW, “Baseline Survey of the Pharmaceutical Sector in Tanzania 2002” [2002]; Tanzania MOHSW “Survey of the Medicines Prices in Tanzania” [2004]; and Tanzania MOHSW, “Medicine Price Monitor – June-July 2007” [2007].

<sup>148</sup> Reportedly, often 40-60% of an order is not fulfilled [Interview with Action Medeor, Dar es Salaam, 16 July 2009].

<sup>149</sup> Interview with JSI/SCMS [Dar es Salaam, 15 July 2009].

<sup>150</sup> The ‘pull’ system started to be gradually introduced around 2004 [Tanzania MOHSW, Survey of the Medicines Prices in Tanzania, 2004: 3].

<sup>151</sup> Under the ILS, the health facilities place their orders with the Medical Stores Department according to their needs and their budget allocation. The ILS is a JSI project [Interview with USAID/JSI, Dar es Salaam, 17 July 2009].

<sup>152</sup> Interview with Regional Pharmacist of the Rukwa region [Sumbawanga, 30 July 2009].

Medical Stores Department is allegedly not sufficient to procure the medicines needed by the health facilities.<sup>153</sup> Fourth, deficiencies can occur when resources are committed but not disbursed by the government.<sup>154</sup> Fifth, there can be delays from the suppliers. Sixth, there can be wastage for theft (the ‘pilferage’ to the private sector is common) or inappropriate use of medicines.<sup>155</sup> Reportedly, only 5-40% (according to the area and the study) of the fevers treated as malaria, if tested, is in fact caused by malaria.<sup>156</sup> With regard to affordability, the government applies user fees and cost sharing for medicines. The fees are higher in the hospitals, whereas in the dispensaries they are generally lower but in fact quite erratic.<sup>157</sup> The consulting fee was on average Tsh. 1000 (US\$ 0.76). Government guidelines recommended the price of medicines to be half of Medical Stores Department procurement price, except for artemether-lumefantrine, which enjoys had subsidised price (Tsh. 1500 or US\$ 1.14 for adults and Tsh. 500 or US\$ 0.38 for children dosage). The prices of the products dispensed, however, were considerably diverse.<sup>158</sup> Importantly, exemptions from payments are prescribed for mothers, children under five years of age, the elderly and patients suffering a series of chronic and epidemic diseases including for instance tuberculosis and AIDS [Tanzania MOH, 2003, National Health Policy]. Again, the policy is not operated systematically.<sup>159</sup>

The private sector offers an alternative avenue for acquiring medicines. Pharmacies, private dispensaries, private hospitals, and ‘duka la dawa baridi’ are the main retailers. In rural areas, often, the ‘duka la dawa baridi’ are the most viable business as they do not require trained medical personnel or a pharmacist [HERA 2006: 5].

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<sup>153</sup> Chief Pharmacist Muhume stated that the money allocated to medicines can meet 70% of needs [Interview with Muhume in Dar es Salaam, 12 August 2009].

<sup>154</sup> Such mismatch has been denounced by health officials but denied by the Chief Pharmacist Muhume, who stated that 97% of the funds were utilised in 2008-2009. *Contra see* interviews at Ifakara Health Institute [Ifakara, 5 August 2009] and USAID [12 August 2009].

<sup>155</sup> Interviews [*e.g.*, National Malaria Control Programme, Dar es Salaam, 19 July 2009], visits to dispensaries.

<sup>156</sup> Interviews with USAID/JSI [Dar es Salaam, 17 July 2009], National Malaria Control Programme [Dar es Salaam, 19 July 2009]. *See* Reyburn et al [2004]; and Mosha et al on the cost implications of improving malaria diagnosis in Tanzania [Mosha et al 2010].

<sup>157</sup> Visits to dispensaries, Sumbawanga municipal area, Ifakara and surroundings.

<sup>158</sup> Visits to dispensaries, Sumbawanga municipal area, Ifakara and surroundings.

<sup>159</sup> Visits to Sumbawanga municipality and Ifakara; interviews. *See also* Save the Children finding that in the region Lindi exemptions were ‘more a favour than right’ [Save the Children 2005: 21-22].

Sometimes duka la dawa baridi exist where there public dispensaries do not.<sup>160</sup> However, they are only qualified to sell over-the-counter products (OTCs),<sup>161</sup> that which precludes the sale, for instance, of the first line anti-malarial artemether-lumefantrine. A new government project, instead, aims at training the shopkeepers so that they can sell a few ‘necessary’ products under prescription. With regard to malaria the rationale is, reportedly, that a significant proportion of fevers (up to 70%) are managed in private sector [Lynch et al 2006: 20; *See also* Kachur et al 2006]. These certified shops are called ‘duka la dawa muhimu’, which is the Swahili for ‘shop of necessary medicines’, and are known internationally as ‘accredited drugs dispensing outlets’ (ADDOs). The ADDO project, in fact, offers an interesting hook for observing the operation of extra-governmental actors on access to medicines in sub-Saharan Africa (the operation of extra-governmental actors is the subject of Chapter 6). Whereas the TFDA is the main implementer of the programme, ADDOs are an international public private partnership (PPP).<sup>162</sup> The initiative has originated from a foreign NGO programme, the Management Science for Health (MSH) “Strategies for Enhancing Access to Medicines” (SEAM). The programme is funded by the Bill and Melinda Gates Foundation “to identify and test innovative approaches for improving access to essential medicines in developing countries through greater participation of the private sector” [SEAM 2003: 1]. Tanzania has been selected together with other six countries for ‘field-testing’ the framework “[a]fter discussions and consultations with experts from WHO, the World Bank, and developing countries” [MSH, SEAM Programs; SEAM 2000]. Therefore, SEAM’s work in Tanzania is motivated by ‘top-down’ considerations. SEAM is currently providing technical assistance to the project, together with other foreign NGOs.

Starting from Ruvuma, the programme is currently run in other five regions: Dar es Salaam, Morogoro, Mtwara, and Rukwa (*see also* the map of Tanzania in Chapter 1

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<sup>160</sup> A recent government proposal envisages one dispensary for every village. The dispensaries I visited generally served 5-10 villages. The policy of multiplying the dispensaries by five or ten seems quite unrealistic, given the resources constraints.

<sup>161</sup> Duka la dawa baridi means in Swahili ‘shop for cold medicines’.

<sup>162</sup> Public private partnerships are commonly defined as voluntary and collaborative relationships between various parties, both state and nonstate, in which all participants agree to work together to achieve a common purpose or undertake a specific task and to share risks, responsibilities, resources, competencies, and benefits [UN Secretary General, Enhanced Cooperation between the United Nations and All Relevant Partners, in Particular the Private Sector, 2003].

section 1.5).<sup>163</sup> With regard to funding, the Tanzanian government is the biggest funder. Other extra-governmental actors fund ADDOs often as part of their vertical aid programmes. ADDOs obtained a grant from the Global Fund for Tuberculosis, AIDS and Malaria (hereinafter Global Fund) round 7 as ADDOs were presented in the application to the fund as playing a role in controlling malaria by selling antimalarials.<sup>164</sup> An application for subsidised artemether-lumefantrine is currently under examination at the Affordable Medicines Facility for Malaria, always part of Global Fund.<sup>165</sup> With regard to bilateral aid, the US President's Malaria Initiative (PMI) is now subsidising artemether-lumefantrine in the ADDOs of Ruvuma and Morogoro. The US agency for foreign aid (USAID) is sponsoring the roll out of ADDOs in Morogoro for the project "IMCI [Integrated Management Childhood Disease] in ADDOs" (a 'special case' of ADDOs particularly focus to child-disease such as malaria, diarrhoea, acute respiratory tract infection).<sup>166</sup> The Novartis Foundation for Sustainable Development, the Ifakara Health Research and Development Centre and the Swiss Tropical Institute are also collaborating with ADDOs through the ACCESS programme, which "[a]ims at understanding and improving access to prompt and effective treatment" [Swiss Tropical Institute 2005: 3]. One of the components of this project are 'social marketing campaigns' to "motivate people to seek timely and correct malaria treatment in the event of fever episodes, as well as improving advice, diagnosis, and treatment in private pharmacies and public health facilities" [*id.*; IFPMA 2007: 38].<sup>167</sup>

The empirical experience and the literature suggest that in terms of availability, ADDOs offer an important alternative to the public sector which is often out of stock. ADDOs expand the range of medicines sold legally as compared to 'duka la dawa

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<sup>163</sup> See also TFDA website [TFDA website, Accreditation, last accessed 6 February 2010].

<sup>164</sup> See "The Tanzanian Proposal Form for Round 7" [United Republic of Tanzania, Proposal Form – Round 7, 2007: 50].

<sup>165</sup> The facility, unlike the ordinary Fund's practice, also provides subsidies for artemether-lumefantrine to the for-profit sector.

<sup>166</sup> Interview with TFDA official [Dar es Salaam, July-August 2009]. See also USAID/BASICS and USAID/RPM/Plus, "Improving Child Health through the Accredited Drug Dispensing Outlet Program" [2008].

<sup>167</sup> See Novartis, website, "Improved access to effective treatment of malaria in Tanzania" [last accessed 5 April 2008] and International Federation of Pharmaceutical Manufacturers & Associations [2007: 38].

baridi'.<sup>168</sup> However, the 'necessary' prescription medicines allowed in ADDOs are in fact a restricted selection and the outlets are not required to hold them in stock. Furthermore, access to medicines in the areas where 'duka la dawa baridi' are absent may not be improved: ADDOs generally replace 'duka la dawa baridi' rather than being set up from scratch.<sup>169</sup> With regard to quality, ADDOs shopkeepers receive training on how to keep and dispense medicines, and are taught to refer patients to other health facilities in complicated cases. Sub-standard products are nevertheless found in ADDOs. Granted, the problem of sub-standard medicines is widespread in Tanzania. It has occurred that dangerous products seized by TFDA during their inspections had in fact received the Authority's clearance at importation, therefore they had been procured by the wholesalers and the shops legitimately.<sup>170</sup> Also worrying with regard to the rational use of medicines is the fact that ADDO shopkeepers often do not check the prescriptions when clients ask for a prescription medicine, as they should do. According to some health professionals some flexibility is warranted as in fact "antimalarials should not be

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<sup>168</sup> With regard to the literature, the ADDO programme has been re-edited as a case-study in global access to medicines policy discussions [Brieger et al 2004; Hetzel et al 2007; Patouillard et al 2007; Quick, Nana-Adjoa, Rankin, and Mbwasi, 2005; Rutta et al 2009; WHO, Partnerships for Malaria Control: Engaging the Formal and Informal Private Sectors, 2006]. Thorough reviews, however, seem to come only from its institutional promoter [STI 2005; HERA 2006; MSH, website, SEAM Country Programs; MSH 2006; SEAM 2003]. The ADDO project is also discussed in Chapters 5 and 6 in light of the implementation of the human right to essential medicines.

<sup>169</sup> *See also* the Tanzania pilot programme for the distribution of subsidised artemether-lumefantrine in duka la dawa baridi undertaken by the Clinton Foundation (the Clinton Foundation obtained a waiver as duka la dawa baridi are not otherwise allowed to sell prescription medicines). With regard to availability, the proportion of remote duka la dawa baridi stocking subsidised artemether-lumefantrine remained limited: "stocking and sales of subsidized ACTs [artemether-lumefantrine] were lower in stores located away from town centers and major roads. At the time of the March audit, 38% of these stores were stocking subsidized ACTs compared with 80% of stores in more densely populated areas" [Clinton Foundation, Tanzania Pilot ACT Subsidy: Report on Findings, 2008: 42].

<sup>170</sup> Interview [National Malaria Control Programme, Dar es Salaam, 19 July 2009]. According to Kihyo, Tanzania Consumer Advocacy Society, 50% of the medicines marketed in Tanzania are fake. The estimate may be inflated but not totally unrealistic considering that some research showed that more than a third of antimalarial drugs sold in Africa have failed quality tests [Bate et al 2008]. Substandard Metakelfin, an antimalarial has been discovered by TFDA in 2009. The product was totally ineffective against malaria and has been withdrawn from the market [TFDA, Taarifa Kwa Kuhusu Kuwepo Kwa Dawa Bandia Za Vidonge Za Metakelfin Katika Soko La Dawa Hapa Nchini, 2009].

prescription medicines where malaria is endemic”.<sup>171</sup> However, fevers are too often attributed to malaria and this can be a risk for the health of the individual if other health conditions are overlooked – and a waste of antimalarials which can also lead to drug resistance, a serious public health concern.<sup>172</sup> Social marketing of artemether-lumefantrine, as per the ACCESS project, I note, could be a double-edged sword, leading to further malaria over-diagnosis.<sup>173</sup> With regard to affordability, ADDOs are more expensive than the public sector. Importantly, as opposed to the public sector, ADDOs do not implement exemptions for protected categories.<sup>174</sup> Indeed, ADDOs are for-profit entities, sometimes bearing considerable logistic costs, and facing little competition. However prices in ADDOs were generally lower than in pharmacies or other private care facilities.<sup>175</sup> Thanks to US President’s Malaria Initiative funds, artemether-lumefantrine is sold at subsidised price in Morogoro and Ruvuma. In terms of access overall, furthermore, some interviewees voiced the concern that pharmaceutical products are pilfered from the public sector to the ADDOs.<sup>176</sup> Finally, a major problem is how to sustain ADDOs financially, considering that the training and accreditation programme relies on donor support [HERA 2006].

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<sup>171</sup> Interview [Dar es Salaam, July 2009]. *See also*, Goodman et al writing on “Drug Shop Regulation and Malaria Treatment in Tanzania – Why do Shops Break the Rules, and Does it Matter?” [Goodman et al 2007].

<sup>172</sup> Interviews with USAID/JSI [Dar es Salaam, 17 July 2009] and National Malaria Control Programme [Dar es Salaam, 19 July 2009]. *See* Reyburn et al [2004]; Mosha et al [2010] on the cost implications of improving malaria diagnosis in Tanzania. *See also* Gwer et al [2007] on the risks of treating only for malaria as a failure to address other life-threatening conditions. The authors therefore suggest that routine use of parenteral antibiotics among children with a slide that indicates malaria is warranted because invasive bacterial infections are likely to be under-ascertained and are associated with increased mortality [Gwer et al 2007].

<sup>173</sup> Social marketing is still laudable in dispelling harmful beliefs in sub-Saharan Africa such as those attributing some diseases’ symptoms to witchcraft. Such beliefs can bring to ineffective treatment of serious conditions – and even to acts of violence against the sick. Reportedly, conditions with convulsions as leading symptoms are often primarily treated with traditional practices but are in fact often linked to malaria [Dillip et al 2009].

<sup>174</sup> *See above*.

<sup>175</sup> *See also* the Tanzania pilot programme for subsidised artemether-lumefantrine undertaken by the Clinton Foundation, which found that the subsidy was generally passed onto the consumers [Clinton Foundation, Tanzania Pilot ACT Subsidy: Report on Findings, 2008].

<sup>176</sup> Interviews [Dar es Salaam, 19 July 2009].

## 2.5 Conclusion

This chapter has illustrated the circumstances, problems and contingencies of access to medicines in sub-Saharan Africa, also recounting the case-study on Tanzania. Sub-Saharan Africa is affected by a huge burden of disease, more than other regions of the world, which invasively impairs the health of its people. The situation is multifarious, as there is not a single pathogen ravaging the region. Rather, there are many conditions, often interrelated. Also, there are many determinants of health, both environmental and humane, which favour such situation. The chapter has further shown that many health conditions affecting sub-Saharan Africa are technically preventable and curable. In effect access to quality medical treatment can prevent, heal or alleviate the suffering of an individual: medicines are one component of treatment, not sufficient on their own, but still necessary. Yet many medicines, and even the ‘essential’ ones, are not widely accessible in sub-Saharan Africa. The chapter has consequently illustrated the technicalities and problems relating to the provision, access and financing of medicines in the region and, in particular, in Tanzania.

It was demonstrated that access to medicines is complex, multidimensional, and involving different factors and actors, private and public. In effect, those actors have power and biopower on access to medicines. Observing in terms of Luhmann’s social systems it is remarked that the decisions of these actors are framed by different subsystems such as: the economic subsystem, communicating in terms of money *e.g.* with regard to profit, political economy, resources available at the national level; the subsystem of science, communicating on truth *e.g.* about epidemiology or treatment options; the subsystem of morality, communicating on good *e.g.* about health, compassion, corporate social responsibility; the subsystem of law, communicating on legality *e.g.* about competition law, intellectual property law; the subsystem of politics, communicating on binding power *e.g.* about quality controls, rational use of medicines, price controls, public health measures. The subsystems are often structurally coupled, in their effort to respond to environmental contingencies and complexities.

Can, shall the human rights subsystem overrule the other subsystems? Recalling my research question exposed in Chapter 1, “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. On the one hand, it has been appraised that the universal need for access to medicines is particularly acute in sub-Saharan Africa and human agency *can* improve access to medicines: indeed, while

the lack of resources is apparently a major impediment for access to medicines, this can be improved through regulation, alternative financial arrangements and voluntary actions. This chapter has in effect shown the variety of interests and rationalities adopted by the actors operating on access to medicines. Such ‘communications’ and ‘programmes’ (recalling Luhmann’s terminology) could arguably be harnessed to the framework of the human right to medicines. On the other hand, also referring to the situation in Tanzania, it has been highlighted how both the needs and the effects of access to medicines are contextual, based on the health and financial situations of the individual as well as the local health, economic and legal systems. Furthermore, these factors are interrelated in a complex, contingent way. Moreover, cognitive limitations (both in the sense of scarcity and inadequacy) of objective, comprehensive and conclusive knowledge of health systems have been pointed out. For example, quantitative studies need to be complemented by qualitative research and empirical work which are essentially subjective. These complexities and contingencies can represent challenges to the utilisation of the human right to medicines to solve the problem of access to medicines in sub-Saharan Africa. Consequently, Chapters 3 and 4 analyse what the international human right to medicines prescribes *de jure* and Chapters 5 and 6 discuss how the duties ensuing from this right can be operationalised (that is, given precise content translating it into policies and good practices), implemented and enforced.

## **CHAPTER 3: THE OBLIGATIONS OF HOME STATES WITH REGARD TO THE HUMAN RIGHT TO MEDICINES *DE JURE***

### **3.1 Introduction**

Chapter 2 illustrated the problem of access to medicines in sub-Saharan Africa, addressing the overall burden of disease, the importance of medicines, the problems and contingencies of access to health care and medicines in the region. It showed that, among other factors, access to medicines is and can be greatly influenced by public policies. Recalling the research question, “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”, Chapter 3 aims to establish whether and what human rights obligations African states bear in relation to the access to medicines. It will be shown in particular that the human right to health enshrined in several widely-accessed human rights treaties binds ‘home states’ to respect, protect and provide – under certain conditions – access to medicines *vis-à-vis* their populations.<sup>177</sup> Therefore, these treaties may sanction an international human right to medicines as part of the human right to health. The legal arguments supporting such statements are discussed in this chapter. Other human rights can also be ancillary to a case for access to medicines, such as the human right to life in claims concerning vital medicines.

The scope of this chapter, together with international law, includes domestic law as well as ‘soft law’. International and national law intertwine – and this is indeed a fundamental premise for the utilisation of the international human right to medicines to solve the problem of access to medicines in sub-Saharan Africa. The implementation and enforcement of human rights takes place primarily at the national level.<sup>178</sup> Furthermore, the wordings of international human rights treaties may influence the phrasing of national constitutions [Hogerzeil 2006: 308] and other law such as the implementing legislation. In domestic courts, international human rights law may influence the interpretation of

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<sup>177</sup> For obligations of ‘home states’ I mean the obligations of states towards the people within their jurisdiction. For the use of the term ‘home state’ *see e.g.* Joseph [2004].

<sup>178</sup> National courts have primary jurisdiction on the legal enforcement of international human rights law, while international adjudication is to be deemed subsidiary [Conforti 2002: 209-210]. *See also* Craven [1993: 367-8] and Alston [1987: 357].

constitutional provisions,<sup>179</sup> or even be claimed and awarded replacing the absence of a constitutional right.<sup>180</sup> On the other hand, national courts applying national and international human rights norms contribute to the development of the international right to medicines.<sup>181</sup> Cases in national courts can also influence foreign cases when similar questions relating to human rights are at issue.<sup>182</sup> Furthermore, the enquiry will deal with soft law, *ie* international non-binding law.<sup>183</sup> There are four main reasons why the study of non-binding law is relevant for the present research in the positive law. First, if enshrining ‘paper practice’ and *opinio juris*, soft law can be an element of customary law. Second, soft law and self-regulation can be explicitly referred to by the positive law enshrining the human right to medicines. Instruments sanctioning the human right to

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<sup>179</sup> In the *Grootboom* judgement, for instance, the South Africa’s Constitutional Court used international law as tool for interpreting the rights inscribed in the South Africa’s Bill of Rights (as also prescribed by art. 39 of the South Africa’s Constitution) [South Africa, Constitutional Court, *Grootboom*, 2000: para. 26].

<sup>180</sup> For example in the *Viceconte* (Argentina) case the Federal Court of Appeals found that any individual may bring complaints concerning the right to health because of the incorporation into the national constitution of international treaties referring to the right [Argentina, Court of Appeals, *Viceconte*, 1998].

<sup>181</sup> The Committee on Economic, Social and Cultural Rights (CESCR), the Special Rapporteur on the right to health, Hunt, and other commentators, for instance, often refer to national case law in order to interpret the right to health and essential medicines prescribed by international human rights law, both in treaty law and in customary law [CESCR 2000; Hestermeyer 2004; Hunt 2006; Yamin 2003]. Similarly Toebe researched the domestic implementation of the international right to health also by studying the national case law, *ie* “cases in which the right to health is invoked before a national judge or before quasi-judicial bodies, either directly on the basis of international treaty provisions or on the basis of national constitutions provisions” [Toebe 1999: 190 et seq].

<sup>182</sup> For example, the South Africa’s Constitutional Court has discussed the Indian case *Paschim Banga Khet Mazdoor Samity v State of West Bengal* in the *Soobramoney* judgment [South Africa, Constitutional Court, *Soobramoney*, 1998: paras. 18-20]. *See also* Lord Woolf considering that “[a]cross the globe there is a comparative approach to human rights” and noting that a British Bill of Rights “would enable us to play our part in the development of human rights jurisprudence internationally” [Woolf 1995: 70].

<sup>183</sup> I adopt the definition of soft law offered by Boyle and Chinkin according to whom soft law, from a law-making perspective, is a description for a variety of non-legally binding instruments used in international relations [Boyle and Chinkin 2007: 212]. On soft law as a ‘law-making instrument’ *see generally* Boyle and Chinkin [2007: 211-229]. *See also, e.g.*, the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, Ruggie, who stated that “[s]oft law is ‘soft’ in the sense that it does not by itself create legally binding obligations. It derives its normative force through recognition of social expectations by States and other key actors... Some soft law instruments may contain elements that already impose, or may come to impose, obligations on States under customary international law, which would give them binding effect independent of the soft law instrument itself” [Ruggie 2007: para. 45].

health and medicines, for example, refer to the Alma Ata Declaration, the WHO regulations and standards, the Universal Declaration of Human Rights, the UN General Assembly Declarations.<sup>184</sup> Binding treaties in effect often also include non-binding ‘aspirational’ provisions. Those dynamics show the structural coupling of law to other subsystems such as the meta-positive ‘subsystem of human rights’ and morality. Third, it is always important to discern the binding law from the non-binding law, in order to ascertain the legal applicability of the (legal) human right to medicines. Fourth, the identification of the instances of the meta-positive ‘human rights subsystem’ is instrumental to the discussion which will take place in Chapters 5 and 6, the critical study of the (positive) human right to medicines undertaken in these chapters will also analyse the meta-positive human right to medicines.

The method of this chapter, in effect, is legal analysis. The study is nonetheless undertaken with a critical attitude, underlining the uncertainty and contingency embedded in the law *de jure*. The strengths, limits and uncertainties of the sources utilised in identifying the law (such as treaties, treaty bodies, international non-binding pledges, international courts, national courts, publicists and other authors) are taken into consideration.<sup>185</sup> With regard to the structure, this chapter is divided into two main sections. Section 3.2 presents the human right to medicines in international (universal and regional) treaty law, as warranted by the human right to health, life or other human rights (including the right not to be subjected to torture, inhuman and degrading treatment; to dignity; to adequate standards of living; to social security; to education; to work; to the benefits of scientific progress). Most attention is dedicated to the human right to health enshrined in the International Covenant on Economic, Social and Cultural Rights (ICESCR) and in the African Charter on Human and Peoples’ Rights (ACHPR) as more precisely related to the human right to medicines. Furthermore, most African

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<sup>184</sup> See e.g., the CESCR comments and the African Commission’s resolution on the human right to medicines [CESCR 1990(b), 2000; AC Res. 141 (2008)].

<sup>185</sup> With particular regard to the decisions of the International Court of Justice (ICJ), for example, it is noted that the Court’s role in establishing international law is important but not definitive. The ICJ’s tasks are to deliver judgment in cases between the parties and to express advisory opinions on demand (“at the request of whatever body may be authorized by or in accordance with the Charter of the United Nations to make such a request” [ICJ Statute, art. 65(1)]) [ICJ Statute arts. 34-38; 65-68]. The statements of the Court are often considered as “the best formulation of international law in force” [Chetail 2003: 235-236]. However, the international legal system does not envisage a hierarchy between the international courts. Cf. Higgins discussing the relevance of the ICJ in “A Babel of Judicial Voices? Ruminations from the Bench” [Higgins 2006].

countries are parties to the ICESCR and all African countries are parties to the ACHPR. Section 3.3 attempts to identify the possible status of the human right to medicines in international customary law and soft law. A conclusion is finally provided in section 3.4 reporting on the possibilities and limitations of a human right to medicines to be utilised, *de jure*, to solve the problem of access to medicines in sub-Saharan Africa with regard to the role of home states. The possibilities derive from the fact that instances of international human rights law prescribing access to medicines as part of other human rights, and in particular the human right to health, are in effect identified and can be named as a ‘human right to medicines’. With regard to the limitations it is pointed out, in particular, that the law is often uncertain with regard to the prescription of the duties that African states shall undertake in order to comply with the human right to medicines.

### **3.2 The human right to medicines in international human rights treaties**

Section 3.2 examines the human right to medicines in international treaty law. The law is complemented by commentaries (including the comments of the related treaty-bodies) and judicial cases. Those sources contribute to the interpretation and, arguably, to the development of the positive law. Interpretation is necessary as the provisions are often unclear or indeterminate.<sup>186</sup> I will be cautious in this section to select the more faithful interpretations of the treaties, nonetheless exposing the uncertainties regarding the positive law which are not settled in the discipline. With regard to the possible evolution of the law, the use of a ‘dynamic’ or ‘evolutionary’ interpretation of human rights provisions has been established in international law, inter alia, by the International Court of Justice (ICJ) and European Court of Human Rights (ECtHR).<sup>187</sup> With particular regard to the International Covenant on Economic, Social and Cultural Rights (ICESCR) in particular Craven has remarked that “the drafters

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<sup>186</sup> According to the Vienna Convention on the Law of Treaties, treaty provisions have to be interpreted by respecting the ordinary meaning of their wording, in the light of the object and purpose of the document. In order to resolve textual ambiguities, preparatory works and the subsequent practice should be utilised [VCLT 1980: arts. 31-32].

<sup>187</sup> See, e.g., ICJ, Advisory Opinion, *Legal Consequences for States of the Continued Presence of South Africa in Namibia (South West Africa) Notwithstanding Security Council Resolution 276 (1970)* [1971] and ECtHR, *Tyrer v United Kingdom* [1978]. On the evolutionary interpretation of human rights treaties see, e.g., Bantekas [2003: 342].

clearly envisaged a continuing process of standard-setting” [Craven 1995: 26].<sup>188</sup> The development of the law is, to note, often contentious and introduces uncertainty in the positive law.

### **3.2.1. Access to medicines as part of the human right to health**

#### *3.2.1.1. The International Covenant on Economic, Social and Cultural Rights (ICESCR)*

The International Covenant on Economic, Social and Cultural Rights (ICESCR), together with the Universal Declaration of Human Rights (UDHR) and the International Covenant on Civil and Political Rights (ICCPR) with its two Optional Protocols, is part of the international Bill of Rights, a project promoted by the UN.<sup>189</sup> With regard to its geographical breadth, the Covenant binds 159 states parties from all world regions [UNOHCHR 2008(b)], including 43 (out of 53) African states [Odinkalu 2003: 23]. The Covenant, in effect, enjoys ascendancy in human rights law; it is a source of inspiration for legislation [Hogerzeil 2006: 308] and it is cited in domestic tribunals.<sup>190</sup> With regard to its subject matter, the Covenant enshrines the human right to health which, as demonstrated below, comprises a human right to medicines. In analysing what the Covenant entails, the pronouncements of the Committee on Economic, Social and Cultural Rights (CESCR) will receive particular attention as, even if not binding per se,

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<sup>188</sup> Craven cites the example of article 8, paragraph 3, of the ICESCR expressly open to the International Labour Organisation standard setting [Craven 1995: 26].

<sup>189</sup> The United Nations Office of the High Commission of Human Rights (UNOHCHR) describes the Bill of Human Rights as a project promoted by the United Nations (UN) in observance of the UN Charter purposes of “promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language or religion” [UN Charter art. 1(3)]. The idea of promulgating an ‘international bill of rights’ was considered by many as basically implicit in the Charter [UNHCHR, Fact Sheet No.2 (Rev.1), *The International Bill of Human Rights*, 1996]. See section 3.2.1.3 presenting the International Covenant on Civil and Political Rights and section 3.3.4 discussing the Universal Declaration of Human Rights, *ie* the other two components of the international Bill of Rights.

<sup>190</sup> See *e.g.* the South African *Ministry of Health v. TAC* case [South African Constitutional Court, *Ministry of Health v. TAC*, 2002, para. 26] and the Argentinean *Viceconte* [Argentina, Court of Appeals, *Viceconte*, 1998].

they can be considered ‘authoritative interpretations’ of the Covenant [Skogly and Gibney 2002: 791].<sup>191</sup> Article 12 enshrines the human right to health providing that:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
  - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
  - (b) The improvement of all aspects of environmental and industrial hygiene;
  - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
  - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness. [ICESCR art. 12]

Regarding the term health, the drafters did not mean simple lack of disease, as demonstrated by the drafting history.<sup>192</sup> With a view to the second paragraph of the article, which lists specific positive duties to be undertaken by the member states, it is apparent that the recognition of the human right to health provides for more than a mere right/freedom to be healthy. As the CESCR suggests, it provides for a right/entitlement as well [CESCR 2000: paras. 4, 8; Toebes 1999: 51-52]. With the possible exception of sub-paragraph b), medicines can be needed for all the aspects of health policies mentioned in paragraph 2. The CESCR clearly identifies the provision of essential medicines as one of the measures to be taken under sub-paragraph d) which, the Committee maintains, “includes the provision of equal and timely access to basic preventive, curative, rehabilitative health services and... the provision of essential

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<sup>191</sup> A few considerations may justify such authority. The Committee is a body of independent experts which was established under ECOSOC Resolution 17 (1985) to carry out the monitoring functions assigned to the United Nations Economic and Social Council (ECOSOC) in Part IV of the ICESCR [UNOHCHR 2008(d)]. The Committee has been active in elaborating General Comments on various ICESCR provisions and on how to better implement the Covenant; issuing reporting guidelines for the ICESCR Parties, relating to issues and policies on which States have to focus their attention; analysing States implementation of the Covenant and expressing ‘concluding considerations’ on them [Niada 2006: 149]. The CESCR comments are also considered by national courts when addressing human rights issues. The South African Constitutional Court has discussed the CESCR General Comment 3 in *Grootboom*, a case relating to the right to housing (although therein the Court rejected the CESCR approach demanding on states the immediate satisfaction of core obligations. See Chapter 5 section 5.4.3.) [South African Constitutional Court, *Grootboom*, 1999: 11-13].

<sup>192</sup> For an account of the drafting process of ICESCR article 12 see Toebes [1999: 40-52].

drugs...” [CESCR 2000: para. 17]. Moreover, according to the CESCR, among the ‘interrelated and essential elements’ contained by the right to essential elements for health, there are ‘functioning public health and health-care facilities’ which have to ‘include... essential drugs’ [*id.*: para. 12]. The view that the human right to health in the ICESCR can imply obligations onto the states parties with regard to medicines is upheld, *inter alia*, by national courts.<sup>193</sup> It can arguably be said, therefore, that access to the medicines needed for health is a human right under the ICESCR. This view is also maintained by the Special Rapporteur on the human right to health [*e.g.*, Hunt 2006: para. 40] and international lawyers [Hestermeyer 2004: 125; Yamin 2003: 111].

It is more difficult, however, to establish what conduct states shall undertake to realise the human right to medicines. The ICESCR does not enucleate precise prescriptions. For example, a direct intervention of states in health care is not required. States have to take steps for “[t]he *creation of conditions* which would assure to all medical service and medical attention...” [ICESCR art. 12(2)(d), *emph. add.*]. In general the ICESCR rights are to be realised, vaguely, “by all appropriate means, including particularly the adoption of legislative measures” [ICESCR art. 2(1)]. The CESCR General Comment on the right to health prescribes conducts to states in a more expansive way. The CESCR holds that according to the ICESCR states have tripartite obligations to *respect*, *protect*, and *fulfil* the human right to health. Some obligations are especially pertinent to access to medicines [CESCR 2000: para. 33]: states have duties to *respect* the human right to health by refraining from interfering in the equal access to treatment [*id.*: para. 34]; *protect* by “controlling the marketing of medical equipment and medicines by third parties” [*id.*: para. 35]; and *fulfil* by “ensur[ing] the provision of health care, including immunization programmes against the major infectious diseases...” [*id.*: para. 36]. These CESCR prescriptions too, however, are quite indeterminate, as it will also be discussed in Chapter 5. In effect the CESCR ultimately states that “[t]he most appropriate feasible measures to implement the human right to health will vary significantly from one state to another. Every state has a margin of discretion in assessing which measures are most suitable to meet its specific circumstances” [*id.*: para. 53]. Furthermore, judicial

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<sup>193</sup> In the *Viceconte* case the Argentinean Federal Court of Appeals also referred to the ICESCR in order to appreciate the social right to health and to assert the state obligation to manufacture the hemorrhagic fever vaccine as requested by the plaintiffs [Argentina, Court of Appeals, *Viceconte*, 1998: para. 5].

enforceability is not prescribed in mandatory terms by the CESCR.<sup>194</sup> The CESCR is instead more assertive with regard to the so-called minimum core obligations, as it is shown below.

Another element of uncertainty regards the fact that the ICESCR stipulates that the rights recognised in the Covenant have to be realised progressively, to the maximum of the available resources:

Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures. [ICESCR art. 2(1)]

A question originates about *how slowly* the steps can be undertaken without constituting violations of the Covenant. The wording ‘achieving progressively’ may be seen as an excuse for delaying the parties’ conduct for the realisation of the rights. Noteworthy, concern about the formula had been expressed during the *travaux préparatoires* by some representatives who argued that it introduced uncertainty in the liability of states for the realisation of the ICESCR rights.<sup>195</sup> The CESCR in its comment states that the concept of progressive realisation in fact “imposes an obligation to move

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<sup>194</sup> The CESCR recommends remedies for the violation of the right to health in non-mandatory terms: “[a]ny person or group victim of a violation of the right to health *should* have access to effective judicial or other appropriate remedies at both national and international levels. All victims of such violations *should* be entitled to adequate reparation, which may take the form of restitution, compensation, satisfaction or guarantees of non-repetition. National ombudsmen, human rights commissions, consumer forums, patients’ rights associations or similar institutions *should* address violations of the right to health” [CESCR 2000: para. 59, *emph. add.*].

<sup>195</sup> Scepticism was expressed during the *travaux* by some country representatives such as those from the Soviet Union, Yugoslavia, and Costa Rica. The former, for instance, stated that the word ‘progressively’ would render the “Commission’s work meaningless; if it were allowed to remain, it would matter little how the remaining articles read, since in any case they would be doomed to [become] a dead letter” [Morozov, Russian representative, 1952: 8]. The French representative however noted that the phrase ‘progressively the full realisation’ replaced the former proposal ‘progressive implementation’ “in order to strengthen rather than weaken the objective set before future contracting parties” [Cassin, French representative, 1951]. Other representatives instead retorted that the word ‘progressively’ emphasised the supposition that progress was supposed to be continuous [Sørensen, Danish representative 1951: 20-21] and that it was necessary to recognise that “[t]he commitment was conditional and depended upon factors outside [state] control such as international cooperation, available resources and progressive action” [Azkoul, Lebanese representative, 1955]. *See* Alston and Quinn [1987].

as expeditiously and effectively as possible towards that goal” [CESCR 1990(b): para. 9]. The CESCR phrasing is however still vague. Next, reference to the ‘maximum of available resources’ also introduces contingency. As Alston and Quinn maintain, “it is clear from the *travaux* that states parties are presumed to have considerable discretion in determining what resources are in fact available for use in economic, social, and cultural right-related concerns” [Alston and Quinn 1987: 180].<sup>196</sup> ICESCR article 12 also possibly concedes some delay in the implementation of the human right to health: in paragraph 1, the Covenant utilises the term ‘highest attainable standard’ which is ambiguous [ICESCR art. 12(1)]. Hestermeyer and Toebes, on the one hand, note that the French version of article 12 recites: “*meilleur état de santé... qu’elle soit capable d’atteindre*”. Thus, it would only refer to the biological preconditions of the individual [Hestermeyer 2004: 127; Toebes 1999: 45-6]. The CESCR, on the other hand, argues that it “takes into account both the individual’s biological and socio-economic preconditions and state’s available resources” [CESCR 2000: para. 9]. In paragraph 2, article 12 prescribes certain ‘steps’ that the parties shall undertake, thereby contemplating a gradual implementation [ICESCR art. 12(2)].

Nonetheless, in the General Comment on the nature of states parties obligations, the CESCR maintains that the ICESCR “also imposes various obligations which are of immediate effect” [CESCR 1990(b): para. 1]. One of these is the guarantee that relevant rights “will be exercised without discrimination” [*id.*]. The other is the act of taking steps [*id.*: para. 2], which includes legislative measures [*id.*: para. 4] and the provision of judicial remedies [*id.*: para. 5]. Lastly, the CESCR expresses the view that “a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State party” [*id.*: para. 10]. Short of these

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<sup>196</sup> For instance, as mentioned by the Danish representative, “many countries were faced with the problem of reconciling defence requirements with those of social services... [so] it would be unrealistic to attempt to dictate to states how they should allocate their resources in that respect” [Sørensen, Danish representative, 1951: 20]. Nevertheless, the Australian representative maintained that states engaging in the Covenant had ‘positive and not... evasive purposes’ [Whitlam, Australian representative, 1951: 15]. The Lebanese representative also specified that the ‘maximum of available resources’ refer to the real resources of a country and not to budgetary appropriations [Azkoul, Lebanese representative, 1952: 5]. See Alston and Quinn who provide a thorough commentary of the ICESCR provisions relating to state parties obligations utilising the *travaux préparatoires*. Odinkalu notes that the analysis of Alston and Quinn is reflected in the CESCR General Comment 3 on the nature of states parties obligations [Odinkalu 2001: 333, footnote 36].

minimum core obligations the covenant ‘would be largely deprived of its *raison d’être*’ [*id.*]. Importantly, according to the CESCR, the provision of ‘essential drugs’ is on its own a core obligation [CESCR 2000: para. 43(d) and note 5]. This view is upheld by Special Rapporteur Hunt, who has also reported to the UN General Assembly about the human right to medicines [Hunt 2006: para. 38]. The CESCR however does not identify ‘essential drugs’. Rather it refers to those drugs “from time to time defined under the WHO Action Programme on Essential Drugs” [CESCR 2000: para. 43(d) and note 5]. It is also noted that, according to the CESCR, the lack of essential medicines in a country is a *prima facie* violation by states of their minimum core obligation if it affects ‘any significant number of individuals’ [CESCR 1990(b): para. 10; 2000: para. 43].

In sum, the ICESCR attributes to home states certain duties to respect, protect and fulfil access to medicines as part of the human right to health. The CESCR, in addition, identifies the provision of ‘essential’ medicines as a core obligation of immediate effect. It can therefore be said that access to medicines is a human right as fundamental part of the human right to health. It was also noted however that the wording of the human right to health is to great extent indeterminate, therefore it is difficult to draw precise obligations for African states. In effect, the ICESCR contains no precise prescription with regard to the conduct that states shall adopt for the realisation of the right. For example, a direct intervention of states in health care is not required. States have to take steps towards the ‘*creation of conditions*’ which would assure to all medical service and medical attention [ICESCR art. 12(2)(d), *emph. add.*]. Apparently, some duties are conditional on the local circumstances, such as the availability of state resources and the characters of the health systems [ICESCR art. 2(1)]. The CESCR, in its general comments, prescribes the conduct of states in a more comprehensive way, yet allowing for margins of discretion. The operationalisation and implementation of the prescriptions of the ICESCR and the CESCR are discussed in Chapter 5.

### 3.2.1.2 *The African Charter on Human and Peoples' Rights (ACHPR)*

Several regional covenants sanction a human right to health, such as the European Social Charter<sup>197</sup> and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.<sup>198</sup> With regard to sub-Saharan Africa, the human right to health is enshrined in the African Charter on Human and Peoples' Rights (ACHPR), adopted in 1981, ratified by all 53 members of the Organisation of African Unity (OAU, now African Union, AU) [Odinkalu 2003: 20].<sup>199</sup> Like the ICESCR, the ACHPR is presided by a treaty body, the African Commission on Human and Peoples' Rights [hereinafter African Commission] which can offer guidance for the interpretation of the right to essential medicines sanctioned in the Charter's regime.<sup>200</sup> There are a series of articles in the Charter dealing with health. Article 16 is the most relevant with regard to access to medicines.<sup>201</sup> The article provides that

Every individual shall have the right to enjoy the best attainable State of physical and mental health. States Parties are obliged to take the necessary measures to protect the health of their peoples and to ensure that they receive medical attention when they are sick. [ACHPR art. 16]

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<sup>197</sup> In the European Social Charter the 47 Members of the Council of Europe “[w]ith a view to ensuring the effective exercise of the right to protection of health... undertake, either directly or in co-operation with public or private organisations, to take appropriate measures designed inter alia: to remove as far as possible the causes of ill-health to prevent as far as possible epidemic, endemic and other diseases” [ESC art. 11].

<sup>198</sup> The Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, also known as Protocol of San Salvador, sets forth a right to health for all individuals [Protocol of San Salvador, art. 10]. The American Declaration of the Rights and Duties of Man establishes the right to the preservation of health through sanitation and social measures (food, clothing, housing and medical care) [ADRDM, Article XI]. *See, e.g.*, Langford and Nolan [2006: 97-99].

<sup>199</sup> The African Charter on Human and Peoples' Rights was adopted in 1981 and entered into force in 1986. The Charter is often called Banjul Charter in order to differentiate it from the Charter of the Organisation of the African Union (OAU) [Peter 1990: 9].

<sup>200</sup> The Commission's mandate is to protect, to interpret, and to promote the rights guaranteed under the ACHPR [ACHPR Arts 45(1)(2)(3)]. Under its protective function, the African Commission receives biennial reports, it can consider communications and complaints by other State parties or NGOs [art. 55], and can formulate recommendations [art. 59] for the implementation of the Charter. So far, the African Commission has not been officially requested to interpret a Charter provision, however, it has expressed authoritative interpretation through the recommendations expressed in the exercise of its protective role [Baderin 2007: 144]. *See also* Chapter 4 section 4.2.2.

<sup>201</sup> For example, article 18 provides that the state “shall take care for the physical health” of the family [ACHPR art. 18]. Article 13 sanctions the right to equal access to the public service of his or her country [*id.*: art. 13]. Article 24 provides for a general satisfactory environment [*id.*: art. 24].

The formulation recalls ICESCR article 12 which describes the human right to health as the right to the highest attainable standard of physical and mental health.<sup>202</sup> It is also remarked that international instruments can be used by the African Commission in order to interpret the Charter [ACHPR: art. 60]. Access to medicines is necessary for the realisation of ACHPR article 16 even though the Charter does not make direct reference to it. In effect the African Commission has recognised the lack of provision of medicines as a violation of the human right to health deciding in a violation complaint.<sup>203</sup> Furthermore, it has recently issued a resolution on access to medicines which, *inter alia*, “urges states to guarantee the full scope of access to medicines” [AC Res. 141 (2008): para. 1], and recognises that “access to needed medicines is a fundamental component of the human right to health and that States parties to the African Charter have an obligation to provide where appropriate needed medicines, or facilitate access to them” [*id.*: preambular para. 4].<sup>204</sup>

With regard to the conduct for the implementation, similarly to the ICESCR [ICESCR art. 2(1)], according to the Charter article 1, the parties “shall recognize the rights, duties and freedoms enshrined in this Charter and shall undertake to adopt legislative or other measures to give effect to them” [ACHPR art. 1]. The Charter is in effect vague, but duties to respect, protect and fulfil the human right to health can be read in the ACHPR provisions. This view has been upheld by the African Commission in its communications.<sup>205</sup> The African Commission’s resolution on the human right to medicines, furthermore, lists the scope of the actions that states should take in order to promote, protect and fulfil the human right to medicines [AC Res. 141 (2008): para. 2]. Among the obligations to fulfil, similarly to the CESCR, the Commission demands “ensuring availability and affordability to all of essential medicines” [*id.*: para. 2(3)(a)]. The Commission identifies the essential medicines referring to the country’s essential

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<sup>202</sup> For the meaning of ‘health’ in the Charter therefore *see* section 3.2.1.1 above. For the comparability of the ACHPR art. 16 to the ICESCR art. 12 formulations *see also* Toebes [1999: 73].

<sup>203</sup> In the *Zaire* case, the Commission found that “[t]he failure of the Government to provide basic services such as safe drinking water and electricity and the shortage of medicine... constitutes a violation of Article 16” [AC, *Zaire*, 1995: para. 47]. *See* Chapter 6 Section 6.4.3.2.

<sup>204</sup> Quite convolutedly the African Commission also recognises that the UN Special Rapporteur on the right to health has explained the right to health mandates that State promote “the realization of the human right to medicines for all” [AC Res. 141 (2008): preambular para. 5].

<sup>205</sup> *See* African Commission, *Nigeria* [2001]. *See also* Kiapi [2005: 12].

medicines list and the WHO Action Programme on Essential Drugs, as it will be discussed in Chapter 5 section 5.4.1.

There is no mention in the African Charter to certain concepts found in the ICESCR, such as the progressive achievement or the availability of resources [ICESCR art. 2(1)]. According to Baderin, scholars are of the view that the economic, social and cultural rights must be achieved progressively owing to the lack of resources and the poor economic situation confronting African states [Baderin 2007: 141].<sup>206</sup> Instead, Odinkalu maintains that the obligations assumed by state parties “are clearly stated as of immediate application” [Odinkalu 2001: 349]. This is because in the Charter, differently to the UN Covenants, “[e]conomic, social and cultural rights are placed on the same footing as all other rights in the Charter” [*id.*]. This interpretation, he argued, is confirmed by the Commission which for instance, in its third Activity Report, acknowledged the difficulty posed by “the present hostile economic circumstances” but reminded the state parties that “[o]ur Charter requires that all these rights and more should be implemented now... It is a task that must be carried out by every ratifying State” [African Commission 1990: 115].<sup>207</sup> In its resolution on the human right to medicines, the African Commission also calls on states to fulfil access to medicines by “*immediately* meeting the minimum core obligations of ensuring availability and affordability to all of essential medicines” [AC Res. 141 (2008): para. 2(3)(i), *emph. add.*].<sup>208</sup>

Thus, the African Charter *de jure* sanctions access to medicines as part of the human right to health [ACHPR art. 16]. In particular, the African Commission (which is however a non-binding treaty-based body) has issued a resolution recognising access to medicines as a fundamental component of the human right to health and urging states to promote, protect and fulfil access to medicines. Essential medicines shall be immediately ensured. Therefore, it can be said that under the ACHPR regime, like under the ICESCR regime, access to medicines is a human right, as part of the human right to health.

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<sup>206</sup> For instance, Baderin refers to Ankumah [1996: 144].

<sup>207</sup> See Odinkalu [2001: 350].

<sup>208</sup> The Commission identifies the core referring to the country’s essential medicines list and the WHO Action Programme on Essential Drugs, as discussed in Chapter 5 section 5.4.1.

### 3.2.1.3 *The human right to health in other treaties*

Other international treaties enshrine special provisions relating to health which can apply to access to medicines. Those treaties however, unlike the ICESCR and the ACHPR, regard specific groups/situations such as women and children.<sup>209</sup> Thus, arguably, the human right to health, sanctioned in treaty law by a host of widely-accessed international covenants, including the principal human rights treaties of the African region, upholds a human right to medicines and its corresponding obligations on the part of states to respect, protect, and fulfil access to medicines.

### 3.2.2 **Access to medicines as part of the right to life**

Access to life-saving medicines can also be supported in international human rights law by the right to life. This right is sanctioned in the International Covenant on Civil and Political Rights (ICCPR), whereby “[e]very human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life” [ICCPR art 6(1)]. Like the ICESCR, the Covenant is part of the Bill of Human

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<sup>209</sup> The United Nations Convention on the Rights of the Child (CRC), ratified by 48 African countries [Odinkalu 2003: 23] and 185 parties worldwide [UNTC 2008], contains a right to health for children which demands, *inter alia*, that states take appropriate measure to “ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care” and “to combat disease and malnutrition, including within the framework of primary health care, through, *inter alia*, the application of readily available technology” [CRC art. 24(2)(b) and (c)]. The African Charter on the Rights and Welfare of the Child, ratified by 37 African countries [African Union, website, 2004], is also comprehensive in providing for the health of the children. Article 14, in effect states that “States Parties... shall take measures... to ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care” [ACRWC art. 14, 14(b)]. Health is recognised in the Convention on the Elimination of all Forms of Discrimination against Women [CEDAW art. 12(2)], ratified by 48 African countries [Odinkalu 2003: 23] and 185 parties worldwide [UNTC 2008], and the Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa, ratified by 27 countries [African Union, website, 2010], which requires states parties “to provide adequate, affordable and accessible health services to women, especially those in rural areas” [Protocol to the African Charter on Human and Peoples’ Rights on the Rights of Women in Africa art. 14].

Rights.<sup>210</sup> The Covenant has been ratified by 162 states [UNOHCHR 2008(a)], out of which 43 are African countries [Odinkalu 2003: 23]. The right to life is also enshrined in the ACHPR, whereby “[e]very human being shall be entitled to respect for his life and the integrity of his person. No one shall be arbitrarily deprived of his life” [ACHPR art. 4]. The inference of a right to medicines from the right to life is not straightforward. Traditionally, the right to life has been interpreted as imposing to states a negative obligation to abstain from arbitrarily depriving the life of individuals [Dinstein 1981: 115]. There are suggestions, however, that the right to life also imposes a responsibility for basic survival conditions. The Human Rights Committee, which oversees the ICCPR, for instance, in its General Comment 6 on the right to life has stated that:<sup>211</sup>

...the right to life has been too often narrowly interpreted. The expression ‘inherent right to life’ cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connection, the Committee considers that it would be desirable for States parties to take all possible measures to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics. [HRC, General Comment 5, 1994: para. 5]

The African Commission has also adopted a broader understanding of the right to life, stating for instance that it can be violated when “pollution and environmental degradation to a level humanly unacceptable has made it living in the Ogoni land a nightmare” [AC, *Nigeria*, 2001: 67]. Some national cases, debating the right to life in the national law also support such broader interpretation, such as some decisions in Indian and Bangladeshi Supreme Courts<sup>212</sup> – where the recognition in the national law of a

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<sup>210</sup> See sub-section 3.2.1.1.

<sup>211</sup> See Chapter 4 section 4.2.3.

<sup>212</sup> In India, in *Frances Mullen v. Union Territory of Delhi* the Supreme Court held that the right to life “includes the right to live with human dignity and all that goes along with it, namely, the bare necessities of life, such as adequate nutrition, clothing and shelter” and the right to live with human dignity includes the right to good health [India, Supreme Court, *Mullen*, 1981: 453]. The Supreme Court of Bangladesh considered this decision by the Indian Supreme Court in *Dr Mohiuddin Farooque v. Bangladesh & Others*. Therein it held that the right to life is not limited to the protection of life and limb, but also includes, among other rights, the protection of the health and normal life longevity of an ordinary human being. Even though the Directive Principle (Article 18 of the Constitution) of raising the level of nutrition and improving public health might not be directly enforceable, the state may be compelled by the courts to remove any threat to public health unless such a threat is justified by law [Bangladesh, Supreme Court, *Dr Mohiuddin Farooque v. Bangladesh & Others*, 1996, reported in Langford and Nolan 2006: 104].

positive, justiciable right to health is absent.<sup>213</sup> A number of cases relating to access to life-saving medication have been awarded in Latin America inter alia referring to the right to life.<sup>214</sup> Indeed, the right to life can reinforce the case for access to medicines. In an analysis of 71 court cases in 12 low and middle income countries in which access to essential medicines was claimed with reference to the human right to health, Hogerzeil et al indeed note that in 80% of cases, the human right to health was linked to the right to life [Hogerzeil et al 2006: 308].<sup>215</sup> Some courts however have preferred to distinguish the scope of those rights. In *Soobramoney* the South African Constitutional Court held that the human right to health care does not have to be inferred from the right to life because section 27 of the Constitution specifically deals with health rights [South Africa, Constitutional Court, *Soobramoney*, 1998: para. 15].

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<sup>213</sup> Namely, India's Constitution is composed of enforceable and non enforceable parts. While the Fundamental Rights in part III are enforceable, the Fundamental Duties and the Directive Principles of State Policy, in part IV and IVa are non-enforceable [Constitution of India, art. 37]. The right to health is sanctioned among the Fundamental Duties and the Directive Principles of State Policy [*id.*: art. 47].

<sup>214</sup> In Venezuela, in *Glenda López y otros c. Instituto Venezolano de los Seguros Sociales (IVSS)*, the Supreme Court granted an *amparo* for a group of persons living with HIV requesting to ensure regular and consistent supply of antiretrovirals and other drugs needed to treat opportunistic diseases, as well as to provide coverage of expenses of all necessary medical tests. The Court found that the failure denounced by the petitioners was a violation of the right to health and a threat to the right to life, as well as a breach of the right to the benefits of scientific and technological progress, and to social security, as set forth by the Constitution of Venezuela and international human rights conventions [Venezuela, Supreme Court, *Glenda López y otros c. Instituto Venezolano de los Seguros Sociales (IVSS)* 2001; Venezuela, Supreme Court, *Loreto Tabares y Otros*, 2002]. In *B. E. A. v. Ministerio de Salud, Banco Nacional de Drogas Antineoplásticas, Ley 16.986*, a successful protection writ action was brought to force the Ministry of Health of Argentina to provide a particular anti-cancer drug necessary for the survival of a 63-year-old woman suffering from colon cancer [Argentina, Supreme Court, *B.E.A.*, 2002; Yamin 2003: 111]. Other cases on antiretrovirals have been successful in Colombia and Costa Rica. As reported by Yamin, the Constitutional Court of Colombia has elaborated an extensive jurisprudence on the right to treatment in cases of HIV/AIDS. For instance in the *Judgment of Fabio Moron Diaz, Magistrado Ponente*, the Court held that denial of costly antiretroviral treatment prescribed for the plaintiff under social security system violated constitutional fundamental right to life [Colombia, Corte Constitucional de Colombia 1998 in Yamin 2003: 111]. *See also* Yamin [2003: 110-111] and Hestermeyer [2004: 152].

<sup>215</sup> Most of the cases identified by Hogerzeil and colleagues were set in Central and Latin America [Hogerzeil et al 2006: 305].

### **3.2.3 Access to medicines and other human rights (right not to be subjected to torture, inhuman and degrading treatment; right to dignity; rights to adequate standards of living, to social security, to education and to work; and to the benefits of scientific progress)**

Access to treatment, under certain circumstances, can be seen as part of the right not to be subjected to torture, inhuman and degrading treatment. The right is sanctioned in the ICCPR [ICCPR art. 7] and in regional conventions including the ACHPR [ACHPR art. 5].<sup>216</sup> The intentionality of pain is in fact often seen as a necessary requirement for the state offence to amount to torture or cruel, inhuman or degrading treatment [Kilkelly 1999: 153]. The jurisprudence is however inconsistent. Violations of the right have been found in a number of cases relating to the treatment in detention of seriously ill individuals. The Human Rights Committee, which oversees the ICCPR,<sup>217</sup> for instance recognised a violation of the right not to be subjected to torture, inhuman and degrading treatment in *Henry and Douglas v. Jamaica*, regarding the failure to provide adequate medical care to prisoners [HRC, *Jamaica*, 1996].<sup>218</sup> In South Africa, on the same grounds the High Court granted parole to a terminally ill cancer patient.<sup>219</sup> In Europe such rights

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<sup>216</sup> See also the Report by the Special Rapporteur on torture and other cruel, inhuman or degrading treatment or punishment, stating that “[t]he right to freedom from cruel, inhuman or degrading treatment or punishment can arise in a variety of ways in the context of HIV/AIDS” [Van Boven 2004: para.51].

<sup>217</sup> See Chapter 4 section 4.2.3.

<sup>218</sup> In *Henry and Douglas v. Jamaica* the Human Rights Committee held that the failure to provide adequate medical care to prisoners (a violation of the social and economic right to health) constituted a violation of the right to freedom from torture or to cruel, inhuman or degrading treatment or punishment and of the right of all persons deprived of their liberty to be treated with humanity and with respect for the inherent dignity of the human person (provided for by Articles 7 and 10 of the ICCPR, respectively) [HRC, *Jamaica*, 1996]. See also Nolan et al [2007: 19].

<sup>219</sup> In *Stanfield v. Minister of Correctional Services & Others*, the High Court of South Africa granted parole to a terminally ill cancer patient [South Africa, High Court – Cape of Good Hope Provincial Division, *Stanfield*, 2003]. The court relied on language in international human rights law with respect to protection from ‘cruel, inhuman and degrading treatment’, echoing Article 7 of the ICCPR (language which was also repeated in the South African Constitution [Constitution of South Africa, art. 12]) [ICCPR art. 7]. The decision also relied on language very similar to Article 10 of the Covenant, which guarantees that all “persons deprived of their liberty shall be treated with humanity and with respect for the inherent dignity of the human person” [ICCPR art. 10]. As UNAIDS notes, “insofar as South African prisoners living with HIV continue to be unable to realize their right to be treated for their illness, many of the arguments made in favour of this applicant should also be pertinent to their rights and entitlements” [UNAIDS,

have been debated with regard to deportation of immigrants (especially former detainees), where such act would entail the interruption of the care needed and provided in the host country even if harm is not intentionally inflicted. The European Court of Human Rights (ECtHR), while recognising the importance of intentionality, has also declared, in *D. v. United Kingdom* that it “must reserve to itself sufficient flexibility to address the application of [Article 3] in other contexts which might arise” [ECtHR, *D. v. United Kingdom*, 1997: para. 49].<sup>220</sup> Yet, such flexibility is reserved to ‘very exceptional circumstances’ [*id.*]. More restrictively, the Venezuela Supreme Court has held that the Venezuelan government’s conduct did not amount to torture or inhuman or degrading treatment because there was no intention to cause pain or inflict damage on people living with HIV or to undermine their dignity.<sup>221</sup> In that case however reference was made to the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or

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Courting Rights 2006: 125]. *Ceteris paribus*, this can be applied to other conditions and treatments. See UNAIDS, Courting Rights [2006].

<sup>220</sup> In *D. v. United Kingdom* the European Court of Human Rights (ECtHR) held that deporting a man in the late stages of AIDS from the United Kingdom back to his home country, where he would face poor general public health conditions and lack of access to treatment for AIDS, qualified as ‘inhuman treatment’ [ECtHR, *D. v. United Kingdom*, 1997: paras. 53, 54]. Consequently, in *Bensaid v. United Kingdom*, the Court could conclude that article 3 had not been violated because, although in serious medical condition, the applicant could get the medical treatment available in Algeria, where he was to be returned [ECtHR, *Bensaid v. United Kingdom*, 2001; Lambert 2005: 40-44; 2006: 29-30]. (Article 3 of the European Convention of Human Rights and Fundamental Freedoms (ECHR) claims that “[n]o one shall be subjected to torture or to inhuman or degrading treatment or punishment” [ECHR art. 3].) See also *Kalashnikov v. Russia*, where the ECtHR held that the applicant’s unhealthy conditions of detention amounted to degrading treatment as “although the question whether the purpose of the treatment was to humiliate or debase the victim is a factor to be taken into account, the absence of any such purpose cannot exclude a finding of violation of Article 3” [ECtHR, *Kalashnikov v. Russia*, 2002: paras. 101-102]. ECtHR *D. v. United Kingdom* influenced the following European national jurisprudence on similar cases, such as the UK’s *N (FC) v. Secretary of State for the Home Department*. In *N (FC) v. Secretary of State for the Home Department*, the House of Lords rejected the appeal of a deportation order filed by a Ugandan woman living with HIV, who argued that expelling her to her country, where access to HIV medication and medical care was uncertain, was in breach of the European Convention [United Kingdom, House of Lords, *N (FC) v. Secretary of State for the Home Department*, 2005; UNAIDS, Courting Rights, 2006: 62-63]. The case went to the ECtHR which also held that expulsion would not cause a violation of article 3 of the ECHR [ECtHR, *N v UK*, 2008].

<sup>221</sup> Namely, in the *Cruz del Valle* case, the applicants brought an *amparo* action against the Ministry of Health and Social Action seeking the supply of prescribed antiretrovirals. While rejecting allegations of torture or cruel, inhuman or degrading treatment, nevertheless, the Court instead found violations of the rights to life, health and the benefits of science and technology. Therefore, it decided in favour of the applicants [UNAIDS, Courting Rights, 2006: 66].

Punishment which requires explicitly intentionality for a conduct to be qualified as torture [Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment art. 1].

The human right to medicines can also be seen as connected to civil and political rights. It has been noted, for instance, that the minimal content of social rights represents an indispensable protection to enjoy civil and political rights.<sup>222</sup> Importantly, health treatment can be seen as claimed as implicating for instance the right to the benefits of scientific and technological progress, the right to social security,<sup>223</sup> other human rights generally,<sup>224</sup> or as a condition for a ‘population’s earning capacity’.<sup>225</sup> It is commented however that, while human rights can be communicated as ‘indivisible’ in principle, in fact, the duties they impose on states can clash.<sup>226</sup> For instance, the right to benefits of scientific progress, sanctioned by art. 15(1)(b) of the ICESCR may conflict with the intellectual property right sanctioned by the same article at subparagraph (c) [ICESCR art. 15(1)]. Furthermore, the fulfilment of the human right to health by the states competes in resources with the fulfilment of other (especially economic and social) rights like, for example, other components of the ‘right to social security’ or the right to education [ICESCR art. 13; ACHPR art. 17]. Overall, the state intervention for the realisation of

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<sup>222</sup> In *Azanca Alhelí Meza García* the Peruvian Tribunal Constitucional accepted the *amparo* action submitted with Peru’s Health Ministry by an HIV/AIDS-positive person, who requested full medical care including permanent supply of drugs and periodical testing, as well as CD4 and viral load tests. The Court noted that social rights standards are not simply programmatic principles of non-immediate effectiveness, as they have been traditionally described to set them apart from immediately effective civil and political rights, since their minimal content represents an indispensable protection to enjoy civil and political rights. The Court also held that the principle of progressive realization of expenses does not rule out setting reasonable timelines or the State’s obligation to take concrete and permanent actions aimed at implementing public policies [Peru, Tribunal Constitucional, *Azanca Alhelí Meza García*, 2004; ESCR-Net, website].

<sup>223</sup> In *Glenda López y otros c. Instituto Venezolano de los Seguros Sociales (IVSS)*, relating to the provision of antiretrovirals, the Venezuelan Supreme Court found a breach of the right to the benefits of scientific and technological progress, and to social security, as set forth by the Constitution of Venezuela and international human rights conventions [Supreme Court of Venezuela, *Glenda López*, 2001; ESCR-Net, website].

<sup>224</sup> This view has been adopted in court cases, such as in *Laverde v. Capresom* by Constitutional Court of Colombia [Yamin 2003: 118, footnote 74].

<sup>225</sup> In *Alejandro Moreno Alvarez v. Estado Colombiano*, the Constitutional Court of Colombia held that the social security institute has obligations to provide essential medication and services to avoid the destruction of the population’s earning capacity [Yamin 2003: 118, footnote 74].

<sup>226</sup> On the indivisibility of civil and political rights from economic, social and cultural rights *see e.g.* ACHPR preambular paragraph 7 [ACHPR preambular para. 7].

human rights requires the collection of resources from the people and can impose other constraints. The impact of the implementation by home states of the human right to medicines on other rights, interests, needs and liberties in society will be discussed in Chapter 5.

In sum, the variety of human rights to which the access to medicines can appeal may be reassuring for the claim of access to medicines as a human right and show how access to medicines is communicated within the ‘human rights subsystem’. However, as opposed to the human right to health, they do not comprehensively sanction for a human right to medicines as such. Access to medicines is sometimes instrumental to those rights or those rights can be instrumental to access to medicines. These rights can reinforce the case for access to medicines, but they do not fit with a right to medicines as comprehensive as the human right to health does. Accordingly, for instance, Langford and Nolan in their analysis of the jurisprudence of economic, social and cultural rights have remarked that the application of the prohibition on torture, inhuman and degrading treatment and punishment “is unlikely to apply to many of the fundamental components of the right to the highest attainable standard of health or to all aspects of other economic, social and cultural rights” [Langford and Nolan 2006: 103]. On a similar line, the Constitutional Court of South Africa, when dealing with the right to treatment in the *Soobramoney* case, decided to refer to the human right to health, as opposed to the right to life, because more comprehensively responding to the circumstances of the case [South Africa Constitutional Court, *Soobramoney*, 1998: para. 15]. Furthermore, the duties imposed to states by human rights norms can in effect contradict. These conflicts will be analysed in Chapter 5, but it can be recalled here that Luhmann specifically identified a paradox in the fact that human rights are justified as ‘indisputable’ values, that is, ‘fully independent of consequences’ [Luhmann 1997(b): 35; 2008: 19] – while they can actually collide between each other [Luhmann 2008: 28, 29].<sup>227</sup>

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<sup>227</sup> See Chapter 1 section 1.4.

### 3.3 The human right to medicines in customary international law and soft law

Section 3.3 discusses the possibility that a human right to medicines be part of customary international law and investigates the correspondent obligations for home states. International customary law is a valuable legal source for both substantive and procedural reasons. Substantively, the obligations relating to the prospective international customary right may not correspond to the provisions relating to the right to medicines envisaged in the human rights treaties that have been examined in the previous sections (which are in any event similar between them but not identical). The right under customary law could be more comprehensive. In fact, custom is a fluid source of law.<sup>228</sup> Conversely, the customary right may lack some parts of the complex bundle of rights and duties entailed by the treaties. Procedurally, the Statute of the International Court of Justice (ICJ) envisages international customary law as a primary source of international law, on the par of treaty law [ICJ Statute: art. 38(b)]. All states are accountable for violations of general international law under the doctrine of state responsibility including ten African states (such as South Africa) and the US, which have not ratified the ICESCR [UNOHCHR 2008(b)].<sup>229</sup> Furthermore, the investigation of customary law will in effect reveal manifestations of the human right to medicines in ‘soft law’, which can be relevant for the positive law.<sup>230</sup> It will also provide a snapshot of the practice which African states undertake to promote access to medicines.

Section 3.3 first presents the technical difficulties of probing customary law (section 3.3.1). Next, some literature is reviewed and some comments expressed on the methodology for identifying a customary human right to medicines (section 3.3.2). Consequently, pieces of evidence of state practice and *opinio juris* are researched analysing ‘paper practice’ (section 3.3.3), ‘factual practice’ and judicial practice (section 3.3.4).<sup>231</sup> Finally, some conclusions on the issues raised are proposed (3.3.5).

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<sup>228</sup> According to Roberts, international custom is more receptive to changes in the states’ wills and beliefs [Roberts 2001: 784].

<sup>229</sup> Human rights can indeed count as obligations *erga omnes*, for which all states have a legal standing in customary international law. See Chapter 5 section 5.3.1 and Chapter 6 section 6.4.3.2.

<sup>230</sup> For the relevance of soft law to the present investigation of the positive law see section 3.1 above.

<sup>231</sup> The terms ‘paper practice’ and ‘factual practice’ are defined in *infra* section 3.3.1.

### 3.3.1 Elements of a customary norm

The assessment of international customary law involves notorious technical difficulties that are exacerbated in the research of norms relating to human rights. The ICJ Statute defines international customary norms as the ‘evidence of a general practice accepted as law’ [ICJ Statute: art. 38(b)]. International customary norms are therefore seen as characterised by two elements: state practice and *opinio juris ac necessitatis*.<sup>232</sup> Identifying those elements is problematic. In brief, to begin with, it is not clear what state actions can be acknowledged as evidence of practice. For instance, D’Amato argues that only ‘factual’ (what I would call ‘implementing’) acts can count as practice [D’Amato 1987: 102]. Hereinafter I will refer to these acts as ‘factual practice’. Conversely, according to Akehurst, also statements and declarations can count [Akehurst 1974-5]. Hereinafter I will refer to this practice as ‘paper practice’.<sup>233</sup> Next, it is difficult to mark the threshold between acts deviating from a candidate norm, therefore representing violations of the emerged norm, and acts that fall within the sovereign will and discretion of a state (thereby disproving the consolidation of a prospective norm).<sup>234</sup> It is hard to identify a customary norm on a subject area already regulated by a treaty, as the state actions may be merely complying with the latter legal source. Also, by contracting out from the general law on state responsibility, the parties to a treaty may establish a special – maybe softer – sanctionary regime, and therefore be more ‘relaxed’ in enucleating duties.<sup>235</sup> Thus, the recognition of a right in a treaty does not necessarily imply the *opinio juris ac necessitatis* of a duty in general international law. Moreover, it has to be established how many states have to comply – and for how long. Brownlie, for instance, maintains that practice should be of a certain duration, uniformity, consistency, and

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<sup>232</sup> See, e.g., Cassese [2005: 157].

<sup>233</sup> On the distinction between ‘factual practice’ and ‘paper practice’ see also Hestermeyer [2004].

<sup>234</sup> It has been observed that this test of customary law assumes that custom is founded on what states mistakenly believe is custom [Geny 1917: 367].

<sup>235</sup> As Pauwelyn notes, by concluding a treaty states can contract out of or deviate from general international law (except from *jus cogens*). For instance, treaty provisions can set up a tailor-made enforcement mechanism (thus deviating from the general rule of State responsibility) [Pauwelyn 2001: 537]. Accordingly, the Draft Articles on State Responsibility state that “[t]hese articles do not apply where and to the extent that the conditions for the existence of an internationally wrongful act or the content or implementation of the international responsibility of a State are governed by special rules of international law” [ILC 2001: art. 55].

generality [Brownlie 2003: 7]. However these requirements are subject to exceptions.<sup>236</sup> Importantly for the present research, there is a view that the requirements of uniformity and generality may be eased in some cases for humanitarian outcomes or human rights norms. The ICJ has adopted this reasoning in decision favouring a ‘humanitarian’ outcome [Chetail 2003: 243].<sup>237</sup> Especially with regard to human rights, there is view that human rights norms should be identified focussing, in fact, on the *opinio juris ac necessitatis* (hereinafter *opinio juris*), that is, the *animus* of the acting state of being in compliance with a norm while performing the acts.<sup>238</sup> Therefore, the requirements of uniformity and generality of state practice may be relaxed.<sup>239</sup> In effect, it can be noted, the legal subsystem manifests its structural coupling to the human rights and ‘morality’

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<sup>236</sup> With regard to duration, according to the ICJ in the case *North Sea Continental Shelf*, “it might be that, even without the passage of any considerable period of time, a very widespread and representative participation in the convention might suffice of itself, provided it included that of States whose interests were specially affected” [ICJ, *North Sea Continental Shelf*, 1969: para 73]. With regard to the uniformity and consistency of the practice, while in the case *North Sea Continental Shelf* the ICJ held that custom has to be ‘extensive and virtually uniform practice’ [ICJ, *North Sea Continental Shelf*, 1969: para 74], in the *Nicaragua* case the Court decided that “[i]t is not to be expected that in the practice of States the application of the rules in question should have been perfect... The Court does not consider that, for a rule to be established as customary, the corresponding practice must be in absolutely rigorous conformity with the rule. In order to deduce the existence of customary rules, the Court deems it sufficient that the conduct of States should, in general, be consistent with such rules, and that instances of State conduct inconsistent with a given rule should generally have been treated as breaches of that rule, not as indications of the recognition of a new rule” [ICJ, *Nicaragua*, 1986, para. 186].

<sup>237</sup> For example, see the ICJ in the *Corfu Channel* and *Nicaragua* cases: “[t]he obligations incumbent upon the Albanian authorities consisted in notifying, for the benefit of shipping in general, the existence of a minefield in Albanian territorial waters and in warning the approaching British warships of the imminent danger to which the minefield exposed them. Such obligations are based, not on the Hague Convention of 1907, No. VIII, which is applicable in time of war, but on certain general and well recognised principles, namely: elementary considerations of humanity, even more exacting in peace than in war; the principle of the freedom of maritime communication; and every State’s obligation not to allow knowingly its territory to be used for acts contrary to the rights of other States” [ICJ, *Corfu Channel Case*, 1949: 22]. In the *Nicaragua* case the ICJ held that “[I]f a State lays mines in any waters whatever... and fails to give any warning or notification whatsoever, in disregard of the security of peaceful shipping, it commits a breach of the principles of humanitarian law underlying the specific provisions of Convention No. VIII of 1907” [ICJ, *Nicaragua*, 1986: 112, para. 215]. See also Chetail [2003: 243].

<sup>238</sup> For the use of the expressions *opinio juris* as opposed to *opinio juris ac necessitatis* see Cassese [2003: 157-8].

<sup>239</sup> The expression is borrowed from the ICJ case *North Sea Continental Shelf* [ICJ, *North Sea Continental Shelf*, 1969: para 74].

subsystems.<sup>240</sup> To this end, ‘paper practice’ such as declarations in international *fora* should provide an increasingly important source of law for human rights obligations, as they more explicitly enshrine *opinio juris* as well.<sup>241</sup> The missing ‘factual practice’, consequently, should be liberally identified as infringement of the norm.<sup>242</sup> This methodology has been used, for instance, by international courts in order to identify the customs relating to international humanitarian law,<sup>243</sup> the crime of genocide,<sup>244</sup> the

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<sup>240</sup> See Chapter 1 section 1.4.

<sup>241</sup> See Roberts [2001]. The same acts are therefore used as state practice and *opinio juris* [*Id.*]. Cf. Mendelson, above, maintaining that the same acts cannot serve the two tests at the same time [Mendelson 1995: 206]

<sup>242</sup> As Meron observed, “[w]hen it comes to human rights or humanitarian conventions... the gap between the norms stated and the actual practice tends to be especially wide” [Meron 1987: 363]. This suggests that the traditional notion of custom, which privileges inductive research in state practice, is at odds with human rights law analysis. Conversely, the inductive focus on state practice should yield to a deductive process that begins with general statements of rules rather than particular instances of practice [*id.*]. Cassese contends that the identification of some customary norms such as those opposing genocide, slavery, torture and racial discrimination is supported by their ‘inherent rational grounds’ [Cassese 2005: 158]. See also Brun [1993]; Chetail [2003]; Lillich [1995-96]; Simma and Alston [1988-89]; Roberts [2001]. See Niada [2006: 174] on the standing of the right to food in customary international law.

<sup>243</sup> For example the ICJ upholds the approach adopted by the Nuremberg International Military Tribunal stating in its advisory opinion on the legality of the threat or use of nuclear weapons that “[t]he Nuremberg International Military Tribunal had already found in 1945 that the humanitarian rules included in the Regulations annexed to the Hague Convention IV of 1907 ‘were recognized by all civilized nations and were regarded as being declaratory of the laws and customs of war’... The extensive codification of humanitarian law and the extent of the accession to the resultant treaties, as well as the fact that the denunciation clauses that existed in the codification instruments have never been used, have provided the international community with a corpus of treaty rules the great majority of which had already become customary and which reflected the most universally recognized humanitarian principles” [ICJ, *Legality of the Threat or Use of Nuclear Weapons*, 1995: 257, paras. 80-82; Chetail 2003: 245].

<sup>244</sup> In *Preliminary objections Bosnia-Herzegovina v. Yugoslavia* the ICJ reiterated its opinion on *Reservations to the Convention on the Prevention and Punishment of the Crime of Genocide*, maintaining that: “[t]he origins of the Convention show that it was the intention of the United Nations to condemn and punish genocide as ‘a crime under international law’ involving a denial of the right of existence of entire human groups, a denial which shocks the conscience of mankind and results in great losses to humanity, and which is contrary to moral law and to the spirit and aims of the United Nations... The first consequence arising from this conception is that the principles underlying the Convention are principles which are recognized by civilized nations as binding on States, even without any conventional obligation. A second consequence is the universal character both of the condemnation of genocide and of the cooperation required ‘in order to liberate mankind from such an odious scourge’ (Preamble to the Convention)” [ICJ, *Preliminary objections Bosnia-Herzegovina v. Yugoslavia*, 1996: 616, para. 31; Chetail 2003: 249].

prohibition of the use of force and the discipline of non-intervention in foreign relations.<sup>245</sup> The application of such method to the identification of a human right to medicines in customary law is critically discussed in sections 3.3.2-3.3.5.

### **3.3.2 The identification of a customary human right to medicines in the scholarly literature and proposal of a methodology**

One of the few elaborate attempts to investigate the possible customary status in international law of the human right to medicines is undertaken by Hestermeyer in his monographic essay “Access to Medication as a Human Right” [Hestermeyer 2004]. His method is interesting. Hestermeyer first examines access to medicines as part of the human right to health and consequently researches a possible self-standing right to medicines. With regard to the human right to medicines as part of the human right to health Hestermeyer identifies some ‘paper practice’, such as the inclusion of the human right to health in over 60 national constitutions [*id.*: 167].<sup>246</sup> However, he concludes that the ‘factual practice’ backing the hypothetical custom is insufficient as not enough case law could be found [Hestermeyer 2004: 167-8]. Hestermeyer also emphasises the position of the US opposing to the existence of economic, social and cultural rights. In effect, other authors as well are sceptical about the existence of an international customary norm on the human right to health [Jamar 1994: footnote 37], or express prudent reservations [Kinney 2001].<sup>247</sup> Nonetheless, Hestermeyer identifies a customary

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<sup>245</sup> The *Nicaragua* judgment, in 1986, represented a landmark case for the identification of a customary norm banning the use of force in foreign relations. While the ICJ maintained that “the Court may not disregard the essential role played by general practice” [ICJ, *Nicaragua*, 1986: para. 184], it provided no evidence or discussion of such practice, relying instead on the reaffirmation by states of article 2(4) of the UN Charter [*id.*: paras. 183-190]. Therefore, it relied on *opinio juris* or/and paper practice.

<sup>246</sup> According to the UNOHCHR and WHO the right to health or the right to health care is recognized in at least 115 constitutions [UNOHCHR and WHO 2008: 10]. At least six other constitutions set out duties in relation to health, such as the duty on the State to develop health services or to allocate a specific budget to them [*id.*]. See also Kinney and Clark [2004] and Hogerzeil [2006: 371].

<sup>247</sup> Kinney discusses the scenario of a custom and its consequences for the US. Kinney in effect suggests that constitutional cases such as the 1977 *Maher v. Roe*, wherein the Supreme Court stated that “the Constitution imposes no obligations on the states to pay... any of the medical expenses of indigents” may one day be outdated [US Supreme Court, 1977: 464; Kinney 2001: 1465]. The current health sector reform can be a step in that direction [The Economist, “Signed, Sealed, Delivered”, 2010]. See *infra* sections 3.3.3-3.3.4.

international norm regarding the provision of access to medicines to groups, for emergencies, namely in pandemics and ‘subject to progressive realization’ [Hestermeyer 2004: 176]. He draws this conclusion from the work of states, including the US, for the universal treatment of HIV/AIDS, as evidenced from the participation to the WHO access initiative ‘3 by 5’ [*id.*: 172]. However, Hestermeyer’s position may not be consistent: Hestermeyer admits the *conduct* of states as a viable practice for a right to medicines in pandemics, even though results are not achieved and court cases are not presented.<sup>248</sup> Instead, for proof of the human right to medicines as part of the human right to health and life he requires legal cases about the recognition of the right [Hestermeyer 2004: 167-8]. Anyway, the international customary norm relating to pandemics identified by Hestermeyer does not actually regard a *human* right; arguably it concerns a right to be rescued in particular situations, in relation to the rule of rescue for urgent care.<sup>249</sup>

Consequently, I venture in a new investigation utilising an original method in order to ascertain the existence of a human right to medicines in international customary law. I note that human rights can be attributed different legal standings in the legal subsystem, for instance they can be claims to freedoms or to entitlements, and be corresponded by obligations of different nature – such as the duties of respect, protection and fulfilment – which can be borne by different actors.<sup>250</sup> This does not only mean that I advance the possibility that *parts* of the human right to health are legally binding in customary law.<sup>251</sup> In fact, it is also suggested that the test to be used in order to verify customary human rights should depend on the nature of the obligation investigated. In other words, the types of state practice and *opinio juris* to be sought shall also differ. The thesis presented by adopting this method is that the acts required as a proof of practice for demonstrating the recognition of a right/freedom may be ‘paper practice’, whereas actions and policies for implementation will be needed in order to prove the character of a customary entitlement. Therefore, I also dissociate from Hestermeyer who, in

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<sup>248</sup> As Hestermeyer himself admits “[d]espite the favourable practice the access situation remains bleak: only 1 percent of the people who need AIDS medication in Southern Africa actually have access to it” [Hestermeyer 2004: 172].

<sup>249</sup> The rule of rescue is a principle of medical ethics. It is set into law, for instance, in the South African Constitution, which states that “[n]o one may be refused emergency medical treatment” [South Africa’s Constitution, art 27(3)]. The rule of rescue will be dealt with in Chapter 5 section 5.4.3 on the implementation of the right to health. *See also* McKie and Richardson [2003].

<sup>250</sup> *See also* the CESCR in General Comment 14 [CESCR 2000: para. 13].

<sup>251</sup> *See* Skogly maintaining that human rights obligations in customary law have negative character [Skogly 2001: 87].

investigating the human right to medicines as part of the rights to health and life, reduced the enquiry of state ‘factual practice’ to an enquiry of the recognition of the human right to medicines in legal cases. As argued below, my contentions are supported by the analysis of the texts constituting ‘paper practice’, considerations of expediency/sensibility, the rulings of international courts, and state practice.

### **3.3.3 Investigating the practice of the presumed customary norm: ‘paper practice’ and its limitations**

My investigation starts with the analysis of the ‘paper practice’, also observing if it is accompanied by ‘factual practice’ – such correspondence can warrant the existence of a customary norm prescribing negative as well as positive duties. The Universal Declaration of Human Rights (UDHR) stands out, as it has been often reported to be part of international customary law as such, even though some international law literature only sees it as *opinio juris*.<sup>252</sup> The UDHR is actually a UN General Assembly resolution, which had been approved unanimously in 1948 by the then members of the UN. Therefore it was not originally meant to be legally binding.<sup>253</sup> It is interesting to see what implications follow from the Declaration’s provisions on a right to health. Article 25 of the UDHR states that:

Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of

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<sup>252</sup> See Buerghental [1988]; Dimitrijevic [2006]; Hannum [1995-96]; Riedel [1991]; Sohn [1982]. See also the US Third Restatement of the Foreign Relations Law (Comments), according to which “[a]ll the rights proclaimed in the Universal Declaration and protected by the principal International Covenants are internationally recognized human rights” [Third Restatement (Comments) 1987: para. 702 (o.)]. A number of countries have reached a similar conclusion. For example, a statement made on behalf of the five Nordic countries of Denmark, Finland, Iceland, Norway, and Sweden indicated that: “[t]he Declaration is generally recognized as having already become a part of universal international law. Therefore, the implementation of the principles of the Declaration is the responsibility of all Member States of the United Nations” [International Centre for Human Rights and Democratic Development, Technical Annex, 1999]. Similar statements have been made by the governments of Austria, Chile, Mexico and Azerbaijan [*id.*].

<sup>253</sup> The Declaration is a resolution by the General Assembly. It was approved unanimously, with eight abstentions (the Soviet Bloc, Saudi Arabia and the Union of South Africa), in 1948 [Sohn 1982: 15].

unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control. [UDHR art. 25]

The human right to health is thus combined to other social issues, as part of the right to an adequate standard of living [UDHR art. 25]. There is no definition of health and an initial text reference to the WHO Constitution had not been finally accepted [Toebes 1999: 40]. According to Toebes, it is possible to read a right to medical care and sickness benefits, although ‘only with some difficulty’ [*id.*]. The question is, to which obligations are states committing. Article 22, which deals with the realisation of economic, social, and cultural rights, may provide some guidance, stating that

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality. [UDHR art. 22]

From a textual point of view, article 22 of the UDHR resembles article 2(1) of the ICESCR,<sup>254</sup> even though it appears to be less committing. For instance, the realisation of the rights is not characterised as ‘full’; the national effort and or the international cooperation are not to be based on the maximum of the available resources but ‘in accordance’ to them; the rights to be realised to everyone are those ‘indispensable for his dignity and the free development of his personality’; the parties do not undertake to take steps, so there is no route demanded – arguably the article may merely refer to an equal share of the resources among the members of society. The Declaration provides nonetheless for an entitlement to realisation of those rights [UDHR art. 22]. However, the wording in the UDHR is vaguer than that in treaties such as the ICESCR or the ACHPR and does not have a treaty-based body which can authoritatively interpret its provisions.<sup>255</sup> Remarkably, it is often noted that the ICESCR was meant to specify with measures of implementation the obligations set as principles in the Declaration [UNOHCHR 1996].

The substance of the UDHR is elusive and we turn to the ‘paper practice’ of declarations more specifically regarding the problem of access to medicines. The Declaration of Alma Ata, which is also referred to by the CESCR in its general comment on the human right to health [CESCR 2000: para. 43], for instance, reads that “health...

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<sup>254</sup> See section 3.2.1.1.

<sup>255</sup> Toebes, indeed, defines article 25 as ‘broad and vague’ [Toebes 1999: 40].

is a fundamental human right” [Declaration of Alma Ata 1978: para. I] and “[p]rimary health care... includes at least... [*inter alia*] provision of essential drugs” [*id.*: para. VII (3)].<sup>256</sup> The states convened also agreed that “[g]overnments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures” [*id.*: para. V]. Thus the Declaration does refer to human rights and state action. However, it should be noted that the Declaration has been accepted in the specific context of primary health care.<sup>257</sup> Furthermore, it is noted that the Declaration is founded on a series of ‘communications’, *including* the human right to health.<sup>258</sup> With regard to the practice of the declaration, it is difficult to maintain that the target of “attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life” has been respected [*id.*]. In effect, primary health care have not been universally realised in an effective way.<sup>259</sup>

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<sup>256</sup> The Declaration was endorsed in 1978 by all 134 WHO members who participated to the international conference on primary health care held by WHO and UNICEF [WHO, Primary Health Care Comes Full Circle, 2008]. It has been reaffirmed, for instance, in 1998 by the WHO Health Assembly with resolution 7 (1998) [WHA Res. 7 (1998); Banerji 2003]. WHO has just celebrated the Declaration’s 30 years, also focusing its 2008 World Health Report on “Primary Health Care – Now More Than Ever” [WHO, World Health Report 2008].

<sup>257</sup> The notion of primary health care is analysed in Chapter 5 section 5.4.1.

<sup>258</sup> For example, “the attainment of the highest possible level of health is a most important world-wide social goal” [Declaration of Alma Ata 1978: para. I] and “[a] main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice” [*Id.*: para. V].

<sup>259</sup> The concept of primary health care has received attention in health-systems policy-making but often has not delivered the promised outcomes [Beaglehole and Bonita 2004]. According to Hong, Director General of the WHO, though, primary health care has not really been adopted in the third world countries. Primary health care has in fact been betrayed by ‘selective’ primary health care, *ie* reduced to ‘selective cost effective interventions’, as proposed by wealthy donors and institutions (such as the Rockefeller Foundation) [Hong 2004: 29]. *Cf.* India’s report to the CESCR: “India is a signatory to the Alma Ata Declaration of 1978 with the commitment to the goal of ‘Health for All’ by 2000 A.D. The National Health Policy 1983 was evolved in this background as a blue print for combined action by the government and voluntary agencies stressing the preventive health care and the need of establishing comprehensive primary health care services to reach the people in the remotest areas. It called for a decentralized system of health care and people’s participation viewing health and human development as vital components of overall integrated socio-economic progress” [CESCR, India, E/C.12/IND/5, 2007: 127, para. 476].

The General Assembly of the UN has also pronounced on the issue of access to medicines in Resolution 179 (2003), which enjoyed near universal acceptance with the unique opposition of the US.<sup>260</sup> In the resolution, the UN members have recognised that “access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” [UN GA Res. 179 (2003): para. 1] and calls upon states to pursue policies which would promote: availability, accessibility and quality of pharmaceutical products or medical technologies used to treat pandemics such as HIV/AIDS, tuberculosis and malaria or the most common opportunistic infections [*id.*: para. 6]. Therefore, the Resolution is centred in the context of pandemics. The Resolution is also founded on groundings other than human rights, such as stability and security [*id.*: preambular para. 20] and on other pledges to combat AIDS and other epidemics [UN GA Res. 179 (2003)]. In effect, no targets or goals have been set with the resolution.

Elements of the human right to medicines are recognised, for instance, by African states in a number of recent non-binding declarations.<sup>261</sup> In the Brazzaville Commitment on Scaling Up Towards Universal Access to HIV and AIDS prevention, treatment, care and support in Africa by 2010, the parties convened, which included African states, explicitly stated that “[b]asic medicines and other basic commodities are a human right and *should* be available and accessible to all who need it in Africa” [Brazzaville Commitment, 2006, para. 4(m), *emph. add.*].<sup>262</sup> This statement is however again linked to occasions, namely ‘emergencies’, not providing for access to medicines. Other pledges to provide treatment do not make explicit mention to a right to health and medicines, nevertheless they can invoke the ‘respect’ of human rights [Abuja Declaration 2001: para. 24; Brazzaville Commitment 2006]. These pledges are generally solicited by specific diseases and emergencies, namely AIDS and/or malaria and/or tuberculosis [Abuja Declaration 2000; OAU Abuja Declaration 2001; AU Abuja Call 2006; Brazzaville Commitment 2006]. Some of these commitments have set targets which, however, have

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<sup>260</sup> See Hestermeyer [2004: 173]. The position of the US with regard to the human rights to health and medicines is discussed in the text below.

<sup>261</sup> See also Commit for Africa, website, Health, last accessed May 2010.

<sup>262</sup> The meeting had been convened by the AU and saw the participation of “ministers, deputy ministers, parliamentarians, high-level officials from governments and regional bodies, civil society activists and people living with HIV, faith-based organizations, donors and international organizations” [UNAIDS Press Release, 2006].

not been fulfilled in practice [Abuja Declaration 2000, para 3(i); Abuja Declaration 2001: para. 26].

It is argued through this analysis that the UDHR and other ‘paper practice’ cannot provide the proof of practice needed for establishing the protection or fulfilment of the human right to health and to medicines. For those duties, the value of ‘paper practice’ is still ‘meta-positive’. ‘Paper practice’ can instead sanction the duty to *respect* the right. With specific regard to the UDHR, it is therefore contended that *parts* of the provisions are binding as international customary law. Incidentally, noteworthy, the arguments supporting the customary status of the UDHR generally rely on other ‘paper practice’.<sup>263</sup> My argument is supported by the analysis of the texts constituting ‘paper practice’, by considerations of expediency/sensibility, by the rulings of international courts, and by state practice. First, the account above underlines the textual limits of the ‘paper practice’ analysed. For instance, texts such as the UDHR are generally vague on the duties required for the implementation. Next the texts often use the conditional rather than indicative mode. Overall, since the commitments are not worded to be legally binding, it is questioned whether they can be read as they were in fact incumbent. Consequently, their significance as *opinio juris* of international law is also to be reconsidered. Furthermore, where access to medicines is mentioned, it is not always seen as a human right but as an instrument for combating pandemics, or upholding economic and social development, peace and security. Such commitments to access to medicines may still contribute to the inductive recognition of a customary international human right to access to medicines if certain substantive elements are present even though, *arguendo*, they are

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<sup>263</sup> The arguments supporting the customary status of the UDHR, indeed, generally rely on other ‘paper practice’. This means that the practice is mainly constituted by the re-affirmation of the Declaration, for instance in international treaties or declarations and in national constitutions. The UDHR has been invoked by governments (even those who initially objected to it) against other governments, or reaffirmed in international declarations such as that granting independence to colonial territories, and that opposing racial discrimination. Other declarations of human rights, such as the 1969 Teheran Declaration, or the Millennium Declaration have also upheld the rights it sanctioned [Sohn 1982: 16; Millennium Declaration, para. 25]. *See also* Buergenthal [1988]. Riedel also notes that the UDHR “has been incorporated in many constitutions of newly-independent States, and has served as an aspiration model for the European Convention on Human Rights, as well as for other Human Rights documents” [Riedel 1991: 69]. Hannum, arguing that the UDHR have force of international law, refers to the virtual universal acceptance of the declaration, also reiterated by national courts [Hannum 1995-96: 287].

not (yet) framed as communications of the meta-positive ‘human rights subsystem’.<sup>264</sup> Second, expediency/sensibility suggests that it may be unwarranted to allege the existence of a consistent international practice of *providing* medicines by founding on declarations or court cases as Hestermeyer has done. Instead, it seems viable to assert an international customary human right in its simplest degree which would require, for instance, universal *respect* and non-discrimination of the human right to health – and thereby to medicines on the part of states.

Third, with regard to the ruling of international courts, it is noted that even when the courts have utilised ‘paper practice’ to identify custom, generally they have drawn principles<sup>265</sup> and have prohibited commissions – or modalities of commission – rather than censuring omissions.<sup>266</sup> Fourth, it is argued that my approach to the identification of international custom permits to comprehend better the articulated practices of some states with regard to economic and social rights. States not parties to the human rights treaties analysed in part. 3.2 of this chapter often express the most complex positions. Incidentally, the practice of states which are not parties to treaties sanctioning certain norms is interesting in order to identify the existence of the customary norm.<sup>267</sup> The US, for instance, are sometimes seen as negating the human right to health because they oppose the entitlement to universal health care,<sup>268</sup> do not commit to international treaties

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<sup>264</sup> The Abuja Call 2006, for example, sanctions human rights requirements such as non-discrimination, and attention to the vulnerable and marginalised, without expressly referring to a human right to essential medicines [AU, Abuja Call, 2006: 4].

<sup>265</sup> The ICJ, for instance, has referred to the UDHR provisions as principles rather than norms. In a 1980 case, the ICJ stated that: “[w]rongfully to deprive human beings of their freedom and to subject them to physical constraint in conditions of hardship is in itself manifestly incompatible with the principles of the Charter of the United Nations, as well as with the fundamental principles enunciated in the Universal Declaration of Human Rights” [ICJ, *Unites States v. Iran*, 1980: para. 91]. To note, arguably, by referring to ‘principles’, the legal subsystem structurally couples to the subsystems of human rights and/or morality, utilising the communications of these subsystems in order to code circumstances (its environment) as legal or illegal.

<sup>266</sup> The duty to *enforce* the Genocide Convention may configure as an exception to this theory [ICJ, Advisory Opinion, *Genocide Convention*, 1951]. See Section 3.3.2 above.

<sup>267</sup> Looking at practice *dehors* of treaty is an interesting starting point. However, some arguments caution against relying uniquely on such strategy. D’Amato notes the paradoxical result that the more participation a treaty has gained, the more difficult it is to find practice outside of it, and thus the more difficult it is to establish a customary norm on the subject regulated [D’Amato 1987: 129]. See also Hestermeyer [2004: 163].

<sup>268</sup> The governmental view was mirrored by the Supreme Court in *Maher v. Roe*, where the Court stated that “the Constitution imposes no obligations on the states to pay... any of the medical expenses of indigents” [US Supreme Court, 1977: 464 quoted in Kinney

sanctioning economic, social and cultural rights, and express sceptical views on the human right to health in other international documents [Hestermeyer 2004: 173; Alston 1990]. Hestermeyer mentions the US dissent to UN General Assembly resolution 179 (2003) (seen above) as prove of the US “track record of objection to economic, social and cultural rights and access to medication” [Hestermeyer 2004: 173]. Remarkably, however, the US have rejected the resolution’s reference to the human right to health specifying that

[w]e do not support an *entitlement* approach; we do not believe that this right should be interpreted as a legally enforceable entitlement, requiring the establishment of judicial or administrative remedies at the national or international levels to adjudicate such presumed rights [United States, Digest of United States Practice in International Law 2003, 2003: chapter 6, sec. 26, emph. add.].

Thus, it can be argued that what the US oppose is an entitlement to health care (and thence medicines) rather than the mere respect of this right.<sup>269</sup> Indeed, the US, in the Third Restatement of international law, conceives the rights sanctioned by the UDHR and the ‘principal international covenants’ as ‘internationally recognised human rights’.<sup>270</sup> We have to be cautious in distinguishing between the ‘recognition’ of meta-

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2001: 1465]. However, the current health sector reform can be seen as a change in the stance of the US with regard to entitlements to health care. On the reform *see, e.g.*, The Economist, “Signed, Sealed, Delivered” [2010]. *See below.*

<sup>269</sup> It has to be acknowledged, however, that some pieces of US practice seem to reject the notion of a right to health in international customary law as such. Hestermeyer refers to the Court of Appeal for the Second Circuit in *Flores et al. v. Southern Peru Copper Corporation* in order to disprove the right to health. Here the Court also denied the status of customary norms of the right to health as well as of the right to life (which instead Hestermeyer recognises as part of international customary law [Hestermeyer 2004: 167-8]), “as prescribed in the ICESCR, the ICCPR, and the UDHR”, as “insufficiently definite to constitute rules of customary international law” [US, *Flores*, 2003: para. 70]. It could be noted that the appraisal of customary law by the Court is shaped by jurisdiction/competence considerations under the Alien Tort Claim Act (ATCA) which was applied in the case [*id.*: para. 129], and that the courts of the Second Circuit hold a particularly restrictive view of customary international law as composed only of those rules that States universally abide by, or accede to, “out of a sense of legal obligation and mutual concern” [*id.*: para. 38]. Compare instead with the US position in the Third Restatement with regard to obligations *erga omnes*: “[v]iolations of the rules stated in this section are violations of obligations to all other states and any state may invoke the ordinary remedies available to a state when its rights under customary law are violated” [Third Restatement (Comments) 1987: para. 702 reproduced in Henkin et al 1999: 349-355, para (o)]. On the Alien Tort Claim Act (ATCA) *see also* Chapter 4 section 4.3.2.2.

<sup>270</sup> *See* the US Third Restatement of the Foreign Relations Law (Comments), according to which “[a]ll the rights proclaimed in the Universal Declaration and protected by the

positive human rights and the obligations to respect human rights in international law, although in this case the term recognition may well imply understanding of an obligation to respect. In sum, most states commit to *respect* the human right to health and thereby the ‘human right to medicines’. The next section explores the practice undertaken by home states for the *realisation* of those rights.

### 3.3.4 Investigating the practice of the presumed customary norm: ‘factual practice’

The next paragraphs try to assess states’ ‘*factual*’ practice in relation to the protection, fulfilment and judicial remedies for the hypothetical customary human right to medicines. There are two main difficulties associated to this endeavour. One concerns the theoretical identification of the practice to look at. The other difficulty concerns the empirical appraisal of this practice. The task is taxing and cannot find here the space that it deserves. A sketchy draw is nonetheless attempted, that may launch further research on the matter. I first present the conduct of states with regard to the protection and fulfilment of access to medicines. In order to assess the fulfilment I also analyse the results in terms of access to medicines. The practice of judiciability is examined subsequently. Special attention is accorded to the practice in sub-Saharan Africa, also considering the possibility of a regional custom on a right to medicines.<sup>271</sup>

With regard to the theoretical identification of the relevant practice, a question shall be posed about the object of the analysis of the practice, whether such object are specific obligations of some kind of conduct, or just an obligation for states to engage in *any* conduct conducive to the realisation of the right to essential medicines.<sup>272</sup> The first view, which would suggest the use of a closed list of indicators for implementation, is unwarranted considering the diversity of economic, social and political conditions across

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principal International Covenants are internationally recognized human rights” [Third Restatement (Comments) 1987: para. 702 (o.)].

<sup>271</sup> The identification of a regional custom shall reportedly satisfy special requirements. Cassese, referring to ICJ *Asylum case (Columbia v. Peru)*, notes that the Court demanded that 1) the custom was tacitly accepted by all parties (so, akin to tacit agreement as per Anzilotti) and 2) the burden of proof be posited on the claiming party (as opposed to the traditional assumption that *jura novit curia*) [ICJ, *Asylum*, 1950: 276] [Cassese 2005: 164]. See also Brownlie [2003: 12].

<sup>272</sup> This difficulty could be avoided, it is noted, if the ‘paper practice’ found in section 3.3.4 had been followed by factual practice. In that case, the ‘factual practice’ would have been relevant for customary norms because enshrining *opinio juris*.

countries.<sup>273</sup> States, in effect, enjoy a ‘margin of discretion’ in implementing the obligations flowing from human rights law.<sup>274</sup> From the empirical point of view, it is difficult, qualitatively, to identify when actions are undertaken by states with the *opinio juris* of a human right to medicines and when, instead, following other ‘communications’ and ‘programmes’: there is a problem of ‘redundancy’ as the same practice can be undertaken for a variety of reasons. Quantitatively, the practice should be general and uniform. These cautions notwithstanding, an indicative idea may be provided utilising some of the parameters measured by the WHO’s surveys on the ‘World Medicines Situation’ and other global institutions. A discussion of the merits of these actions is reserved to Chapter 5. According to WHO, most states have regulatory authorities and formal requirements on the safety of medicines [WHO, *The World Medicines Situation*, 2004: 93], even though regulatory gaps are common, for instance with regard to the quality and safety of medicines distributed in the informal sector [*id.*: 103].<sup>275</sup> The number of states adopting national medicines policies has grown from 5 in 1985 to 108 in 1999 [*id.*: 53].<sup>276</sup> WHO remarks that this growth has mostly taken place in low-income countries.<sup>277</sup> However, WHO notes that two-thirds of the states adopting national medicines policies have failed to establish implementation plans [*id.*]. The majority of countries have adopted a national essential medicines list (EML). WHO calculates that, in 2003, 72% of reporting countries (82 out of 114) had a (EML) updated within the last five years [WHO *Medicines strategy 2004-2007*, 2004: 117]. Nearly all developing countries – 95% – have a published EML, 86% have updated it in the past five years [UN, *Delivering on the Global Partnerships for Achieving the Millennium Development Goals*, 2008: 36]. With regard to price regulation, WHO reports that almost 40% of respondent countries (53/135) implement no price regulation policy at all [WHO, *World Medicines Situation 2004*, 2004: 66]. While low and middle-income countries regulate prices more

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<sup>273</sup> See also Chapter 5.

<sup>274</sup> See also CESCR [2000: para. 53].

<sup>275</sup> WHO has assessed that 50%-90% of samples of antimalarial drugs failed quality control tests and more than half of antiretrovirals assessed did not meet international standards [WHO, *WHO Medicines strategy 2004-2007*, 2004: 5].

<sup>276</sup> According to WHO, national medicines policies are meant to deal with: selection of essential medicines, affordability, financing options, supply systems, regulation and quality assurance, rational use, research, human resources, monitoring and evaluation [WHO, *How to Develop and Implement a National Drug Policy*, 2001: 7].

<sup>277</sup> “Among low-income countries, 90% of responding countries had official national medicines policy documents in 1999 compared with 66% for middle-income countries and only 22% for high-income countries”. The last available data are from 1999 [WHO, *The World Medicines Situation 2004*, 2004: 55-56]

often – above half of low and middle-income countries (54/104) do regulate prices [*id.*: 72] – WHO laments that only 10% of them uses all of the identified regulatory approaches and combinations surveyed to control domestic prices.<sup>278</sup> Thus, WHO concludes that in both purchasing practices and in domestic price regulation measures many low and middle-income countries appear to be missing opportunities to ensure that medicine prices are affordable [*id.*] – even though this policy may impair availability.<sup>279</sup>

Until 2010 the US have been the only wealthy, industrialized nation that would not ensure that all citizens have social insurance coverage [Institute of Medicine of the National Academies 2004; The Economist, “Signed, Sealed, Delivered”, 2010] but in developing countries the prevalence is inverted. Protection by social insurance coverage in Africa, for instance, covers less than 8% of the population [WHO and WTO Secretariats 2001: 7]. With specific regard to medicines, overall, 68% of the countries reporting to WHO have public health insurance covering the cost of medicines (79 out of 117 countries) [WHO Medicines strategy 2004-2007, 2004: 65]. Moreover, WHO reckons that in 2003, out of 105 countries reporting, 32 (30%) had adopted ‘TRIPS Agreement flexibilities’ to protect public health into the national legislation [WHO Medicines strategy 2004-2007, 2004: 33]. According to WHO the adoption of TRIPS flexibilities is a benchmark of the attention to medicines by a country. A discussion of intellectual property, TRIPS, flexibilities and TRIPS-plus will take place in Chapter 5. Next, it can be acknowledged that the number of countries promoting research and development of new active substances in 2003 was 21 out of 114 countries reporting (18%) [*id.*: 37]. Finally, an element of state conduct of recognising the human right to medicines can be seen in the diffused practice of states of collaborating with non-state and foreign institutions working in access to medicines. The cooperation with UN agencies (such as WHO, UNAIDS) may confer an international sanction to those states actions with respect to access to medicines.

In sum, some action is been taken worldwide with regard to access to medicines. However, some discrepancies in the conduct of states stand out, such as the low provision of social insurance covering medicines in sub-Saharan Africa. The optimal pieces of state conduct, furthermore, depend on the characters of the country at issue. So far, thus, evidence of an obligation to protect and provide essential medicines could not

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<sup>278</sup> In high-income countries, the proportion is double, amounting to 22% [WHO, World Medicines Situation 2004, 2004: 72]

<sup>279</sup> See Chapter 5 section 5.3.2.

be found. The achievement of *results* is consequently looked at in order to identify the alleged customary entitlement to access to medicines. It is reasonable to set as benchmark that at least a core list of essential medicines should be immediately provided. The national surveys on the access to medicines collected by WHO may provide a rough estimate. Those surveys assess the access to 20 medicines deemed essential by the WHO [World Medicines Situation 2004: 61]. The following tables visualise the world situation relating to access to medicines from the 1999 Drug Survey.

WHO Region	Percentage of population with regular access to essential medicines				Total Countries
	Very low access (< 50%)	Low to medium access (50%–80%)	Medium to high access (81%–95%)	Very high access (> 95%)	
	Number of countries	Number of countries	Number of countries	Number of countries	
Africa	14	23	5	3	45
Americas	7	14	7	7	35
Eastern Mediterranean	2	7	5	8	22
European	3	12	6	25	46
South-East Asia	2	4	3	0	9
Western Pacific	1	8	8	9	26
Total countries*	29	68	34	52	183

Number of countries in different WHO world regions with different levels of regular access to a core list of essential medicines, 1999 data. Source: WHO, World Medicines Situation 2004 [2004: 62]

Country income group	Number of countries	Population	Population without access to essential medicines		
		Number (million)	Number (million)	As % of country income group	As % of global total without access
Low-income	63	3548	1369	38.6	79.4
Middle-income	86	1447	350	24.2	20.3
High-income	34	859	5	0.6	0.3
Total countries and population	183	5854	1724	n.a	100

Number of people in different income groups without access to medicines, 1999 data. Source: WHO, World Medicines Situation 2004 [2004: 63]

It is apparent that access to essential medicines varies greatly between the world geographical regions and between the country income groups. While in Europe the majority of countries have population with an access to essential medicines greater than 95%, and so is in the US, the other regions of the world score much less satisfying

results.<sup>280</sup> The largest part of the world population lacking access to medicines is in Africa and India. However, the number of people with access to essential medicines has increased over time. WHO has estimated that access has jumped from 2.1 billion in 1977 to 3.8 billion in 1997 [WHO, *Equitable Access to Essential Medicines: A Framework for Collective Action*, 2004: 1]. WHO nevertheless notes that access is still ‘inequitable’, as 30% of the world’s population lacks regular access to essential medicines, and in the poorest parts of Africa and Asia the figure rises to over 50% [*id.*].<sup>281</sup> Importantly, those are the regions where the highest incidence of remediable mortality and morbidity are reported.<sup>282</sup> Furthermore, in 15% of the countries reporting to WHO (15/103) more than 50% of the population does not have access to medicines [WHO, *WHO Medicines Strategy 2004-2007*, 2004: 59]. Moreover, these surveys regard a handful of essential medicines, far from fulfilling all vital medical needs.<sup>283</sup> Indeed, national essential medicines lists generally contain between 200 and 400 medicines [WHO and HAI 2008: 34]. In the private sector, often, several thousands of medicines are available [*id.*]. Another caveat regards the fact that the data collected on the results – *ie*, the effective status of the realisation of the human right to medicines – have to be adjusted for the causes of changes, which can be out of the retain of state action. In fact, the results obtained with regard to access to medicines can be due to many factors other than state policies relating to access to medicines. Eventually, conduct and results complement each other in the assessment of the state obligations with respect to the fulfilment of a human right to medicines. In conclusion, from the account provided above, a general and uniform practice sanctioning the protection and fulfilment of access to essential medicines could not be identified.

Lastly, it is enquired about the judiciability and enforceability of a human right to medicines as a (national or international) human right. These issues are dealt with more extensively in Chapter 5 section 5.4.5. Here it is noted that some states, like the US, explicitly reject the character of entitlement of a right to health, and do not accept its judicial – domestic and international – judicial enforceability. Even the UK, where the

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<sup>280</sup> The percentage of population with regular access to a core of essential medicines in 1999 is found at WHO, *World Medicines Situation* [2004: 136]. On the practice of the US *see also* Section 3.3.4.

<sup>281</sup> The number of countries providing HIV/AIDS-related medicines free at primary public health facilities was 60 out of 104 countries reporting (58%) [WHO *Medicines Strategy 2004-2007*, 2004: 41].

<sup>282</sup> *See* Chapter 2 on sub-Saharan Africa.

<sup>283</sup> *See also* Chapter 2 section 2.3.1.

National Health Service (NHS) provides universal provision of health care,<sup>284</sup> expresses scepticism towards the enforceability of the provisions enshrined in the ICESCR, which it has ratified.<sup>285</sup> States in sub-Saharan Africa are particularly reluctant to provide judicial remedies for the enforcement of economic, social and cultural rights. Mushayavanhu notes that, for instance in Southern Africa (*ie*, among the 14 SADC countries),<sup>286</sup> nine states have enshrined a right to health in their constitutions. Out of them, five states have characterised it as a justiciable right, while the other four incorporate the right as part of the principles of state policy.<sup>287</sup> Further, within the four states where the constitutions guarantee a justiciable right to health, no case-law exist to demonstrate the application of these provisions in practice [Mushayavanhu 2007: 140]. In fact, the only state in the Southern Africa region where the human right to health and to medical treatment has been subject to judicial procedures is South Africa. Here, the Constitutional Court decided in favour of the provision of Nevirapine in public health facilities [South Africa, Constitutional Court, *Ministry of Health v. TAC*].<sup>288</sup> In sum, judicial enforcement of the human right to medicines is not an obligation under customary law on its own.

Finally, it is also noted that the hypothetically customary human right to medicines does not generally enjoy consistent international enforcement by international courts other than treaty-based supervisory bodies.<sup>289</sup> The lack of legal action for international law, especially with regard to human rights, however, does not necessarily constitute acquiescence [Roberts 2001: 777]. Chapter 6 will deal with the international

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<sup>284</sup> See NHS, website, About NHS, 2008 and NHS, website, NHS Core Principles, 2008.

<sup>285</sup> For example, as a response to the Concluding Observations of the UN Committee on Economic, Social and Cultural Rights, the UK Foreign and Commonwealth Office (FCO), has stated in 2003 that: “[t]he Government considers that the greater part of the provisions of the ICESCR are Statements of principle and objectives which do not lend themselves to specific incorporation into legislation or to justiciable processes” [Rommel 2003: para. 23; cited in UK Joint Committee on Human Rights 2004: para. 52].

<sup>286</sup> The 14 parties to the SADC Protocol: Angola, Botswana, The Democratic Republic of Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, The United Republic of Tanzania, Zambia and Zimbabwe [SADC Protocol on Health].

<sup>287</sup> The five states which have characterised the human right to health as a justiciable right are Angola, Democratic Republic of Congo, Madagascar, Mozambique and South Africa. The four states which incorporate the right as part of the principles of state policy are Lesotho, Malawi, Namibia, Swaziland [Mushayavanhu 2007].

<sup>288</sup> See Chapter 5 section 5.4.5.

<sup>289</sup> See, *e.g.*, Toebes on the implementation of the right to health at the UN level [Toebes 1999: 170-182]. See Chapter 6 section 6.4.3 on the international enforcement of the human right to medicines.

adjudication of states regarding their international responsibility with respect to the international human right to health.

### **3.3.5 The performance of the customary right to essential medicines with respect to the goals sought**

However tentative, the contentions presented above can attempt to answer the questions posed at the beginning of section 3.3 relating to the existence of an international customary human right to medicines, its corresponding state obligations, and the ensuing international state responsibility under general international law for cases of violations. According to the original methodology utilised, the state practice and *opinio juris* required as evidence of a customary norm depend on the type of obligations sought – namely, if obligations to *respect*, *protect* or *fulfil* the human right to medicines. ‘Paper practice’ can support the duty to *respect* the human right to medicines in customary law but not other duties. It is concluded from the investigation that all states, including those states not bound by treaty law to recognise the human right to medicines as part of the human right to health, are bound to *respect* the human right to medicines as part of the customary human right to health. Customary obligations of *protection*, *fulfilment* and *adjudication* of the human right to medicines in domestic courts could not be found. A regional customary right to medicines in sub-Saharan Africa has also been discounted. Furthermore, section 3.3 has demonstrated that the soft law enshrined in international non-binding pledges is more generous, envisaging for example health, health care and medicines for all. However, these pledges are framed in the ‘human rights subsystem’ as well as in other subsystems such as politics, morality, economics. Furthermore, the practice of access to medicines was also founded on other ‘communications’ and ‘programmes’, for example as a political commitment as well as an offshoot of other policies and actions in society.

### 3.4 Conclusion

This chapter has illustrated that the situation of access to medicines in sub-Saharan African countries is addressed by several instances of international human rights law which may sanction a human right to medicines. In *treaty law*, a human right to medicines is mainly found in the human right to health, enshrined in widely accessed agreements such as the ICESCR (which binds 43 African states) and the ACHPR (which binds all African states) [ICESCR art. 12; ACHPR art. 16]. States bound to these treaties bear obligations to respect, protect and fulfil access to medicines. Next, it has been ascertained that many human rights such as the right to life and freedom from torture, inhuman and degrading treatment can enrich a case for access to medicines, even if falling short of the comprehensive prescriptions provided by the human right to health. It has been underlined however that the international law on the human right to medicines presents notable contingencies. For example, the obligations contained in the human rights treaties are often vague and indeterminate, not indicating clear legal/illegal prescriptions. Treaty-bodies, international and national adjudication as well as authoritative commentaries have been utilised to interpret and elaborate such obligations (also by virtue of the principle of evolutionary interpretation of human rights treaties). However, these sources are not binding per se and can add uncertainty to the positive law. In addition, with particular reference to the CESCR and the ACHPR, it was noted that these sources are often expressing their statements in conditional terms. Furthermore, the CESCR and the ACHPR have importantly maintained that access to essential medicines shall be provided immediately by African states. Yet, they have not identified ‘essential’ medicines, and have instead referred to the non-binding and open-ended definitions of WHO and individual states. Moreover, it has been noted that treaties generally accord margins of discretion to the action of states. Also, it has been mentioned that while many human rights can support access to medicines, these rights may not be ‘indivisible and interdependent’, as often contended by the human right subsystem. In fact, ‘indisputable’ human rights (recalling Luhmann’s critique) compete for their realisation by the state.

Next it has been argued that *customary international law* sanctions the universal *respect* of the human right to medicines. Again, this right is fundamental part of the customary human right to health. There are notable difficulties in ascertaining customary duties to *protect* and *fulfil* the human right to medicines. To note, the international lawyer should establish *a priori* the conduct to observe, but this is not straightforward as the

policies for access to medicines can vary given the local contingencies. Overall, uniform and general practice of protection and fulfilment of the human right to medicines could not be established. Furthermore, the *results* of home states' action for access to medicines in sub-Saharan Africa are indeed poor. The *judiciability* of the human right to medicines is, overall, not developed. Such conclusions have been drawn through an original research, as the identification of customary law on the human right to medicines has not been investigated thoroughly in the literature. Next, the analysis of the 'paper practice', the 'factual practice' and the 'soft law' have illustrated that the soft law is more generous, envisaging for example health, health care and medicines for all. This meta-positive law can be seen as communicated by the 'human rights subsystem', which can conceive a more comprehensive intervention of home states with regard to the realisation of the human right to medicines. It should be pointed out however that the soft law was also framed in other subsystems such as politics, morality, economics. Furthermore, the practice of access to medicines was founded on other 'communications' and 'programmes' as well, for example other political commitments, policies and actions in society not invoking human rights. This thesis in effect investigates whether the positivisation of the meta-positive human right to medicines provides a better alternative with respect to those other communications. The possible impact, *de facto*, in sub-Saharan Africa, of the operationalisation and implementation of the human right to medicines with regard to the obligations of African home states will be critically enquired in Chapter 5.

## CHAPTER 4: THE OBLIGATIONS OF ‘EXTRA-GOVERNMENTAL ACTORS’ WITH REGARD TO THE HUMAN RIGHT TO MEDICINES *DE JURE*

### 4.1 Introduction

Chapter 4 aims at establishing whether and how ‘extra-governmental entities’, that is, foreign states and non-state actors, are subject to international obligations in relation to a human right to medicines. For ‘foreign states’ I refer to those states (African and non-African) whose actions have consequences on the enjoyment of the human right to medicines in another state.<sup>290</sup> ‘Non-state actors’ encompass, as proposed by Ssenyonjo: international organisations, international financial institutions, non-governmental organisations, multinational companies, professional bodies, civil society and groups [Ssenyonjo 2008: 727].<sup>291</sup> These actors can exercise a strong influence on access to medicines, as anticipated in Chapter 2, and as it will be further discussed in Chapters 5 and 6. The legal position of foreign states and non-state actors with regard to the human right to medicines is particularly difficult, and they are therefore dedicated a separate chapter.

As a preliminary issue I shall address the matter that the very capacity of non-state actors to be responsible and liable for human rights and international law obligations is contentious in the legal doctrine. I identify two major theoretical problems. Firstly, as some scholars contend, typically only states are legal subjects of international law.<sup>292</sup> This theory however overlooks the fact that non-state actors *are* sometimes conferred rights or duties under international law, and is not universally accepted by the literature.<sup>293</sup> Thus I will generally adopt the hypothesis that in principle international

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<sup>290</sup> For the use of the term ‘foreign state’ *see e.g.* Scullion and Gerstein [2007].

<sup>291</sup> *Cf.* Alston’s critique to the term ‘non-state actors’. As a negative term, its notion and contents are not exactly agreed [Alston 2005: 3].

<sup>292</sup> *See* Ssenyonjo [2008: 725]. *See* for instance Brownlie arguing that corporations do not, in principle, have international legal personality [Brownlie 2003: 65].

<sup>293</sup> For example, individuals are directly liable in international law for international crimes [Cassese 2003: 23]. *See also* Alston [2005], Clapham and Rubio [2002], Duruigbo [2008], Joseph [2003] and Higgins [1995] attributing rights and duties to non-state actors. Higgins takes a decisive stance arguing that “[t]he whole notion of subjects and objects has no credible reality and... no functional purpose” thus it would be better to speak of ‘participants’ who make claims [Higgins 1995: 49-50]. *See also* the International Law Commission Draft Articles on State Responsibility maintaining that

legal personality derives from – rather than gives origin to – the attribution of rights and duties [De Schutter 2006: 33-34].<sup>294</sup> Nevertheless, in the investigation of customary law I will also consider the case of applying international customary duties onto the non-state actors which have international legal personality, as suggested by some literature [Skogly 2001; Ssenyonjo 2008]. Secondly, it is asked if non-state actors can have duties with regard to human rights. This issue recalls the classic problem of the horizontal effect of constitutional, human rights provision on third (non-state) parties. As Barak aptly puts it, human rights provisions are ‘textually’ dedicated to states [Barak 2001]. Weissbrodt indeed rejects the notion that non-state actors can ‘violate’ human rights and suggest that “they should be criticized for ‘abusing’ the rights of individuals” [Weissbrodt 1998: 195 in Clapham and Rubio 2002: 3]. Yet, it is a fact that human rights, and the human right to health is no exception, are used in some courts to decide about private law cases and are referred to in policies regarding non-state actors.<sup>295</sup> The liability of non-state actors for violations of the human right to medicines will be critically researched. It is stressed here that, with a few exceptions, an international law literature on this topic is virtually non-existent.<sup>296</sup> This chapter therefore pioneers a field of international law, pointing out theoretical gaps in the discipline.

The scope of this chapter is legal analysis of the obligations of ‘extra-governmental actors’ under international law with regard to the human right to medicines *de jure*. With regard to the method, as in Chapter 3,<sup>297</sup> I study treaties and custom, but also domestic law and cases as well as soft law and the self-regulation of non-state

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rights may accrue directly from international obligations to any person or entity other than a state [ILC Draft Articles 2001: 33(2)].

<sup>294</sup> See also Jägers: “[w]here entities have not been granted legal personality by treaty provisions or by explicit recognition by other parties, the best way to ascertain whether an entity does or does not have legal personality is to find out if in fact possesses any rights or duties under international law” [Jägers 1999: 264].

<sup>295</sup> For instance, the Italian Constitutional Court held that the right to health applies in both public law and private relations, imposing on individuals the duty to refrain from injuring or endangering by their behaviour the health of another person [Toebe 1999: 210].

<sup>296</sup> *But see* Yamin on the obligations of other actors towards the human right to medicines [2003: 138-143]; Joseph on the responsibility of transnational corporations [2004] and of pharmaceutical corporations for access to medicines [2003]; Skogly on the responsibilities for human rights of foreign states for transboundary damages [2006] and the responsibilities of international the International Monetary Fund (IMF) and the World Bank [2001].

<sup>297</sup> See Chapter 3 section 3.1.

actors.<sup>298</sup> The enquiry in this chapter is, again, undertaken with a critical attitude, underlining the uncertainty and contingency embedded in the law *de jure*. The strengths, limits and uncertainties of the sources utilised in ascertaining the law (such as treaties, treaty bodies, international non-binding pledges, international courts, national courts, publicists and other authors) are taken in consideration.<sup>299</sup>

Following the structure of Chapter 3, treaty law is explored in the first part of Chapter 4 (section 4.2) while customary, soft law and self-regulation are assessed in the second part (section 4.3). Where possible, the obligations are studied as obligations to respect, protect, fulfil and enforce the human right to medicines. A conclusion is finally provided identifying the duties of extra-governmental actors under international law and contrasting these limited positive duties to the expansive communications of the meta-positive human right (section 4.4).

## **4.2 International human rights treaties**

Section 4.2 looks at the obligations of foreign states and non-state actors towards the human right to medicines sanctioned by the most important human rights treaties. For every treaty I focus on the obligations of foreign states to respect, protect, fulfil and enforce the right. I subsequently look for the obligations directly imposed on non-state actors. The law is complemented by commentaries and comments of the treaty-bodies as those sources contribute to the interpretation and, arguably, to the development of the positive law.<sup>300</sup>

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<sup>298</sup> For self-regulation I mean the regulation of an institution issued and enforced by the institution itself. For the importance of soft law *see* Chapter 3 section 3.1.

<sup>299</sup> *See also* Chapter 3 section 3.1.

<sup>300</sup> *See* Chapter 3 section 3.2.

#### 4.2.1 The International Covenant on Economic, Social and Cultural Rights (ICESCR)

The ICESCR binds 159 states parties from all world regions [UNOHCHR 2008(b)].<sup>301</sup> ICESCR article 12 does not set a territorial scope for the obligation of state parties to realise the human right to health. Indeed, unlike other human rights treaties such as the ICCPR, the ICESCR does not contain territorial or jurisdictional limitation in its chapeau articles.<sup>302</sup> However, it is generally accepted that article 12, as other ICESCR obligations to realise the human rights therein sanctioned, are directed to home states. In effect, in several places the wording of the treaty does distinguish the action of home and foreign countries, for instance obliging states “to take steps, individually and through international assistance and co-operation, especially economic and technical with a view to achieving progressively the full realization of the rights recognized in the present Covenant” [ICESCR art. 2(1)].<sup>303</sup> I have consequently searched whether and what legal obligations are borne by the state parties with regard to the enjoyment of the human right to health – and thereby medicines – abroad. It follows from the object, purpose and preamble of the treaty that foreign states shall *respect* the human right to medicines in other countries.<sup>304</sup> The CESCR, specifically commenting on the human right to health, has indeed identified incumbent duties to *respect* and *protect* (prevent violations of) the human right to health abroad [CESCR 2000: art. 39].

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<sup>301</sup> In particular, the ICESCR binds 43 (out of 53) African states [Odinkalu 2003: 23]. The US, notably, are not parties to the Covenant [UNOHCHR 2008(b)].

<sup>302</sup> Note that the identification of jurisdiction is problematic as it does not necessarily correspond to the state territory. This issue has been raised for instance by the European Court of Human Rights (ECtHR). The scope of application of the European Convention on Human Rights and Fundamental Freedoms is limited to the parties’ jurisdiction [ECHR art.1]. Nonetheless in *Loizidou v. Turkey*, the ECtHR held that “responsibility of Contracting Parties can be involved because of acts of their authorities, whether performed within or outside national boundaries, which produce effects outside their own territory” [ECtHR, *Loizidou v. Turkey*, 1995: para. 65].

<sup>303</sup> See also Dennis and Stewart affirming that the ICESCR rights are to be realised by the homes states. They note that the ICESCR recommends the realisation of the rights through legislative measures, that which defines the limits of state action within legal jurisdiction [ICESCR art 2(1); ICCPR art 2(1)]. See also Skogly [2002: 790].

<sup>304</sup> The purpose of the treaty, as expressed in the preamble, suggests an extra-territorial concern. In the preamble the parties consider “the obligation of States under the Charter of the United Nations to promote universal respect for, and observance of, human rights and freedoms...” [ICESCR preambular para. 4]. In international treaties, the preambles are not binding, but they offer a basis for interpreting the provisions therein, providing the context. See Vienna Convention on the Law of the Treaties [VCLT art. 31(1), (2)].

More uncertain is the attribution of duties to *fulfil*. The ICESCR recognises the role of international cooperation and assistance in a number of articles and preambular paragraphs [ICESCR art. 2(1), 11(1), 23; preambular para. 4].<sup>305</sup> The wording of those provisions however does not clearly prescribe legal obligations. Moreover, the *travaux préparatoires* indicate that dim is the responsibility of a state to *fulfil* the access to medicines in other countries.<sup>306</sup> Other provisions in the Covenant, in addition, recommend a caution with regard to the entity of the assistance to be provided abroad.<sup>307</sup> The CESCR does indeed maintain that foreign states *should* take action to facilitate access to health facilities, goods and services in other countries [CESCR 2000: para. 39]. The action is also conditioned on the availability of resources [*id.*]. Nonetheless, in its comment on the nature of states parties' obligations, the CESCR maintains that foreign states have an obligation to cooperation [CESCR 1990(b): para. 14]. The obligation is vague and refers to a variety of other international commitments, namely the ICESCR itself, the UN Charter, the UN General Assembly Declaration on the Right to Development [UN GA Res. 128 (1986)], and the 'well-established principles of international law' [*id.*]. With regard to the *enforcement* by foreign states of the human right to health and other ICESCR obligations, the ICESCR engages the parties to report to the ECOSOC, which has subsequently appointed the CESCR to the task [ICESCR arts. 16-22; ECOSOC resolution 17 (1985)]. The CESCR examines countries' reports, but has

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<sup>305</sup> The ICESCR sanctions the agreement of states "to take steps, individually and through international assistance and co-operation, especially economic and technical with a view to achieving progressively the full realization of the rights recognized in the present Covenant" [ICESCR art. 2(1)]. In article 11, on the improvement of living conditions, states recognise "the essential importance of international co-operation based on free consent" [*id.*: art. 11(1)]. With article 23, the states parties "agree that international action for the achievement of the rights recognized in the present Covenant includes such methods as... the furnishing of technical assistance" [*id.*: art. 23]. In the preamble the parties take into consideration "the obligation of States under the Charter of the United Nations to promote universal respect for, and observance of, human rights and freedoms" [*id.*: preambular para. 4]. In the preamble the parties also recognise that "the inherent dignity and... the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world" [*id.*: preambular para. 1].

<sup>306</sup> As Alston and Quinn noted, "the only formal suggestion on the existence of a binding obligation came from the Chilean representative who observed 'that international assistance to under-developed countries had in a sense become mandatory as a result of commitments assumed by States in the United Nations'" [Diaz Casanueva 1962: para 10; Alston and Quinn 1987: 189].

<sup>307</sup> See also article 24 stating that "[n]othing in the present Covenant shall be interpreted as impairing the inherent right of all peoples to enjoy and utilize fully and freely their natural wealth and resources" [ICESCR art. 24].

no power to redress situations and does not hear intra-state complaints and complaints from individuals or groups.<sup>308</sup> An optional protocol to the ICESCR has been adopted by the UN General Assembly in December 2008 to consider individual and group communications, but is not yet operational for want of ratifications [ICESCR-OP art. 1; UN GA Res. 117 (2008)].<sup>309</sup> The protocol also provides for the possibility of ‘interim measures’ and establishes an inquiry procedure for the CESCR [ICESCR-OP art. 5, 11].

No direct obligation originates from the ICESCR onto *non-state actors*. With regard to international organisations the treaty provides for a voluntary mechanism for the reporting of UN specialised agencies about “the progress made in achieving the observance of the provisions of the present Covenant falling within the scope of their activities” [ICESCR art. 18]. The CESCR furthermore maintains that UN agencies, regional development banks and the WTO *should* cooperate effectively in relation to the implementation of the human right to health and ascribes to them roles and recommendations rather than duties [CESCR 2000: para. 64-5]. With regard to other entities, in the preamble the ICESCR parties realise that the individual has responsibility for the promotion and observance of the rights recognized in the Covenant [preambular para. 5]. Preambles are not binding but a duty to respect can be read into article 5 stating that “[n]othing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or perform any act aimed at the destruction of any of the rights and freedoms recognized herein...” [ICESCR art. 5(1)]. However, it has been remarked that this provision is meant to prevent states or third parties from relying on a ICESCR right as a pretext for activities implying the destruction of the ICESCR rights [Sepúlveda 2003: 305].<sup>310</sup> Others conclude that article 5 offers mere guidelines for the behaviour of both individuals and states as opposed to imposing any direct accountability to non-state actors [Daes 1990: para. 2; Ssenyonjo 2008: 738]. Indeed, analysing the preparatory works, and in particular the decisions of the

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<sup>308</sup> See CESCR Revised General Guidelines [1991] and ECOSOC Resolution 17 (1985).

<sup>309</sup> The protocol has been opened for signatures in March 2009 and will enter into force three months after the date of deposit with the UN-Secretary General of the tenth instrument of ratification or accession [Raja 2008]. As of May 2010 the Protocol has 32 signatories and yet no parties [United Nations Treaty Collection, website, 2010(a)].

<sup>310</sup> Indeed the provision emphasises the importance of the ‘aim’ of a given activity [ICESCR art. 5(1)]. Sepúlveda also argues that ICESCR article 5(1) is ancillary to other provisions by analogy to the jurisprudence of the ECtHR and the HRC deciding respectively on similar articles of the ECHR and the ICCPR [ECHR art. 17; ICCPR art. 5(1); Sepúlveda 2003: 305].

Commission on Human Rights, Alston and Quinn affirm that the ICESCR is not designed to govern private relations [Alston and Quinn 1987: 196]. Nevertheless, it can govern non-state actors indirectly through state regulation, by attributing to states the responsibility to protect the human rights in question.<sup>311</sup>

#### 4.2.2 The African Charter on Human and Peoples' Rights (ACHPR)

The ACHPR has been ratified by all 53 members of the Organisation of African Unity (now African Union) [Odinkalu 2003: 20]. With regard to the obligations of *foreign states*, similarly to the ICESCR, the ACHPR does not identify a territorial jurisdiction. Nonetheless, as the ICESCR, the ACHPR does refer to distinctions between the conducts of home states and foreign countries.<sup>312</sup> Again, the purpose of the treaty and the preamble present a cross-border concern which suggests duties to *respect* the ACHPR rights abroad. For example the preamble reads: “fundamental human rights stem from the attributes of human beings which justifies their national and international protection” [ACHPR: preambular para. 5]. The Charter is in fact very vague on the duty of international *protection*. With regard to international *fulfilment*, the ACHPR provides that the free disposal of wealth and natural resources which is sanctioned in the Charter “shall be exercised without prejudice to the obligation of promoting international economic cooperation based on mutual respect, equitable exchange and the principles of international law” [ACHPR: 21(1)(3)]. The obligation is indefinite, vaguely referring to an external source, that is, general international law.<sup>313</sup> African unity and solidarity seems to take pre-eminence for ACHPR members [art. 21(4)]. Yet this provision is

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<sup>311</sup> See also the CESCR attributing to those non-state actors roles and responsibilities but holding states as ultimately accountable: “[w]hile only States are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society – individuals, including health professionals, families, local communities, intergovernmental and non-governmental organizations, civil society organizations, as well as the private business sector – have responsibilities regarding the realization of the right to health. State parties should therefore provide an environment which facilitates the discharge of these responsibilities” [CESCR 2000: para. 42].

<sup>312</sup> Moreover, the same reasoning that Dennis and Stewart utilised for the ICESCR with regard to the fact that the ICESCR recommends the realisation of the rights through legislative measures (that which defines the limits of state action within legal jurisdiction) can be applied to the ACHPR which also recommends the adoption of legislative or other measures [ACHPR: art 1]. See *supra* section 4.2.1.

<sup>313</sup> On the obligations of international cooperation in the ACHPR see generally Ouguergouz [2003].

arguably dedicated to the joint management of common resources rather than the sharing of resources over which they may have exclusive jurisdiction [*id.*; Ouguerouz 2003: 283]. The African Commission's resolution on the human right to medicines does not provide for international cooperation except with regard to research and development for neglected diseases [AC Res. 141 (2008)]. The ACHPR regime provides for *enforcement* mechanisms stronger than those currently implemented under the ICESCR regime. The African Commission, in addition to analysing states' reports, examines violation complaints and case-based reporting, also hearing individual and group cases [ACHPR: art. 30, 55-59, 62; Odinkalu 2001: 351]. The African Commission also has special investigative powers with respect to emergency situations [ACHPR art. 59; Odinkalu 2001: 352]. However, the Commission has no power of sanction or police and does not grant redress for individuals. Furthermore, in 2006 the African Court on Human and Peoples' Rights has become operational. The Court, as opposed to the Commission, is set to deliver binding judgments and to provide remedies [ACtHR Protocol art. 30]. The Court however does not have enforcement power on its own [Lyons 2006].

With regard to *non-state* actors, the ACHPR does not address international organisations but it dedicates one of its two chapters of the substantive law to the duties of individuals (which can include private business activities as well). For instance, the Charter sanctions that “[e]very individual shall have duties towards his family and society, the State and other legally recognized communities and the international community” [ACHPR art. 27(1)]. As Brems notes, the provision does not have self-standing meaning, as it introduces the subsequent articles on the duties of the individuals [Brems 2001: 114].<sup>314</sup> Relevant for the case of access to medicines, the charter affirms that the individual has duties “[t]o serve his national community by placing his physical and intellectual abilities at its service” [ACHPR art. 29(2)]. Reportedly, however, this provision was mainly conceived to address the problem of ‘brain drain’.<sup>315</sup> It has to be remarked that the wording of the provisions on individual duties are very vague. The legal function of those duties is indeed uncertain, thence arguably impossible to enforce

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<sup>314</sup> See also the preamble, wherein the parties agree to the Charter “[c]onsidering that the enjoyment of rights and freedoms also implies the performance of duties on the part of everyone; Convinced that it is henceforth essential to pay a particular attention to the right to development and that civil and political rights cannot be dissociated from economic, social and cultural rights in their conception as well as universality and that the satisfaction of economic, social and cultural rights is a guarantee for the enjoyment of civil and political rights” [ACHPR: preambular para. 6].

<sup>315</sup> See Brems [2001: 116] and Benedek [1985: 87].

as such [Brems 2001: 112]. In effect some commentators interpret the autonomous individual duties in the ACHPR as non-binding, ethical obligations [Ahanhanzo 1984: 526], a ‘code of good conduct’, not capable of effective implementation [D’Sa 1985: 77]. Furthermore, at the international level, as underlined by Brems, the defendants before the African Commission are states [Brems 2001: 113]. In that sense, the Charter imposes an obligation of due diligence, as the state must prevent the violation by individuals of their duties in its legal order and it must “inculcate these duties as well as their underlying principles and ideals in its citizens” [*id.*].<sup>316</sup>

#### 4.2.3 Other treaties supporting the human right to medicines

Section 4.2.3 examines the obligations flowing on foreign states and non-state actors from other relevant treaties sanctioning the human right to health and medicines. Particular attention is given to obligations of foreign states to protect, cooperate, fulfil and enforce, which have demonstrated to be uncertain under the ICESCR and the ACHPR. As seen in Chapter 3 section 3.2.1.3, the human right to medicines is supported by the human right to health sanctioned by human rights treaties relating to certain groups, namely, the UN Convention on the Rights of the Child (CRC), the African Charter on the Rights and Welfare of the Child (ACRWC), the UN Convention on the Elimination of All forms of Discrimination against Women (CEDAW), the Optional Protocol to the African Charter on Human and Peoples Rights on Women’s Rights (Optional Protocol to the ACHPR on Women), the UN Convention on the Elimination of All forms of Racial Discrimination (CERD). Among those treaties, only the CRC demands international *cooperation*, although falling short of prescribing specific obligations in regard [CRC art. 4, 23, 24(4) preambular para. 13].<sup>317</sup> All those treaties establish monitoring mechanisms for *enforcement*, but most of them do not envisage binding enforcement procedures and some do not receive individual or group complaints

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<sup>316</sup> The African Commission has indeed condemned states for failing to perform due diligence. For example in the *SERAC v. Nigeria* communications the African Commission held that “the Nigerian Government has given the green light to private actors, and the oil Companies in particular, to devastatingly affect the well-being of the Ogonis” [AC, *Nigeria*, 2001: para. 54] and this fell afoul of the provisions of the Charter [*id.*: para. 58].

<sup>317</sup> See also Committee on the Rights of the Child [1996: para. 21], Detrick [1999: 110].

[ACRWC: arts 42-45; CEDAW: art. 18].<sup>318</sup> With regard to the CEDAW, for those countries which have ratified the CEDAW Optional Protocol, the treaty monitoring Committee also receives complaints from individuals or groups victims of violations of the CEDAW [Langford and Nolan 2006: 198].<sup>319</sup> Furthermore, unresolved disputes between states are referred to the International Court of Justice [CEDAW: art. 29(1)]. The Optional Protocol to the ACHPR on Women is subject to the same procedure as the ACHPR [Musa 2007]. The CERD provides for individual petitions to the Committee on the Elimination of Racial Discrimination, although the consent of the state in question is required [*id.* art. 14(1)]. Some of those treaties attribute roles and responsibilities on non-state actors, yet without imposing direct duties [ACRWC: preambular para. 7; CRC art. 45(a)].

The ICCPR has been ratified by 162 states, including the US (which are not parties to most of the treaties mentioned in sections 4.2.2 and 4.2.3 above) [UNOHCHR 2008(a)], out of which 43 are African countries [Odinkalu 2003: 23]. As seen in Chapter 3, the ICCPR sanctions some rights ancillary to the human right to medicines, such as the right to life and the right to freedom from torture, inhuman and degrading treatment [ICCPR art. 6(1); 7]. With regard to obligations of *foreign states*, in the ICCPR preamble the parties consider “the obligation of States under the Charter of the United Nations to promote universal respect for, and observance of, human rights and freedoms” [ICCPR preambular para. 5]. However, beside the preamble, the binding articles of the treaty impose obligations with respect to the individuals within a state’s territory and subject to its jurisdiction [ICCPR 2(1)]. With regard to *enforcement* the Covenant is overseen by the Human Rights Committee (HRC) which monitors the treaty implementation and hears inter-state complaints. Furthermore, according to the First Optional Protocol, the HRC can examine individual complaints.<sup>320</sup> With regard to the behaviour of *non-state actors*, the ICCPR enshrines the ICESCR common provision preventing states, groups and individuals from undermining the rights and freedoms recognised in the ICCPR

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<sup>318</sup> On the CRC *see* Archard [2004: 59] and Detrick [1999: 41]. On the ACRWC *see* Olowu [2002: 131].

<sup>319</sup> The CEDAW Optional Protocol Convention has been ratified by 99 States, as of May 2010 [United Nations Treaty Collection, 2010(b)].

<sup>320</sup> The protocol has 111 parties, as of 5 March 2008 [UNOHCHR 2008c], of which 31 African countries [Odinkalu 2003: 23]. *See* Lanford and Nolan on the procedure to submit a complaint [Langford and Nolan 2006: 180-188].

[ICCPR art. 5(1); ICESCR art. 5(1)].<sup>321</sup> Furthermore, in the preamble the parties realise that the individual also has responsibility for the promotion and observance of the Covenant rights [ICCPR preambular para. 6]. While a specific liability of non-state actors seems not to be envisaged, just as like for the ICESCR, states have to protect their populations against violations by other parties [Hestermeyer 2004: 153].

Finally, the UN Charter should be looked at, as it is often referred to by human rights treaties and the literature to make a case for international cooperation and assistance on human rights.<sup>322</sup> In effect the UN Charter enjoys pre-eminence in international law among the UN members [UN Charter art. 103].<sup>323</sup> Other human rights treaties such as the ICESCR also refer to the UN Charter [ICESCR preambular para. 4]. It has to be noted however that the human right to health and medicines are not explicitly identified in the Charter. Still, the Charter mentions ‘standards of living’, ‘international health problems’ and ‘human rights’ as goals that the UN shall promote [UN Charter art. 55(a), (b) and (c)]. Although an international human right to health was not commonly recognised at the time of the drafting of the UN Charter, the Charter’s human rights provision should arguably be read through ‘dynamic’ or ‘evolutionary’ interpretations.<sup>324</sup> The UDHR has been seen as an authoritative declaration of the UN Charter’s provisions, but this argument is controversial.<sup>325</sup> In effect, the UDHR was not designed as a legally

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<sup>321</sup> See above section 4.2.1.

<sup>322</sup> For example, as seen in *supra* section 4.2.1, the UN Charter is referred to by the CESCR General Comment on international technical assistance measures [1990(a): para. 14].

<sup>323</sup> The Charter is currently ratified by 192 states [UN Treaty Collection, website, Charter of the United Nations, 2009].

<sup>324</sup> On the dynamic or evolutionary interpretation of treaties *see* Chapter 3 section 3.2.

<sup>325</sup> According to Sohn, the Declaration spells out the meaning of the phrase ‘human rights and fundamental freedoms’ enshrined in article 56 of the Charter [Sohn 1982: 17]. At first glance, this may entail that “the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care and necessary social services...” is made an obligation under the UN Charter [UDHR art. 25; UN Charter arts. 55-6, 103]. Hestermeyer is sceptical on this point, noting that the UN General Assembly is not endowed with such declaratory power. Indeed a Belgian proposal to incorporate it was explicitly rejected [Hestermeyer 2004: 157]. Cassese also notes that, by introducing the proviso of article 2(7) about domestic jurisdiction, the San Francisco Conference in 1945 weakened the original proposals made at the Dumbarton Oaks Conference in 1944 regarding the powers of the UN General Assembly in the field of human rights. The powers were already ‘boiled down’ to making recommendations and conducting studies [Cassese 2005: 379]. However, this does not mean that the attitude of (and powers conferred to) the UN and the Generally Assembly with respect to human rights may have not changed over time [*id.*: 379 et seq.].

binding document. Nevertheless, Chapter 3 section 3.3.3 and section 4.3 in this chapter argue that some of its provisions with regard to the human right to medicines are *in part* customary law. Therefore, obligations can be derived from the Declaration, through the evolution of customary law, and the respect of the human right to health is supposedly one of those.<sup>326</sup> Furthermore, the UN includes specialised agencies which directly recognise the human right to health. The WHO, namely, enshrines the human right to health in its Constitution [WHO Constitution: preambular para. 2]. The WHO Constitution can be seen as practice related to the UN and contribute to the interpretation of UN provisions.<sup>327</sup> Thus it can be assumed that the human right to health is among the human rights considered by the UN Charter. It is consequently asked what international rules, if any, follow from this recognition, binding foreign states and non-state actors.

With regard to the duties of *foreign states*, in the Charter UN members pledge “to take joint and separate action in co-operation with the Organization” [UN Charter art. 56] for the achievement of “higher standards of living... and conditions of economic and social progress and development; solutions of international economic, social, health, and related problems; and international cultural and educational cooperation” [*id.*: art. 55(a), (b)]. From a literal point of view, the legal value of these provisions is not clear. As Skogly remarks, “whether the wording in articles 55 and 56 represents a legal obligation upon states to cooperate in the international community to attain the goals of the United Nations has been disputed” [Skogly 2002: 786].<sup>328</sup> Cassese, analysing the drafting history reminds us that such provisions are not meant to be definitively compelling. With regard to article 56, a proposal for broadening the scope to “member States’ joint and separate action for the promotion of economic and social co-operation” had been explicitly rejected by the US during the drafting of the Charter. Further, article 2(7) on the domestic jurisdiction was also adopted as a safeguard from undue interference from the UN [Cassese 2005: 379]. Thus while the UN should promote the human right to health as

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<sup>326</sup> See Chapter 3 section 3.3.3 and *infra* section 4.3.

<sup>327</sup> The Vienna Convention on the Law of Treaties states that the context to of a treaty is constituted inter alia by “any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation” [VCLT art 31(3)(b)].

<sup>328</sup> Even more nuanced is article 1 sanctioning as one of the purposes of the UN “[t]o achieve international cooperation in solving international problems of an economic, social, cultural, or humanitarian character, and in promoting and encouraging respect for human rights and for fundamental freedoms for all without distinction as to race, sex, language, or religion” [UN Charter art. 1(2), *emph. add.*].

a human right, through article 55 the Charter does not impose clear obligations on the members to fulfil the human right to health abroad.

With regard to international *enforcement*, the UN ultimately remits to the International Court of Justice (ICJ) as its judicial organ [ICJ statute art. 1; UN Charter art. 92]. The ICJ is set to produce binding judgments on disputes between states to be decided in accordance with international law, which sanctions the human right to medicines in various instances (as demonstrated in Chapter 3) [ICJ Statute arts. 36-38]. However, the Court has no enforcement power and jurisdiction to the Court is optional – unless the parties opt to be subject to compulsory jurisdiction [*id.*: art. 36]. States can also undertake by agreement to have certain disputes decided by the Court.<sup>329</sup> Finally, with regard to *non-state actors*, the UN Charter does not address the duties of individuals. International organisations are not mentioned as such, but the Charter does contain provisions relating to particular ‘specialised agencies’, which should be brought into agreement with the UN [UN Charter arts. 57 and 63]. However the agencies, for instance the IMF and World Bank, enjoy autonomy and do not refer to human rights in their founding agreements [Agreement between UN and the IMF art 1(2); Agreement between UN and the IBRD].<sup>330</sup>

Thus, all the treaties examined in section 4.2 bind *foreign states* to *respect* the human right to medicines as part of the human right to health or, with regard to vital medicines, the human right to life. Duties relating to the other types of obligations vary among the treaties reviewed. The ICESCR, according to the CESCR, demands international protection. Most treaties demand international *cooperation* for the realisation of human rights abroad. However, those obligations are quite indeterminate. It is not clear, for example, what foreign states have to do in order to satisfy their obligation to cooperate: the obligation does not imply the full realisation of the right in other countries. The mechanisms for international *enforcement* vary. The treaties generally establish monitoring bodies which oversee the treaties’ implementation but do not normally issue binding decisions. The decisions of the African Court of Human Rights and the International Court of Justice are instead binding. No enforcement mechanism is however provided to enact the rulings and the ICJ does not have compulsory jurisdiction

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<sup>329</sup> For example, disputes not resolved by the CEDAW Committee are to be referred to the ICJ [CEDAW: art. 29(1)]. *See supra* section 4.2.3.

<sup>330</sup> *See also infra* section 4.3.2.1.

by default.<sup>331</sup> None of those treaties gives to the treaty-based bodies power of sanction or police. Procedures to redress the complaints of individuals are not envisaged by several treaties, included the ICESCR regime (the Optional Protocol redresses this shortcoming but is not in force as of yet). Reparations for individual situations are not prescribed by the treaties analysed.<sup>332</sup> Besides the treaty bodies, nevertheless, states can recur to state responsibility for breaches of obligations *erga omnes*. This means that all states parties to human rights treaties can hold another party responsible for breaches, even if those breaches do not directly injure the claiming party [Cassese 2005: 262].<sup>333</sup> Moreover, according to Cassese, the responsibility for *erga omnes* obligations in human rights treaty law is extended to minor or sporadic breaches of obligations, not merely to gross and serious breaches as provided for in customary international law [*id.*: 276]. Next, most treaties sanctioning access to medicines as a human right attribute to international organisations, individuals and other *non-state actors* roles and responsibilities with regard to the human rights they enshrine. However these provisions are vague and do not prescribe obligations *directly* on the non-state actors: states have the duty and international liability to implement those norms.

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<sup>331</sup> The jurisdiction of the African Court of Human Rights is instead compulsory except for cases presented by NGOs and individuals [ACtHR Protocol 34(6)].

<sup>332</sup> Other regional systems such as the European Court of Human rights do provide monetary compensation [ECHR art. 41]. But *cf.* Nowak arguing that even such 'just satisfaction' system is inadequate and it does not even cover legal expenses [Nowak 2007: 257].

<sup>333</sup> Cassese underlines that human rights treaties are not synallagmatic therefore they do not relate to reciprocal interests [Cassese 2005: 262].

### 4.3 Custom, soft law, self-regulation

Section 4.3 searches whether and what duties international customary law, soft law and self-regulation prescribe onto extra-governmental actors in relation to the human right to medicines. Section 4.3.1 discusses the obligations of foreign states, while 4.3.2 discusses the obligations of international organisations (section 4.3.2.1), non-governmental organisations (4.3.2.2), and other private parties, with particular regard to pharmaceutical companies (4.3.2.3). This endeavour is overwhelming, especially considering that the international law literature on the obligations of extra-governmental actors towards the human right to medicines in customary law is minimal.<sup>334</sup>

#### 4.3.1 Foreign states

Chapter 3, in section 3.3, profusely dealt with the identification of a human right to medicines in international customary law and the duties thereby originated on the home states. Section 4.3.1 looks at the duties of respect, protection, fulfilment and enforcement possibly borne under this law by foreign states. The methodology applied is, *ceteris paribus*, the one elaborated in Chapter 3. To begin with *opinio juris* and ‘paper practice’, often occurring as soft law, are analysed also observing if they are accompanied by ‘factual practice’ – such correspondence could warrant the existence of a customary norm prescribing negative as well as positive duties. For duties of protection, fulfilment and enforcement instances of ‘factual practice’ are specifically researched.

I start the investigation of the obligations of foreign states under customary international law with respect to the human right to medicines by considering the Universal Declaration on Human Rights (UDHR). Parts of the Declaration are indeed seen as customary law as such. It was argued in Chapter 3 that the duty of home states to respect the human right to medicines sanctioned by the Declaration is also a duty in customary law [UDHR art. 25].<sup>335</sup> With regard to international action for the rights named therein, the Declaration provides that:

Everyone, as a member of society, has the right to social security and is entitled to realization, through national effort and international co-operation and in

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<sup>334</sup> See Yamin on the duties concerning the human right to medicines borne by ‘other actors’ [2003: 138-143].

<sup>335</sup> See Chapter 3 section 3.3.4.

accordance with the organization and resources of each State, of the economic, social and cultural rights indispensable for his dignity and the free development of his personality. [UDHR art. 22]

Everyone is entitled to a social and international order in which the rights and freedoms set forth in this Declaration can be fully realized. [UDHR art. 28]

Thus the Declaration recognises the importance of international cooperation. However, it does not identify precise duties. Skogly in effect states that those provisions cannot be read as firm obligations to fulfil economic, social and cultural rights abroad [Skogly 2006: 123]. Next, ‘paper practice’ demonstrating the concern of states for the universal realisation of the human right to medicines can be found in the widespread access to human rights treaties sanctioning the human right to health.<sup>336</sup> Yet, even these texts were not conclusive on duties of international protection, cooperation and enforcement. The UN General Assembly resolution enshrining the ‘Millennium Declaration’ is arguably a high-mark point in the activity of the Assembly concerning international cooperation. The Millennium Declaration presents the commitment by the UN members to, *inter alia*, ‘freeing the entire human race from want’, realising the right to development and ‘civil, political, economic, social and cultural rights for all’ [UN GA Res. 2 (2000), paras. 11, 25]. The human right to medicines, the human right to health or health itself are not mentioned in the document, but the members resolve “[t]o help Africa build up its capacity to tackle the spread of the HIV/AIDS pandemic and other infectious diseases” [*id.*: para. 28]. This is in fact undertaken in order to “support the consolidation of democracy in Africa and assist Africans in their struggle for lasting peace, poverty eradication and sustainable development, thereby bringing Africa into the mainstream of the world economy” [*id.*: para. 27]. Nevertheless, health is the object of three Millennium Development Goals (MDGs), subsequently developed as indicators of the fulfilment of the Declaration.<sup>337</sup> One of the MDGs, in effect, precisely concerns the

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<sup>336</sup> For some considerations on the relationship between treaties and custom *see, e.g.* Meron [1987], Boyle and Chinkin [2007: 234-238].

<sup>337</sup> The MDGs more directly affecting health are the reduction of child mortality (MDG 4), the improvement of maternal health (MDG 5), and the combat of HIV/AIDS, tuberculosis, and malaria (MDG 6) [United Nations, Millennium Goals, 2010; United Nations, About the Millennium Development Goals Indicators, 2010]. The MDGs have been elaborated in targets and indicators to track the commitment made to development and poverty eradication over the period from 1990 to 2015 [UN GA 2 (2000): para. 19].

provision of access to medicines.<sup>338</sup> However, the MDGs are not being fulfilled as scheduled in the practice [UN, The Millennium Development Goals Report 2010, 2010].

Some ‘paper practice’ explicitly refers to the human right to health or medicines, as also seen in Chapter 3 section 3.3.3, and sanctions international cooperation, but again does not set targets for cooperation and may point to access to medicines for selected conditions. The Alma Ata Declaration reaffirms the human right to health [Alma Ata Declaration: para. I].<sup>339</sup> In the Alma Ata Declaration states maintained that they should cooperate for the operation of primary health care, which also comprehends access to certain medicines throughout the world.<sup>340</sup> The reasons for cooperation are in effect diverse.<sup>341</sup> Furthermore it is noted that primary health care does not exhaust the need for medicines.<sup>342</sup> The 2003 UN General Assembly Resolution 179 (2003) recognises that access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria is a fundamental element for the realisation of the human right to health [UN GA Res. 179 (2003): para. 1].<sup>343</sup> The resolution calls upon “the international community, in particular the developed countries, to continue to assist developing countries in the fight against [such pandemics] through financial and technical support as well as through the training of personnel” [*id.*: paras. 10(a), 15]. However, resolution 179 (2003) adopts a

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<sup>338</sup> Target 46 of Goal 8 (developing a global partnership for development) reads that states have to, “[i]n cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries” [United Nations, Millennium Goals, 2010; United Nations, website, About the Millennium Development Goals Indicators, 2010].

<sup>339</sup> The Declaration was endorsed in 1978 by all the 134 WHO members who participated to the international conference on primary health care held by WHO and UNICEF [World Health Organization, Primary Health Care Comes Full Circle, 2008]. *See* Chapter 3 section 3.3.3.

<sup>340</sup> Primary health care necessitates of access to certain medicines, as mentioned in Chapter 3 section 3.3.3. *See also* Chapter 5 section 5.4.1.

<sup>341</sup> The Declaration refers to the role of international organisations and the whole world community as “[a] main social target of governments, international organizations and the whole world community in the coming decades should be the attainment by all peoples of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life. Primary health care is the key to attaining this target as part of development in the spirit of social justice” [*Id.*: para. V]. Moreover the Declaration states that: “[a]ll countries should cooperate in a spirit of partnership and service to ensure primary health care for all people since the attainment of health by people in any one country directly concerns and benefits every other country” [Alma Ata Declaration: para. IX].

<sup>342</sup> *See* Chapter 3 section 3.3.3 and Chapter 5 sections 5.4.1 and 5.4.2.

<sup>343</sup> It is recalled that UN General Assembly resolution 179 (2003) enjoyed near universal acceptance, with the unique opposition of the US [Hestermeyer 2004: 173].

vertical approach to public health problems, focussed on specific diseases. To note, both the Alma Ata Declaration and the UN General Assembly resolution 179 (2003) refer for their justification on the human right to health and/or medicines *as well as* on other ‘communications’.<sup>344</sup> Furthermore, access to medicines is *indirectly* recognised in other fields of states’ international relations, such as the international regulation of intellectual property. The concern for ‘public health’ has been recognised, for instance, in the WTO through the 2001 Doha Declaration on the TRIPS Agreement and Public Health [Doha Declaration 2001 paras. 1, 4-5] and the 2003 Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health [TRIPS Decision 2003]. However, the realisation of the human right to health arguably requires more than public health.<sup>345</sup>

In sum, states pledge to recognise human rights internationally, and to cooperate for the human right to health and access to medicines. Therefore, a duty to respect the human right to medicines abroad can be established for foreign states. However, I contend that hypothetical customary duties to protect, fulfil and enforce cannot rest on ‘paper practice’ but have to be corresponded by ‘factual practice’. Analogously, Skogly has maintained with regard to the UDHR that “[i]t may be possible to argue that Article 22 (and Article 28) do not constitute a firm international law obligation to fulfil economic, social and cultural rights, but there may be an obligation to *respect* and *protect* economic, social and cultural rights beyond national borders” [Skogly 2006: 123]. The identification of the ‘factual practice’ is however challenging. As discussed in Chapter 3, there are difficulties in establishing, theoretically, which conduct to look and in finding, practically, sufficient uniform and general practice.<sup>346</sup> With regard to international *protection*, *ie* the protection of states against the behaviour of third parties affecting access to medicines across national borders, some practice can be identified in the participation to the WHO, which has a preminent role in international public health regulation. Most international normative activity, including that arranged by the WHO, is however non-binding and even binding regulations are not accompanied by a sanctionary regime.<sup>347</sup> Apart from the action within international organisations, however, states do

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<sup>344</sup> See Chapter 3 section 3.3.3.

<sup>345</sup> See Chapter 5 sections 5.4.1 and 5.4.2.

<sup>346</sup> See Chapter 3 section 3.3.4.

<sup>347</sup> See *generally* Burci and Vignes [2004] and Minelli [2003]. WHO can adopt binding agreements and conventions [WHO Constitution arts. 19-20], issue recommendations [*id.*: 21-22] and other non-binding standards, such as the WHO Essential Drugs Model

not uniformly undertake to protect access to medicines in other countries from actions originated by third parties on which they have control.<sup>348</sup> Some countries control the quality of the medicines exported. For instance medicines exported from the US, including donations, have to be registered with the FDA.<sup>349</sup> The trade in sub-standard and counterfeit medicines is however rife, transnational policing is not consistent and international responsibility is not generally claimed for this [WHO, *Combating Counterfeit Drugs*: 2005].

With regard to fulfilment, a proliferation of initiatives for improving the access to medicines is undertaken by foreign states as bilateral donors or part of multilateral agencies [Leach et al 2005: 41-57]. WHO, for instance, is increasingly engaged in operational functions such as the management of the ‘3 by 5’ programme (for the provision of antiretrovirals)<sup>350</sup> and the coordination of global health partnerships for access to medicines [The Economist, 1.3 by 5, 2006; Ruger and Yach 2005: 1100; WHO, *Engaging for Health*, 2006: iii]. WHO’s budget on essential medicines is also rising.<sup>351</sup>

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List (EDL) [*id.*: art. 23; Burci and Vignes 2004: 141]. The International Health Regulation are a rare example of binding regulations but the procedure for the settlement of disputes is not particularly developed: “[i]n the event of a dispute between WHO and one or more States Parties concerning the interpretation or application of these Regulations, the matter shall be submitted to the Health Assembly” [WHO, *International Health Regulation*, 2005: art. 56]. Furthermore, the Regulations aim at the prevention of international spread of diseases, thus states ultimately participate by virtue of self-interest rather than out of concern for other states public health situations.

<sup>348</sup> See also *infra* on the poor practice of extra-territorial jurisdiction for the violations of the human right to medicines.

<sup>349</sup> Such requirement may however be problematic for access to medicines, as it will be analysed in Chapter 6 section 6.2.1.1.

<sup>350</sup> The ‘3 by 5’ programme was launched by WHO and UNAIDS in 2003 to serve as catalyst for other funding sources. It addresses a variety of issues such as training of health workers, development of health systems, improving infrastructure and developing standards. WHO provides technical support, technical assistance and seeds money. See, e.g., The Economist, “1.3 by 5” [2006].

<sup>351</sup> Reportedly the budget for WHO’s work in essential medicines is rising and has amounted to US\$ 71.7 million in 2006 (states are the major founders followed by private charities, such as the Bill & Melinda Gates Foundation, and international organisations, such as UNITAID) [WHO, *Essential Medicines Annual Report 2006*, 2006: 22]. The scope of WHO’s action related to access to medicines has generally expanded. In 1992 WHO started to act as leader of global health initiatives [Brown et al 17]. Among these, mention can be made to the Roll Back Malaria, the Accelerating Access Initiative, the Global Fund for AIDS, Tuberculosis and Malaria, the Global Alliance to Eliminate Leprosy, The Global Program to Eliminate Lymphatic Filariasis, the Global Polio Eradication Initiative [WHO Programmes and Projects, 2010; IFPMA 2009]. See also WHO, *Medicines, About Us* [website, last accessed 2010].

Furthermore, states donate through funds engaged in access to medicines such as Global Fund for AIDS, Tuberculosis and Malaria.<sup>352</sup> Moreover, states intervene in health abroad through foreign aid [CMH Working Group 6, 2002: 17]. As a result, external funding amounts to 15% of total health expenditures in sub-Saharan Africa [WHO, World Health Statistics 2006, my elaboration].<sup>353</sup> However, the conduct of states is not general and uniform. Furthermore, it is noted that the quality and effectiveness of the external intervention is also important in order to fulfil the human right to medicines. Foreign assistance can for example be a distortion of local resources and can be volatile. In effect, with regard to results, access to medicines in sub-Saharan Africa is still shortcoming. Often the agencies miss the very targets they fixed.<sup>354</sup> Furthermore, the identification of the fulfilment of the human right to medicines is complex, as it will be discussed in Chapters 5 and 6. For example, it can be asked if the aid for time-limited projects and health ‘emergencies’ responds to the fulfilment of the human right to medicines.

Finally, with regard to international enforcement, I am not aware of foreign states invoking another state’s international responsibility for the human right to medicines.<sup>355</sup> Also, I could not find cases of foreign states acting for the infringement of such human right as a violation of an obligation *erga omnes*.<sup>356</sup> In sum, while foreign states bear a

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<sup>352</sup> To date (May 2010), states have paid more than US\$ 15 billions to the Fund [GFATM, website, 2010, Pledges and Contributions].

<sup>353</sup> See also Commit for Africa, website Health, last accessed 2010.

<sup>354</sup> To make just one example, the WHO’s ‘3 by 5’ initiative to treat three million people with HIV drugs by end 2005 has decidedly missed its target, as only 1.6 million are now on antiretroviral treatment in developing countries. The case is explored in further detail in Chapter 6 section 6.4.1.

<sup>355</sup> State responsibility is part of customary law, although the definition of some of its aspects is still controversial. The UN International Law Commission has been working on the codification – and arguably progressive development – of state responsibility for almost six decades. As of yet, the Draft Articles on the Responsibility of States for Internationally Wrongful Acts are being considered by the General Assembly [UN GA Res. 35 (2004)]. See also International Law Commission, website [2006].

<sup>356</sup> It seems established that any state holds a legal interest to intervene against gross and large-scale violations of internationally recognized human rights, which therefore violate obligations *erga omnes*, even if the violations occur abroad [Cassese 2005: 393-4]. See also the US Third Restatement, stating that a foreign state commits violations of obligations *erga omnes* when it engages in a consistent pattern of gross violations of internationally recognised human rights [Third Restatement (Comments) 1987: para. 702 (o.)]. In those cases the foreign states can use diplomatic or economic retortions, peaceful countermeasures or recur to international adjudication, for instance through the ICJ [Cassese 2005: 394]. Cf. Henkin, maintaining that the foreign state could in fact have a *duty* to call the violator to account [Henkin 2003: 395]. On the international enforcement of the human right to medicines see Chapter 6 section 6.4.3.2.

duty to respect the human right to medicines abroad, a general and uniform ‘factual practice’ of duties to protect, fulfil and enforce the human right to medicines could not be identified to be certainly incumbent on foreign states.<sup>357</sup> Nevertheless, states undertake actions for the protection and fulfilment of access to medicines abroad (even though those actions are not necessarily framed as contributions to the realisation of human rights) and profusely pledge to cooperate for human rights, the human right to health/medicines or access to treatment abroad.

#### 4.3.2 Non-state actors

Section 4.3.2 explores the customary law, the soft law and self-regulation of non-state actors – in particular international organisations, NGOs and pharmaceutical companies – with regard to the human right to medicines. The sub-sections first research whether and what duties originate *directly* onto those non-state actors from customary international law with regard to the human right to medicines – that means, as opposed to the obligations that are imposed on them by states. Direct duties imply that non-state actors are directly legally accountable for the related violations of customary international law. The identification of human rights customary norms for non-state actors, it is pointed out, incurs in notable paradoxes. International custom is in fact classically established through the practice of *states* accompanied by *opinio juris*. What sense does it make to look at state practice, indeed, to identify customary duties binding non-state actors? Certain non-state actors can be seen as having legal personality under international law and therefore being bound by international customary law and the general principles of law (as argued in Chapter 3 section 3.3 the respect of the human right to health is a duty under international customary law). However customary law, like treaty law, is ‘textually’ dedicated to states, and can be applied to the conduct of non-state actors only in a very general way.<sup>358</sup> Secondly, the sub-sections investigate whether and what duties are attributed by soft law and self-regulation to international

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<sup>357</sup> See also Skogly concluding on the human rights obligations of foreign states under customary law that “[i]n terms of transnational obligations based on customary international law, it would be fair to assume that the content of the obligation would be of a negative nature – states should refrain from actions in their international or transnational operations that will fail to respect the human rights of people in other states” [Skogly 2002: 788].

<sup>358</sup> This is the classic problem of the horizontal effect of constitutional, human rights provision on third (non-state) parties. See Barak [2001].

organisations, NGOs and pharmaceutical organisations with regard to the human right to medicines. It will be noticed that such types of commitments often envisage expansive roles and responsibilities for these non-state actors.

#### 4.3.2.1 International governmental organisations

Skogly maintains that the international organisations which have international legal personality are bound by customary international law and the general principles of law.<sup>359</sup> Therefore, they are bound to *respect* the human rights which are part of customary international law [Skogly 2001: 87].<sup>360</sup> Accordingly, customary international law would impose to international organisations obligations to respect the human right to health – if we accept that the human right to health is part of customary law.<sup>361</sup> The duty is however vague, and can only be applied if watered down to make it compatible to the characters of international organisations. Customary norms, in effect, are ‘textually’ dedicated to states, their powers and characters.

International soft law and the self-regulation (or mandates) of international organisations themselves often sanction a role with regard to international human rights and access to health care which is more extensive than that provided in the positive law. In effect, states often urge in their international declarations the support for health care and access to medicines from some international organisations [Alma Ata: X; Abuja

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<sup>359</sup> Skogly demonstrates the *de facto* legal personality of these institutions assessing their powers and operations and referring to the ICJ which in its advisory opinion *WHO and Egypt* declared that “[i]nternational organizations are subjects of international law and, as such, are bound by any obligations incumbent upon them under general rules of international law, under their constitutions or under international agreements to which they are parties” [ICJ, *WHO and Egypt*, 1980: para. 37; Skogly 2001: 76-91]. For the capacity of international organisations to hold autonomy and legal personality *see also* the ICJ *Reparation* case, whereby the Court advised that the UN had the personality to bring an international claim in respect of injury to its personnel, on the lines of diplomatic protection, and in respect of injuries to the UN caused by the injury to its agents. Even though the UN Charter does not contain explicit provisions on the legal personality of the organisation, the ICJ could draw from other articles of the document stating the mandate of the UN [ICJ, *Reparation*, 1949: 179; Brownlie 2003: 648-650]. *See generally* Amerasinghe [2005: 80-81]. For the capacity of international organisations to be subject to customary and international law *see e.g.* Joseph [2003: 437].

<sup>360</sup> According to Skogly, “the *nature of obligations* in regards to customary international law will often have a negative character” [Skogly 2001: 87, *emph. orig.*].

<sup>361</sup> *See* Chapter 3 section 3.3.

Declaration: para. 18, 27]. Furthermore, it is looked at self-regulation and mandates of a sample of global international organisations which have great impact on access to medicines, namely the WHO, UNICEF, the World Bank, the IMF and the WTO.<sup>362</sup> WHO's Constitution does recognise the human right to health, as seen in above section 4.2.3. The UNICEF's Mission Statement claims that, inter alia, the organisation is mandated by the UN General Assembly to advocate for the protection of children's rights and to help meet their basic needs [UNICEF's mission statement 2004: para. 1]. Children's rights are sourced from the Convention on the Rights of the Child [*id.*: para. 2; CRC]. The IMF and the World Bank are also UN agencies but they enjoy autonomy from the organisation and do not refer to human rights in their founding agreements [UN Charter arts. 57 and 63; Agreement between UN and the IMF art 1(2); Agreement between UN and the IBRD].<sup>363</sup> Traditionally, the IMF and World Bank claim that human rights are a political issue within a country's domestic affairs.<sup>364</sup> However, the World Bank has more recently declared seeking to "ensure that human rights are fully respected in connection with the projects it supports" and trying to "reflect the principles enshrined in the [Universal Declaration of Human Rights] into all of [the Bank's] work" [World Bank, Development and Human Rights: The Role of the World Bank, 1998: 2]. The IMF remains more laodicean with regard to human rights. With regard to the IMF work on

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<sup>362</sup> I look at these organisations considering also that the CESCR in its comment on the right to health especially mentions that UN agencies, regional development banks and the WTO should cooperate effectively in relation to the implementation of the right to health [CESCR 2000: para. 64]. Thus these organisations have been identified to have an impact on health.

<sup>363</sup> Cf. Ssenyonjo arguing that Article 103 of the Charter links the two institutions' Articles of Agreement to the Charter [Ssenyonjo 2008: 741]. Furthermore, "human rights issues are implicitly part of the development mandate of the World Bank and central to the success of the poverty alleviation programmes of the Bank and the IMF" [Ssenyonjo 2008: 741]. Such reasoning is sensible but gives little guidance on the legal responsibility of these institutions. See Shrijver identifying a difference between the IBRD (World Bank) and the IMF, the former not being controlled by the UN. Shrijver argues that the relationship agreement between the UN and the IBRD states that the UN recognises that the action to be taken by the Bank on any loan is a matter to be determined by the independent exercise of the Bank's own judgment in accordance with the Bank's Articles of Agreement [Agreement between UN and the International Bank for Reconstruction and Development, 1947: art IV para 2]. Such provision is not present in the Agreement between the UN and the IMF, thus *a contrario* one could argue that in the case of the IMF the United Nations is free to intervene [Shrijver 2001: 8]. Cf. Feyter who contrasts the agreements between the UN and the IMF or the World Bank on the one hand and the agreement between the UN and the WHO on the other hand, whereby the WHO agrees to enter consultation with the UN with respect to recommendations [Agreement between the United Nations and the World Health Organisation, 1948: art. IV; Feyter 2001: 77].

<sup>364</sup> See Ssenyonjo [2008: 741].

Poverty Reduction Strategy Papers, for instance, Pereira Leite from the IMF External Relations Department declares that “[w]hile human rights advocates should be given every opportunity to participate in the PRSP consultations, they should not expect the IMF to impose human rights conditions on its assistance to member countries. The IMF simply does not have the expertise required to make judgments in this area” [Pereira Leite 2001]. The Agreement Establishing the WTO does not mention human rights or health but in the preamble the parties recognise “that their relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living...” [Agreement Establishing the WTO, preambular para. 1] and that special attention is to be dedicated to developing countries [*Id.*, para. 2].<sup>365</sup>

#### 4.3.2.2 *Non-governmental organisations (NGOs)*

Some authors maintain that NGOs<sup>366</sup> bear duties under international customary law arguing deductively that NGOs perform a public role and core customary human rights obligations are to be binding on every entity that has the capacity to bear such obligations [Clapham 2006; Hobe 2004; Rossi 2008: 13-15].<sup>367</sup> This type of argument is slightly tautological and does not solve the question of the ‘textual’ applicability of customary international human rights norms on non-state actors. It is not clear, in other words, when NGOs violate the respect of the human right to health and medicines. In effect, I could not find any judicial practice of holding NGOs legally responsible for violating the customary human right to health or medicines. Nevertheless I note that NGOs are attributed roles with regard to human rights and access to health care under international soft law and their own self-regulation. For example, the UN General Assembly has issued in 1999 the “Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms” [UN GA Res. 144 (1999)]. The

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<sup>365</sup> More specifically “there is need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development” [Agreement Establishing the WTO, preambular para. 2]

<sup>366</sup> An NGO is here understood as a private nonprofit organisation. *Cf.* Lehr-Lehnardt [2005: 3-4].

<sup>367</sup> Rossi maintains nonetheless that NGOs do not have personality in international law, as they have been excluded from work of International Law Commission on the Responsibility of International Organizations [Rossi 2008: 11].

declaration states that NGOs have roles and responsibilities “in contributing, as appropriate, to the promotion of the right of everyone to a social and international order in which the rights and freedoms set forth in the Universal Declaration of Human Rights and other human rights instruments can be fully realized” [*id.*: art. 18(3)]. No legal duty is in fact directly established and it is not clear what NGOs should do for ‘promoting’ human rights. Incidentally, a suggestion by the former UN Secretary-General Kofi Annan that UN members drew up a code of conduct to ensure that NGOs commit themselves to the aims of the UN Charter and act in a manner that reflects the intergovernmental character of the UN had not been yielded as of yet [UN Secretary General, 354 (2004): para. 34; Rossi 2008: 22].<sup>368</sup>

For their part, NGOs produce instances of self-regulation regarding their position with respect to human rights. In 2005 some international NGOs, including some organisations having influence on access to medicines worldwide, drew up the “International Non-Governmental Organizations Accountability Charter” [INGO Accountability Charter, 2003].<sup>369</sup> The NGOs identify themselves as “independent non-profit organisations that work globally to advance human rights” [INGO Accountability Charter, 2003: Who We Are, para. 1]. Human rights are mentioned in the Charter only as objective in “seek[ing] to advance international and national laws that promote human rights... and other public goods” [*id.*: Principles, para. 1]. Therefore, NGOs are not seen as accountable for the respect of human rights.<sup>370</sup> Other standards and codes of conduct have been agreed, but the human right to health is not directly addressed.<sup>371</sup> Individually, NGOs may express more direct views on human rights and the human right to health.

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<sup>368</sup> Some instance of scrutiny of NGOs working on international economic and social issues is offered by the ECOSOC which regulates the NGOs consultative status in the institution. Pursuant to ECOSOC Resolution 1996/31, implementing Article 71 of the UN Charter, NGOs in consultative status with ECOSOC must conform to the principles governing the establishment and nature of their consultative arrangements and have to report to the ECOSOC [ECOSOC Res. 31 (1996) para. 55]. Interestingly, among those organisations to be accorded special consultative status are those which “because of their interest in the field of human rights should pursue the goals of promotion and protection of human rights in accordance with the spirit of the Charter of the United Nations, the Universal Declaration of Human Rights and the Vienna Declaration and Programme of Action” [*id.*: para. 25]. Other international organisations also established consultative arrangements [Rossi 2008: 22].

<sup>369</sup> The signatories include Action Aid International, Amnesty International, International Save the Children Alliance, Oxfam International, Plan International, Survival International [INGO, website, Accountability Charter, 2009].

<sup>370</sup> Nevertheless, the parties pledge not to discriminate [*id.*: Principles, para. 5].

<sup>371</sup> See Rossi [2008] and Lehr-Lehnard [2005].

Among NGOs active on access to medicines, Médecins Sans Frontières (MSF) “sets out to alleviate human suffering, to protect life and health and to restore and ensure respect for the human beings and their fundamental human rights” [MSF, website, About MSF, 2005].<sup>372</sup> Management Science for Health (MSH), instead, does not mention human rights among its vision [MSH, website, About Us, 2009]. Oxfam asserts that “[g]ood health care is a fundamental right, not a luxury” [Oxfam, website, 2009, Oxfam in Action – Health]. However, no commitment is made by the organisation itself to comply with human rights.

#### 4.3.2.3 *The private, business, trans-national corporations (TNCs)*

This section investigates whether and what obligations customary international law imposes directly onto some private parties, with a focus on pharmaceutical companies. From the point of view of legal capacity, section 4.1 demonstrated that individuals and corporations can be bound by international customary norms. In particular, it is noted that these non-state actors can be directly liable for international human rights customary norms. An example of adjudication of this liability is offered by the US Alien Tort Claims Act (ATCA), which provides to US courts jurisdiction on torts committed in violation of international law abroad.<sup>373</sup> Under ATCA, US courts have in effect held corporations responsible for certain violations of human rights.<sup>374</sup> However, they have rejected jurisdiction on the human right to health which was not recognised as part of customary law.<sup>375</sup> In effect, I could not find adjudication or literature relating to

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<sup>372</sup> The MSF Charter does not mention human rights or the right to health [MSF, 2006, MSF’s Charter].

<sup>373</sup> Enacted in 1789, the Alien Tort Claims Act more specifically gives federal courts in the United States jurisdiction over “any civil action by an alien for a tort only, committed in violation of the law of nations or a treaty of the United States” [28 U.S. Code § 1350]. It permits suits against individual private actors, non-governmental groups such as corporations and unincorporated associations including paramilitary groups which violate international law binding the US [Stephens 2000: 280, 284-5]. The norm violated must be ‘universal, obligatory and definable’ [*Forti v. Suarez-Mason*, 672 F. Supp. 707 (N.D. Cal. 1987) in Stephens 2000: 281].

<sup>374</sup> This judicial jurisdiction has not been cause of protest from foreign states relating to the subject matter. Protest on the subject matter jurisdiction could have been urged by the fact that the ATCA sanctions extra-territorial jurisdiction. Therefore, there seem to be acquiescence by the international community that non-state actors such as corporations can be liable for violations of human rights under customary law.

<sup>375</sup> See Chapter 3 section 3.3.3.

the duty of companies to respect the human right to health in customary law. Some literature in fact expresses scepticism on the idea of holding corporations accountable for violations of human rights under customary law. For example Skogly states that this (referring to transnational corporations) would be ‘difficult’ and the “instances of human rights problems where it would be possible to grant responsibility to these companies would be very limited” [Skogly 1999: 251].

Nevertheless soft-law, often under the aegis of the UN, attributes roles, responsibilities and duties to business corporations with regard to human rights, including the human right to medicines as part of the human right to health. Some documents can be listed here: the 2000 UN Global Compact [UN Global Compact], the 2003 Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights of the UN Sub-Commission on the Promotion and Protection of Human Rights [Norms on the Responsibilities of Business], the International Labour Organization (ILO) Tripartite Declaration of Principles concerning Multinational Enterprises and Social Policy [ILO Tripartite Declaration]. Those instruments are not binding and can be quite liberal in their affirmations, for example, the Norms on the Responsibilities of Business recite inter alia that:

[w]ithin their respective spheres of activity and influence, transnational corporations and other business enterprises have the obligation to promote, secure the fulfilment of, respect, ensure respect of and protect human rights recognized in international as well as national law. [Norms on the Responsibilities of Business, art. 1]

To note, the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, Ruggie, has remarked, the ‘textual’ problem of applying to non-state actors norms which are designed for states. Ruggie has indeed criticised the ‘exaggerated legal claims and conceptual ambiguities’ of the Norms on the Responsibilities of Business which, in his view, had taken “existing State-based human rights instruments and simply [asserted] that many of their provisions now are binding on corporations as well” [Special Representative Ruggie, 2006: para. 59].<sup>376</sup> This has “little authoritative base in international law – hard, soft or

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<sup>376</sup> In the preamble the Norms on the Responsibilities of Business identify the responsibilities and norms to be respected as including “the International Covenant on Economic, Social and Cultural Rights... the ‘Health for All in the Twenty-First Century’ policy of the World Health Organization... the African Charter on Human and Peoples’ Rights... the African Charter on Human and Peoples’ Rights...” [preambular para. 4].

otherwise” [*id.*]. Particular mention, furthermore, is due to the Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, compiled by the former UN Special Rapporteur on the human right to health [Hunt 2007(a): para. i]. The guidelines are an interesting effort to obviate the indeterminacy of the responsibilities of corporations with respect to the human right to medicines, and will be recalled in Chapter 6. However, it has to be noted that the UN General Assembly has not taken action as of yet to endorse the document [*id.*].<sup>377</sup>

Moreover, it is remarked that many pharmaceutical companies themselves commit to human rights. Some pharmaceutical companies have participated to the UN Global Compact, the 2003 Norms on the Responsibilities of Business and the ILO Tripartite Declaration. The Special Representative Ruggie, who has conducted a systematic study also administering questionnaires to the Fortune Global 500, has concluded that most companies are interested in human rights.<sup>378</sup> I have consequently reviewed the statements of several pharmaceutical companies influent on access to medicines in sub-Saharan Africa.<sup>379</sup> Boehringer Ingelheim (BI) declares to comply with the Global Compact. It does not mention a human right to health or medicines, but in its policy paper on HIV/AIDS the company “shares the view that access to medicines saving human lives cannot be limited to those who can afford them” and a multi-sectoral response by different parties is required, also including the effort of pharmaceutical companies [BI 2009(a)]. Cipla’s website does not mention human rights, access to medicines or corporate social responsibility. GlaxoSmithKlein (GSK) is signatory to the Global Compact and proclaims to uphold the UDHR, the OECD Guidelines and the ILO core labour standards. The firm recognizes that businesses also have responsibilities with regard to human rights and it claims to “work hard to uphold human rights within our sphere of influence...As a marketer of medicines, we strive to make them as widely

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<sup>377</sup> For an account of the draft guidelines for pharmaceutical companies see Joseph [2005: 10].

<sup>378</sup> More precisely, most companies referenced international instruments in formulating their policies. Most worked with external stakeholders on the human rights policies. Most had reporting systems to monitor human rights performances [Ruggie 2007].

<sup>379</sup> The selection, presented in alphabetical order, is based on a combination of factors. Shelys is the most important pharmaceutical company in Tanzania. Cipla and Ranbaxy are chosen because they trade extensively generic products to Africa. The others are among the 20 biggest pharmaceutical companies for sale and revenue, vastly exporting to sub-Saharan Africa. GSK and BI have also been involved in the notorious case *TAC v. GSK, BI and others* at the South Africa Competition Commission [Tau et al 2002]. See Chapter 5 section 5.3.2.

available as possible while running our business in a sustainable way” [GSK 2009]. Merck & Co. is committed to respecting human rights as defined in the UDHR and its subsequent changes, the ICESCR, ICCPR, the OECD Guidelines and the ILO core labour standards [Merck & Co. 2009]. Merck & Co. also undertakes to produce reporting according to external guidelines and measurements frameworks which include the Global Reporting Initiative Guidelines, the Millennium Development Goals and the Access to Medicines Index [Merck & Co. 2008: iii]. Novartis claims to respect and support human rights, as also enshrined in the UDHR, and is signatory to the Global Compact [Novartis 2003; website, Human Rights, 2009]. Pfizer does not mention human rights, but declares its commitment to access to medicines and presents its awards in philanthropic activities [Pfizer 2007]. Ranbaxy does not refer to human rights but claims to be engaged in corporate social responsibility activities, including access to medicines and primary health care. I could not find any reference to human rights or ‘access to medicines’ at the website of Shelys, the most important pharmaceutical company in Tanzania [Shelys, website, Vision and Values, last accessed 7 December 2009].

In sum, international organisations, NGOs and pharmaceutical companies may be liable for the violation of the respect of the human right to medicines – as part of the human right to health – under customary law, but such provision would be extremely vague and is controversial in the doctrine of international law. The soft law reviewed in section 4.3.2, often promoted through the UN, is instead readier to attribute onto these non-state actors (non-binding) duties to respect and/or support the realisation of human rights, the human right to health/medicines, and access to medicines. Furthermore, some international organisations, NGOs and pharmaceutical companies commit in their self-regulation and mandates to human rights in general, the human right to health and/or access to medicines.

#### 4.4 Conclusion

Chapter 4 has shown that foreign states and non-state actors are subject to certain obligations under international law relating to the human right to medicines. The treaty law analysed in section 4.2 generally obligates *foreign states* to *respect* and *cooperate* for the human right to medicines (as part of the human right to health) in other countries. The ICESCR, according to the CESCR, binds states to *protect* the human right to medicines internationally. There is no specific obligation to realise the right through fulfilment; foreign cooperation and assistance are vague concepts. To note, these treaty provisions are mandatory in nature, but their substance is often uncertain. A duty to *enforce* the human right to medicines abroad could not be found. A legitimate interest in the realisation of the human right to medicines by other states parties to the treaties is nonetheless sanctioned. Treaty-based bodies have been established in order to monitor the conduct of the parties with regard to the human rights sanctioned by the treaties. However, most treaty-based bodies do not exercise a judicial function proper. Procedures to redress the complaints of individuals are not envisaged by several treaties, included the ICESCR regime (the Optional Protocol redresses this shortcoming but is not in force as of yet). Reparations for individual situations are not envisaged by the treaties analysed.<sup>380</sup> Furthermore, not all the bodies receive inter-state complaints.<sup>381</sup> Even those who receive such complaints rarely have the power to issue actionable interim measures,<sup>382</sup> and have no policing capacity.<sup>383</sup> Regardless, states can recur to state responsibility for breaches of obligations *erga omnes*. Under international customary law, it has been argued, foreign states have to *respect* access to medicines in other countries.

Furthermore, some treaties enshrining the human right to health and medicines attribute duties to *non-state actors*. Individuals, groups or international organisations are often demanded respect of human rights and recognised responsibilities with regard to the realisation of these rights but clear obligations are absent. Moreover, these parties were found not to be directly liable, as the duties are instead ultimately binding on the

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<sup>380</sup> Other regional systems such as the European Court of Human rights do provide monetary compensation [ECHR art. 41]. But *cf.* Nowak arguing that even such ‘just satisfaction’ system is inadequate and it does not even cover legal expenses [Nowak 2007: 257].

<sup>381</sup> The CESCR, for instance, does not. *See* section 4.2.1.

<sup>382</sup> For instance, within the ICESCR regime, interim measures are not provided in the Covenant but have been included in the (not yet operational) Optional Protocol (*see* above Section 4.2.1).

<sup>383</sup> *See* Chapter 6 section 6.4.3.

states parties to the treaties.<sup>384</sup> The identification of duties from customary international law has proved to be extremely tentative, as I could not overcome the paradox of whose practice, whose *opinio juris* should be searched when seeking the inter-national custom binding *non-state* actors. I have confined the scope of my enquiry to verify whether international organisations, NGOs and pharmaceutical companies were bound by the international customary human right to health and medicines which (arguably) binds states. I have concluded that a case can be presented to hold those actors accountable under international customary law for the *respect* of the human right to medicines in their operations. However, such duty is extremely vague, also considering that it is deduced from (a vague) obligation ‘textually’ formulated for states.

Thus custom has revealed to be a weak instrument for the positivisation of the human right to medicines with regard to extra-governmental actors. In contrast certain instances of soft law, state practice and non-state actors’ self-regulation, overall, show an attitude readier to frame the roles and responsibilities of extra-governmental actors, also with respect to access to medicines, as human rights duties. Such duties however are not meant to be legally binding. Rather, they can be regarded as aspirations, communications framed in the ‘human rights subsystem’. In this ‘utopian’ subsystem, *arguendo*, all actors have a role in the realisation of human rights. Given the resources needed to fulfil economic, social and cultural rights, and who has the power to master them, the ‘human rights subsystem’ is inclined to bind and rely on extra-governmental actors as well as home states. However, the legal subsystem struggles to frame such communications as legal/illegal.<sup>385</sup> So “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?” This chapter has demonstrated some potentials and limitations of the international human right to medicines to bind extra-governmental actors. Chapter 6 will critically analyse the operationalisation, implementation and enforcement of the right regarding those actors *de facto*.

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<sup>384</sup> See also, e.g., Special Representative Ruggie [2007: paras. 33-44].

<sup>385</sup> For example, it is recalled that the provisions relating to non-state actors and individuals generally have no direct applicability. As seen in section 4.2 individuals are contemplated in treaties but those prescriptions may be seen, borrowing Brems’ words with regard to the ACHPR, to “inculcate these duties as well as their underlying principles and ideals in its citizens” [Brems 2001: 113].

## CHAPTER 5: THE OBLIGATIONS OF HOME STATES WITH REGARD TO THE HUMAN RIGHT TO MEDICINES *DE FACTO*

### 5.1 Introduction

Chapter 2 showed that home states exert considerable influence on access to medicines in sub-Saharan Africa. Chapter 3 demonstrated that all African states bear obligations under international human rights law relating to access to medicines. Access to medicines is part of the human right to health enshrined in widely-accessed international human rights treaties such as the International Covenant on Economic, Social and Cultural Rights (ICESCR), binding 43 African states, and the African Charter on Human and Peoples' Rights (ACHPR), which binds all African states [Odinkalu 2003: 20]. Access to medicines is also supported by other human rights such as the right to life and the right not to be subjected to torture, inhuman and degrading treatment. International custom, arguably, endorses the respect of the human right to medicines. This chapter contributes to answering the research questions of this thesis, "can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?", by providing a critical analysis and a normative discussion of the possible utilisation, *de facto*, of this right to guide and redress the conduct of African home states.

With regard to the scope, the enquiry critically analyses the indications which international human rights law gives for the operationalisation, implementation and enforcement of the human right to medicines by home states.<sup>386</sup> According to the formulations of the human right to medicines binding African countries, home states are obliged to respect, protect and fulfil the human right to medicines. It will be shown that the operationalisation of the human right to medicines however encounters several paradoxes. From a legal perspective, as noted in Chapter 3, states enjoy 'margins of discretion' with regard to the realisation of human rights.<sup>387</sup> In effect, not all state actions diminishing access to medicines violate the respect of the human right to medicines. Not

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<sup>386</sup> Operationalisation is here defined as the attribution of precise content to a concept, in this case the human right to medicines, through the identification of good practices and policies. This expression has been used by the UN Human Rights Council [Human Right Council, Res. 29 (2007): para. 2(c)]. On the operationalisation of political 'steering' programmes *see* Luhmann [1997: 51].

<sup>387</sup> *See also* CESCR [2000: para. 53].

all shortcomings in protection and fulfilment of access to medicines violate this right. Moreover, human rights can be contradictory. The human right to medicines has both an individual and a collective dimension which can in effect clash. From an ethical and normative perspective it is underlined that while human rights are deemed to be founded on indisputable norms, ‘fully independent of consequences’ [Luhmann 1997(b): 35; 2008: 19], the decisions relating to the regulation and policies of access to medicines are characterised by delicate ethical predicaments concerning the effects on health as well as other rights, interests, needs and liberties in society. Those choices in effect entail conspicuous power and biopower. Furthermore, the practical limits of the steering of law and politics in addressing problems in society shall be considered.<sup>388</sup>

According to its broad scope, this chapter utilises a multidimensional, interdisciplinary methodology. To begin with, it deals with the legal analysis of the human right to medicines and health utilising: the ICESCR and the ACHPR, as they set up the most comprehensive regimes of international human rights obligations on access to medicines; the comments and decisions of treaty bodies, focussing on the CESCR (the ICESCR treaty body), the African Commission (the ACHPR treaty body); the decisions of international and national courts; the work of the UN Special Rapporteur on the human right to health, academics and other authoritative sources. Next, the normative analysis expands considering the ethics, economics, politics and science involved in the realisation of access to medicines. Socio-legal studies, mainly drawing from Luhmann and Foucault, are also utilised. Furthermore, the investigation employs an empirical study regarding access to medicines, with particular focus on sub-Saharan Africa and Tanzania where I undertook field work.

This chapter is constituted by three parts which follow the tripartite distinction of home states duties to respect, protect and fulfil the human right to health and medicines.<sup>389</sup> Attention is dedicated to the most problematic aspects of regulation,

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<sup>388</sup> As mentioned in Chapter 1 section 1.4, with regard to the steering of law, “law does not necessarily solve the original conflicts but only those that it can construct on its own terms” [Luhmann 2004: 169]. The steering of the political subsystem incurs in three major limits, namely: 1) the unexpected and/or undesired side-effects 2) the so-called ‘deficits of execution’ and 3) the so-called ‘self-fulfilling’ or ‘self-defeating prophecies’ (obtain the opposite of what sought) [Luhmann 1997: 44].

<sup>389</sup> The distinction is enshrined by the ICESCR and ACHPR provisions on the right to health and has been adopted, among others, by the CESCR, the African Commission, and the UN Special Rapporteur on the right to health [CESCR 2000: paras. 33-36; AC Res. 141 (2008); Hunt: paras. 59-60]. *See* Yamin and Hestermeyer for an account of the three

policies and actions having an effect on access to medicines. Section 5.2 examines the duties of *respect*, namely the injunction of no harm and non-discrimination. Particular focus is given to the impact on access to medicines of the protection of intellectual property rights and to the problematic identification of duties of *de facto* and substantive non-discrimination. Section 5.3 examines the duty to *protect* and is divided between the duty to ensure the respect by third parties and the regulation of the promotion of access to medicines involving third parties. This part expands on price controls and the possible abuses of competition by pharmaceutical companies such as ‘excessive pricing’. Section 5.4 examines the contingencies of the *fulfilment* of the human right to medicines, analysing the problems in medical ethics of prioritising health-care interventions and access to medicines. This part also studies the judicial *enforcement* of the human right to medicines. Finally, a conclusion is provided reflecting on the uncertainties of a human right to medicines in regulating and redressing the conduct of home states in relation to access to medicines.

## 5.2 Respect

Neither the ICESCR nor the ACHPR explicitly use the expression ‘respect’ when prescribing the duties of home states towards the human right to health. The obligation of respect is instead explicitly identified by the CESCR and the African Commission, with direct regard to the human right to medicines [CESCR 2000: para. 34; AC Res. 141 (2008): para. 2(1)].<sup>390</sup> Two overarching concepts may be derived from these prescriptions and will be examined in turn. The first is that states shall not directly impede access to medicines (section 4.2.1). The second is that states shall not exercise discrimination in actions having an influence on access to medicines (section 4.2.2).

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types of duties befalling on the State parties with regard to access to medicines [Hestermeyer 2004 132-138; Yamin 2003: 127-138]. *See also* Chapter 3 section 3.2.1.

<sup>390</sup> While the African Commission defines the first set of duties in relation to access to medicines as ‘promotion’, substantively it refers to negative actions of *respect* by ‘refraining’ from a (non-exhaustive) list of actions [AC Res. 141 (2008): para. 2(1)].

### 5.2.1 No harm

With regard to the prescriptions of no impediment of access to medicines, violations are most evident when the state actively undermines access to medicines, for example by interfering with the provision of humanitarian aid in internal conflicts [AC Res. 141 (2008): para. 2(1)(c)].<sup>391</sup> The adoption of tariffs and taxes on pharmaceutical products can reduce the economic affordability of medicines [Hunt 2006: para. 49] yet they can be instrumental to the development of a nascent national pharmaceutical industry aimed at improving access to medicines.<sup>392</sup> Notably, certain interventions of states in the regulation and provision of medicines can diminish access to certain medicines, for example the selection of the treatments available in public health facilities.<sup>393</sup> These types of state interventions are further investigated later in this chapter with regard to the protection and fulfilment of the human right to medicines.<sup>394</sup>

Furthermore, states can influence the enjoyment of access to medicines by protecting intellectual property rights and in particular patents on medicines. The African Commission in its resolution on access to medicines maintains that states shall stimulate intellectual property, but adopt the ‘TRIPS flexibilities’ [AC Res. 141 (2008): paras.

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<sup>391</sup> See, e.g., the communication *The Social and Economic Rights Action Center for Economic and Social Rights v. Nigeria* at the African Commission. The African Commission found that the government of Nigeria had directly participated in the contamination of air, water and soil, thereby harming the health of the Ogoni population. The government had also refused to permit scientists and environmental organisations from entering Ogoniland to undertake studies regarding hazardous operations and materials relating to oil production [AC, *Nigeria*, 2001: para. 50 and Findings].

<sup>392</sup> It has been reported for example that the average tariff in Tanzania, Burkina Faso and other countries is above 30% [Bale 2001: 10]. See also Ocay and Laing [2005].

<sup>393</sup> In *Ministry of Health v. TAC*, for instance, the South African Constitutional Court held that the State’s policy not to make nevirapine available was unreasonable and, inter alia, “[t]he State has failed to meet its obligation ‘to desist from preventing or impairing’ the right of access to health care” [South Africa, *Ministry of Health v. TAC*, 2002: para. 3.21.1]. The plaintiff, the NGO Treatment Action Campaign (TAC), asked the South African Constitutional Court to allow the provision of nevirapine to all HIV-positive pregnant women (the provision of nevirapine, an antiretroviral drug, reduces the woman-to-foetus HIV transmission) at hospitals and clinics other than the research and training hospitals, as it was instead decided by the state [South Africa, *Ministry of Health v. TAC*, paras. 57-58]. The case is discussed in *infra* section 5.4.3. See also Langford and Nolan arguing that the restrictions on the provision of certain medicines by medical practitioners can amount to failure to respect the right to health [Langford and Nolan 2006: 28].

<sup>394</sup> For the registration of medicines see Section 5.3.1; for the selection of essential medicines lists (EMLs) and the selection of the treatments accessible in public health facilities see Section 5.4.

2(2)(d), 2(1)(e)]. Setting aside for the moment the Trade-Related Intellectual Property Agreement (TRIPS), its ‘flexibilities’ (*e.g.* compulsory licensing, parallel trading) and other international agreements, the relationship between the protection of intellectual property and access to medicines is generally problematic.<sup>395</sup> Patents are a form of intellectual property rights that are typically attributed to original, innovative inventions adapt to commercial use.<sup>396</sup> The holder of a patent is granted a time-limited monopoly on the commercialisation of her product. Therefore, she can set the product’s price without the pressure of competition, unless she grants a licence. This can curtail the affordability of medicines for states and individuals. It has been estimated indeed that most patented medicines are sold at 20-100 times their marginal costs [Mossialos and Dukes 2001: 6-7].<sup>397</sup> However, reportedly, all countries in Africa except Angola and Eritrea currently offer patent protection on pharmaceuticals [Grace 2003: 53; CIPR: 46, 27; Thorpe 2002].

Nevertheless, intellectual property protection may be morally justified and advantageous for access to medicines. The literature on intellectual property usually identifies three competing rationales for the protection of intellectual ‘property’: the labour, personality and utilitarian arguments [Fisher 2001; May 2000]. The first two seek to identify natural rights originating from the relationship between the inventor and the invention. The ICESCR recognises such values and sanctions the human right to benefit from the protection of the moral and material interests resulting from scientific, literary or artistic production [ICESCR article 15(c)]. Nonetheless, personality and utilitarian

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<sup>395</sup> The TRIPS and its flexibilities will be analysed in more detail in Chapter 6 section 6.2.1 regarding the foreign and ‘non-state’ dimension of access to medicines.

<sup>396</sup> *See, e.g.*, TRIPS article 27 [TRIPS art. 27, note 5].

<sup>397</sup> According to the microeconomic tenet, in regimes of perfect competition prices tend to correspond to the marginal cost of production. Firms have a stimulus to enter competitive markets and compete on the price until the market price allows for some profit. *See, e.g.*, Katz and Rosen [1997]. Yet, the pharmaceutical sector is naturally not perfectly competitive for the barriers to entry such as the continuous, dynamic innovation, the high fixed and sunk costs. *See* Chapter 2 section 2.3.2. Nonetheless, there are great differences between the prices of on-patent and generic products. For example, in India, where the originator company has sold a 500 mg dose of ciprofloxacin for US\$ 4.40, the Indian company Cipla is able to make and sell an identical product profitably for US\$ 0.12, a 36-fold difference in price. In Thailand, Fluconazole, costs US\$ 14.00 per treatment day in branded form whereas a generic Thai version of the same drug is available at a price corresponding to US\$ 0.75 per treatment day [Mossialos and Dukes 2001: 6-7]. The minimum cost of a first-line antiretroviral triple-combination (stavudine, lamivudine, nevirapine) generally amounts to US\$ 132 per patient per year if sold by Cipla, an Indian generic manufacturer, whereas up until 2000 the originator was selling the same product for US\$ 10,438 [MSF, *Too Little for Too Few*, 2006: 6].

justifications are not always applicable to the current industrial organisation of pharmaceutical research and innovation [May 2000: 15, 97]. The third principle is founded on a utilitarian account of right utilised in certain economic theory.<sup>398</sup> Mainstream microeconomic theory hypothesises that knowledge is a sort of public good as it enjoys to some extent non-rivalrous consumption and non-excludability (non-appropriability) [Drahoš and Braithwaite 2002: 216; Maskus and Reichman 2004]. The non-exclusive character entails that incentives *may* lack for the good to be produced at a societal optimal level.<sup>399</sup> Utilitarian considerations consequently prompt a public authority to create and protect property rights for the creations of the intellect, such as patents. Thence knowledge is appropriated and traded in the market, that which is supposed to deliver the maximum efficiency to society.

Utilitarian arguments however do not indicate a precise policy on patents. In fact, utilitarian economists also note that the curtailment of the enjoyment of the good that would naturally not be scarce (non-rivalrous) is a loss of society welfare.<sup>400</sup> According to Stiglitz, a balance needs to be found between dynamic and static efficiency [Stiglitz 1991: 6 in Roffe et al: 67]. Furthermore, it shall be noticed that some uses of the patent systems can undermine innovation.<sup>401</sup> Nevertheless, the research-based pharmaceutical sector is

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<sup>398</sup> According to Bentham's rule of utility, "the good is whatever brings the greatest happiness to the greatest number of people" [Bentham 2009/1780].

<sup>399</sup> This means, society as a whole would be willing to pay for this level of knowledge production, if it was given the choice.

<sup>400</sup> The utilisation of a non-rivalrous good by one does not undermine the utilisation by another. Note: a piece of knowledge can be rivalrous when it produces advantages for she who holds that piece of knowledge (for example in the case of information asymmetries). In that case knowledge is rivalrous as wider availability of the knowledge would cause such advantage to evaporate. *Cf.* May's rebuttal to such contention [May 2003].

<sup>401</sup> If overly strong, patent systems can hinder dynamic and static efficiency as well as dynamic and static competition [Stiglitz 1991: 6 in Roffe et al: 67]. Patenting on intermediate technology can be detrimental to innovation in knowledge-based industries – and the pharmaceutical is certainly such – wherein "the process of innovation may be cumulative, and iterative, drawing on a range of prior inventions invented independently, and feeding into further independent research processes by others" [CIPR 2002: 112]. Examples of vicious use of patents are 'preemptive patenting', 'sleeping patents' [Pugatch 2004: 27; Gilbert and Newbery 1982: 514-26], 'patent suppression' [Landes and Posner 2003: 320-4], patent racing [CIPR 2002: 126; Trebilcock and Howse 2005: 399]. Similar concerns have also been expressed by the people working in the biotechnological sector that I have interviewed.

adamant about patents.<sup>402</sup> Economists specialised on the pharmaceutical sector emphasise that the pharmaceutical industry heavily depends on the patent system [Scherer 2001] as the costs of developing a new drug are high and the costs of developing processes for copying a new drug are low [Grabowski 2002; Sykes 2002: 16]. It is also reckoned that the pharmaceutical and biotechnology sectors are overall the sectors spending the most in research and development [Willman 2007]. Moreover, indirectly, patent protection can foster development through transfer of technology, foreign direct investment and economic growth. Again, some cautions are expressed with regard to the transfer of technology and economic growth.<sup>403</sup> As Pugatch argues, the information disclosed by (foreign) innovators applying for patents in patents offices could in fact be obtained from other (foreign) patent offices. Furthermore, know-how is not transferred with the information disclosed in a patent [Pugatch 2004: 57]. With regard to economic growth, the effect depends on many circumstantial variables in a country. The economic literature on the influence of patent protection on economic growth and other economic variables is uncertain, failing to identify a clear trend. Qualitative considerations suggest that the outcome depends on the level and type of technology, education, culture, interest, entrepreneurship in the country.<sup>404</sup>

In addition, the effects of patent protection on the access to existing medicines depend on environmental contingencies such as the resources of individuals and health systems to buy medicines. As seen in Chapter 2, medicines are provided within complex health systems.<sup>405</sup> Determinant is, for example, the type of financing and distribution of medicines: as out-of-pocket expenditures for instance make the African poor particularly sensitive to the medicines' prices.<sup>406</sup> Furthermore, the impact of intellectual property rights depends on the actual utilisation of the rights by pharmaceutical companies deciding whether to apply for patent protection of innovative products (which does not occur systematically in sub-Saharan Africa); whether to grant licenses; and whether to

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<sup>402</sup> For instance, patents are strongly lobbied for, internationally, by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) [Gerhardsen 2006; IFPMA, website, About US]

<sup>403</sup> With regard to foreign investment Pugatch, who overall opposes the global intellectual property regime, concludes that "although no clear-cut conclusion is currently available, it is still plausible that a stronger IPR environment may indeed have a positive effect on the overall decision of foreign firms to invest and to utilize their technologies in developing countries..." [Pugatch 2004: 64].

<sup>404</sup> See Maskus and Reichman [2004: 289].

<sup>405</sup> See Chapter 2 section 2.3.2.

<sup>406</sup> See Chapter 2 section 2.3.3 and *infra* sections 5.3 and 5.4.

enforce patent rights. Foreign states can also influence the implementation and enforcement of intellectual property rights in African countries. On the other hand, especially considering the finances of African countries, foreign states can contribute to access to medicines in poorer African countries through aid and cooperation, funding the purchase of patented medicines. Chapter 6 will investigate whether and how the human right to medicines regulates the behaviour of pharmaceutical companies and foreign states with regard to intellectual property in sub-Saharan Africa.<sup>407</sup>

Therefore, contingencies distort the causality between patent regulation and access to patentable medicines, which is not linear. In sum, it is not clear what type of intellectual property protection African states can implement without undermining access to medicines. The case of Tanzania, which I have enquired during my field work in July-August 2009, illustrates how the effects of intellectual property protection can be contingent. The Tanzanian government, the Tanzania Food and Drug Authority (TFDA) and WHO officials report that the country has not experienced ‘public health’ problems with patents on pharmaceutical products.<sup>408</sup> Tanzania’s patent law does cover pharmaceutical products.<sup>409</sup> However, the originator pharmaceutical companies have not patented, for instance, the first-line antiretrovirals and the first line antimalarial (the ALu ‘Coartem’). An interviewee at TFDA indeed declared that 99% of the medicines used in Tanzania are generic products [Interview, TFDA, Dar es Salaam, August 2009]. The situation of Tanzania may nonetheless become more precarious with the adoption of TRIPS obligations by some of its exporters, such as China and India, as it will be discussed in Chapter 6. On the other hand, the level of development of the Tanzanian pharmaceutical sector does not invite patent protection because, overall, it does not innovate.<sup>410</sup>

Therefore, a ‘fundamentalist’ approach to patents is questionable, in that it overlooks other rights, interests, needs and liberties in society. As Luhmann remarked with regard to the indisputability of norms, values in effect do clash [Luhmann 2008: 28,

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<sup>407</sup> See Chapter 6 section 6.2.1.

<sup>408</sup> Interviews with the Chief Pharmacist at the Ministry of Health and Social Welfare, TFDA and WHO [Dar es Salaam, July-August 2009].

<sup>409</sup> Tanzania grants patents for both processes and products, without expressly excluding pharmaceutical products, since the Tanzania’s Patents Act of 1987 [Tanzania’s Patents Act, 1987: Art 7(1)].

<sup>410</sup> Interviews with leading pharmaceutical companies [Dar es Salaam, July-August 2009].

29]. Intellectual property protection can provide dynamic efficiency through innovation and investment in the pharmaceutical sector. Thus, in considering access to medicines African states also have to encourage research, also considering the need of treatment for the so-called ‘neglected’ disease – endogenous conditions that are not effectively researched [WHO, Diseases of Poverty and the 10/90 Gap, 2004; UNAIDS 2002: 105]. Furthermore, intellectual property can be beneficial for reasons which do not fall within the calculation of access to medicines such as the recognition of reward for the inventive effort or economic growth of the country. The African Commission seems to recognise the positive aspect of patents and therefore condones the action of African states in protecting patents that could in fact *reduce* access to medicines [AC Res. 141 (2008): para. 2(2)(e)].

### 5.2.2 Non-discrimination

The second set of state obligations originating from the duty to respect the human right to medicines relates to the prohibition of discrimination. The ICESCR prohibits discrimination on so-called internationally prohibited grounds which include “race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status” [ICESCR art. 2(2)]. The ACHPR provides a similar list, with the addition of the categories of ethnic groups and the replacement of property with fortune [ACHPR art. 2]. According to the CDESCR the duty of non-discrimination is also a ‘core obligation’, that states should realise immediately, in relation to the human right to health [CESCR 2000: 30, 43(a), 50]. Violations of non-discrimination in access to health care have been found by the African Commission in the context of political detainees.<sup>411</sup> However, the obligation of non-discrimination, which is rooted in the

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<sup>411</sup> Discrimination on internationally prohibited grounds in matters of access to health has been identified with regard to health by the African Commission in the *Mauritania* and in *Media Rights Agenda and Others v. Nigeria* cases relating to non-discrimination of ‘political’ detainees [AC, *Mauritania*, 2000; AC, *Nigeria*, 1998]. Indeed, with regard to the equal access to health services, the CDESCR explicitly mentions prisoners and detainees [CESCR 2000: para. 34]. The non-discrimination of detainees outside the context of prohibited grounds, however, raises its own questions about the extent to which medicines that are not accessible to the whole population shall be provided in prisons by the state – while the prisoner depends entirely for her health care on her custodian. UNAIDS for instance analyses some cases of access to antiretrovirals in Africa [UNAIDS, *Courting Rights*, 2006]. UNAIDS contends that in South Africa

principle of equality, is sometimes seen as incomplete without duties of *substantive* non-discrimination. Unlike formal discrimination, which requires all situations to be treated equally, substantive non-discrimination prescribes that like situations are treated alike and different situations are treated differently.<sup>412</sup> Reading the ICESCR, it seems that at least the child deserves particular attention [ICESCR art 12(2)(a)].<sup>413</sup> Many international treaties for example deal specifically with categories such as women and children, as seen in Chapter 3 section 3.2.1.3. The African Commission has identified an obligation to respect substantive non-discrimination for instance with regard to the treatment of mental illness.<sup>414</sup> According to the CDESCR, states also have to “ensur[e] that... health care staff are trained to recognize and respond to the specific needs of vulnerable or marginalized groups” [CESCR 2000: para. 37(ii)].<sup>415</sup> The CDESCR is however silent on the identity of the ‘vulnerable’ and ‘marginalised’ people. The Special Rapporteur instead identifies ‘vulnerable individuals’ and ‘disadvantaged groups’ as including “women and girls, ethnic minority and indigenous populations, people living in poverty, people living with HIV/AIDS, internally displaced people, the elderly, people with disabilities, prisoners and others” [Hunt 2006: para. 52]. The Special Rapporteur insists that “a State is obliged to establish a national medicine supply system that includes programmes specifically tailored to reach the vulnerable and disadvantaged” [Hunt 2006: para. 54].

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prisoners living with HIV are unable to realise their right to be treated for their illness [*id.*: 125].

<sup>412</sup> Substantive non-discrimination may entail affirmative action facilitating the exercise of rights for some groups. *See* Yamin [2003: 124] specifically on the right to medication (also discussing affirmative action). *See also* the WTO case *EC – Generalised System of Preferences* wherein the WTO Appellate Body held that different treatment can be accorded to different situations in international trade without impinging the non-discrimination clause of the GATT Agreement [WTO, *EC – Generalised System of Preferences*, 2002: para. 172].

<sup>413</sup> The article lists as one of the steps necessary to the realisation of the right to health “[t]he provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child” [ICESCR art. 12(2)(a)].

<sup>414</sup> For instance, in *Purohit and Moore v. The Gambia* the African Commission remarked that mental health patients should be accorded special treatment to enable them to attain and sustain their optimum level of independence and performance [AC, *The Gambia*, 2003: para. 81]. This would be consistent with the ACHPR art 18(4). The Commission also refers to the UN Principles for the Protection of Persons with Mental Illness and Improvement of Mental Health Care [*id.*].

<sup>415</sup> Furthermore, those groups are entitled to priority provision of international medical aid [*id.*: paras. 40, 65]. *See also* Chapter 6 section 6.2.2.

Those remarks are appealing in principle. For example women need special attention for their sexual and reproductive health (*see also* Chapter 2 section 2.2.2) and are often the carers of those who are sick [Oxfam, website, Access to Medicines]. It is not clear however what these indications really entail. Furthermore, typically, the creation of categories excludes those who do not fit into those categories. We shall see in section 5.4 that the prioritisation of health-care resources poses momentous dilemmas for example as the principles of equity, medical need and aggregate welfare clash between each other. Indeed, Luhmann calls for a critical approach with regard to the operationalisation of the right to equality. He notes that this right is exercised with respect to each subsystem in isolation, therefore it is inherently paradoxical, as it does not consider the person as a whole or the context [Luhmann 2004: 135]. As Luhmann stated, “[e]quality means: that no other principles of inclusion are accepted from those that the function systems [*ie* subsystems] themselves determine” [Luhmann 1997(b): 1075 in Moeller 2008: 137]. The efforts of the legal subsystem to operationalise *substantive* non-discrimination, in effect, are also subject to this paradox.

For example I found that the great geographical disparities in access to medicines throughout African states are not necessarily addressed through the application of the principle of non-discrimination.<sup>416</sup> Are such disparities not discrimination?<sup>417</sup> Generally, rural areas tend to be less served by effective state health care facilities, which instead tend to be concentrated in urban areas. In terms of geographical availability of medicines, people living in rural areas often need to utilise private pharmacies or shops [WHO, World Medicines Situation 2004, 2004: 47].<sup>418</sup> This situation influences the affordability of medicines, considering that the private sector tends to be more expensive [*id.*] and that 75% of African poor live in rural areas [IFAD 2001: 1].<sup>419</sup> Furthermore there can be disparities among regions. Indeed, territorial differences in health services can be due to overt, intentional discrimination, in so far as the reason for disparities in public interventions relating to medicines is motivated by the favour of the policy makers for the kith and kin or out of clientelar relations that often affect the African public sphere.<sup>420</sup>

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<sup>416</sup> *See, e.g.*, with regard to antiretrovirals in Uganda, Whyte et al [2004].

<sup>417</sup> *See also* Daniels on morally relevant discrimination [Daniels 1982].

<sup>418</sup> *See* Chapter 2 sections 2.3 and 2.4.

<sup>419</sup> Also recall that few African countries adopt reimbursement schemes on the purchase of pharmaceuticals. *See* Chapter 2 section 2.3.3.

<sup>420</sup> For an account of African political economy, and in particular about the phenomenon of clientelism in the region *see* Chabal and Daloz [1999: 38, 44].

Those bonds can also lead to unintentional discrimination. According to Yamin’s reading of the CESCR, “geographic areas may closely overlap with religious, racial or ethnic identities and discrimination need not be intentional under international law, but merely needs to have the effect of nullifying or impairing the enjoyment of rights” [Yamin 2003: 125]. However, discrimination based on identities does not explain all territorial differences in health-care provision. Individuals can always travel but it is undeniable that disparities in health services exist according to the location – and certainly this occurs worldwide.

To note, policies attempting to obviate those problems sometimes incur in what Luhmann called ‘self-defeating prophecies’, one of the practical limits of political steering [Luhmann 1997: 44]. The Tanzanian Accredited Drug-Dispensing Outlets (ADDOs) programme was meant to increase access to quality medicines in remote areas where access to medicines is poorer.<sup>421</sup> However, it could be seen as *de facto* and substantively discriminatory, privileging the areas where it is implemented. Started in 2003, the programme was supposed to be extended to the whole country by 2011, but just five regions have been covered until now (June 2010). As I had the chance to see, the pilot is managed as a quasi-parallel system for access to medicines in the private sector in the regions where it is implemented rather than as a provisory arrangement.<sup>422</sup> Notably, however, the selection of the pilot regions had not been precisely based on health needs. Among other factors influencing the decision about where the ADDOs would be set up, there were the demands of foreign aid agencies to establish the project in the regions where they were already active.<sup>423</sup> Arguably, nevertheless, there is a trade-off between the quality and reach of policies. Furthermore it can be considered that the resources used on ADDOs are to great extent additional – rather than fungible – to the Tanzanian resources, as they are obtained from extra-governmental actors for this project.<sup>424</sup>

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<sup>421</sup> See Chapter 2 section 2.4 and Chapter 5 section 5.2.2.

<sup>422</sup> For example, the Clinton Foundation and the US President’s Malaria Initiative (PMI) for runs pilot programmes subsidising Coartem in the ADDOs located in selected areas [Clinton Foundation 2008; interviews, Dar es Salaam, July-August 2009]. See Chapter 2 section 2.4.

<sup>423</sup> Interviews with TFDA [Dar es Salaam, July-August 2010].

<sup>424</sup> See generally Chapter 2 section 2.4.

### 5.3 Protect

The CESCR and the African Commission name some activities that states shall undertake in order to *protect* the human right to health in relation to access to medicines [CESCR 2000: 35; AC Res. 141 (2008): para. 2(2)]. Section 4.3.1 investigates the role of states in ensuring respect by third parties while section 4.3.2 analyse the regulation of third parties' behaviour to secure the promotion of access to medicines.

#### 5.3.1 Ensure respect by other actors

States shall act against active, violent impairment of access to medicines or discrimination.<sup>425</sup> Also considering the difficulties in the identification of substantive and or *de facto* non-discrimination seen in section 5.2.2, it is not straightforward to establish if private initiatives, extraordinary programmes, public-private partnerships for the provision of access to medicines perform prohibited discrimination, for instance by charging certain categories higher prices for health insurance, selecting the territory where they operate, providing good care for a limited catchment area (as in the case of ADDOs seen above), or focussing on a single disease, neglecting other health needs. For example, states may prohibit private health insurance schemes which charge with higher prices unappetising categories such as the elderly, the chronically ill or the disabled [CESCR 2000: para. 35]. In this case, the discrimination operated by the insurer is not *intentioned* to harm any group – it is instead *intentioned* to maximise the profit through market skimming – therefore it *arguably* represents *de facto* discrimination.<sup>426</sup> It has to be noted moreover that in effect this state intervention has drawbacks in terms of access

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<sup>425</sup> See Ssenyonjo on the obligation of states to protect against violation of economic, social and cultural rights committed by non-state actors. For instance, reading the IACtHR case *Velasquez Rodriguez v. Honduras*, Ssenyonjo notes that the “responsibility of the state is engaged when there is failure to prevent violations by NSAs where the possibility of such violation is reasonably foreseeable” [Ssenyonjo 2008: 731]. See Chapters 4 and 6 for the direct responsibility of non-state actors.

<sup>426</sup> On the problems of operationalising the prohibition of *de facto* discrimination see section 5.2.2 above with regard to home states' duties and Chapter 6 section 6.2.2 with regard to non-state actors' duties.

to medicines overall, as it increases the costs for insurance companies and consequently the prices of insurance.<sup>427</sup>

Furthermore, states may protect the human right to medicines by controlling the quality of the medicines marketed in their jurisdiction. Quality control entails different activities such as control of manufacturing practices, registration of safe products and control of the products circulating in the market against counterfeits. The trade of counterfeit medicines, for example, is rife in Africa and demands rigorous, expensive policing efforts.<sup>428</sup> The registration of new medicines (*ie* the approval of a new medicine in the market on the basis of safety, quality and efficacy) is particularly problematic. Medicines regulation implies gate-keeping of health risk and therefore entails conspicuous biopower. States however have to take regulatory decisions under uncertainty or even ‘ignorance’, as the safety and efficacy of certain products may not be conclusively established in science and medicines [Paterson 2010].<sup>429</sup> In effect, it is not possible to determine *a priori*, for example with clinical trials, all the consequences of a medicine’s intake. Reportedly, worldwide the regulatory requirements are becoming

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<sup>427</sup> States could instead opt to insure by themselves the neglected categories.

<sup>428</sup> According to WHO, “[m]any countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit” [WHO, Counterfeit Drugs Kill, 2008: 3]. Furthermore, a WHO survey of the quality of antimalarials in seven African countries revealed that between 20% and 90% of the products failed quality testing (*ie*, they were ‘substandard’) [WHO, World Health Organization Steps Up Action Against Substandard and Counterfeit Medicines, 2003]. *See also* Bate et al [2008]. Substandard Metakelfin, an antimalarial has been discovered in Tanzania by TFDA in 2009. The product was totally ineffective against malaria and has been withdrawn from the market [TFDA, Taarifa Kwa Kuhusu Kuwepo Kwa Dawa Bandia Za Vidonge Za Metakelfin Katika Soko La Dawa Hapa Nchini, 2009]. Substandard medicines are dangerous for the individual who takes them as they can be diluted with poisonous materials or anyway be ineffective against the condition she suffers. They are also dangerous in terms of public health, as they can contain a reduced dosage of active ingredient which would stimulate the resistance of the antigen treated.

<sup>429</sup> Paterson in particular analyses the possibility of judicial review of the state policies and regulations which implement the precautionary principle. Utilising the framework of systems theory Paterson concludes that judicial review in this field is warranted, if judges reflexively comprehend the problem of environmental ignorance – that is, the impossibility to assign probabilities to different choices [Paterson 2010]. On the importance of ignorance as a strategic resource within regulatory and bureaucratic organizations *see* Luhmann [1998] and McGoey providing an empirical application of these concepts with regard to drugs regulation [McGoey 2007].

more demanding.<sup>430</sup> However, such trend has been subject to critique as delays in the registration of pharmaceuticals mean retarded availability of the products<sup>431</sup> and costs for the pharmaceutical firms.<sup>432</sup> Some have indeed argued that in poorer countries the balance should be all the more tilted in favour of new medicines, because of the greater burden of disease and the lower level of medical resources available [Jack 2007].<sup>433</sup> In effect, the registration of continuously new medicines poses a particular challenge to African regulatory authorities which often lack scientific and technical means for assessing the most advanced formulations.<sup>434</sup> Médecins Sans Frontières (MSF) has specifically reported on the slowness of such procedures for access to antiretrovirals in

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<sup>430</sup> OECD reckons that over the period from 1960s to 1990s the number of clinical trials per drug application raised from 30 to 60, and the number of patients in trials doubled [OECD 2001: 39].

<sup>431</sup> A literature has developed arguing that the approach of regulatory agencies such as the US Food and Drug Administration (FDA) is too skewed against risk – and therefore potential benefit. Referring to the FDA, The Economist proposes that “[f]aster approval of new drugs in humans should be matched by more rigorous post-launch testing and surveillance... The starting point is that the FDA and its counterparts across the world need to move from a risk-obsessed, ‘one size fits all’ approach to a more flexible system that considers the risks and benefits of new therapies. Rather than asking drugs to undergo many years of costly trials in the vain pursuit of medicines that are safe for all in all circumstances, regulators should allow speedier conditional approvals” especially considering targeted therapies based on genomics [The Economist, From Bench to Bedside, 2007]. See also Sauer and Sauer [2005]. See also Chapter 6 section 6.2.1.1.

<sup>432</sup> Abraham reports that a manufacturer can lose on average over US\$1 million for each day’s delay in gaining marketing approval from the FDA [Abraham 2002: 1498].

<sup>433</sup> Jack reports that “[o]ne problem for such developers is that the regulators’ assessment of the relative balance of risks and benefits of a new medicine or vaccine in the developed world is not the same as for their counterparts in poorer countries, because of the greater burden of disease and the lower level of medical resources available. For example, when Wyeth’s RotaShield vaccine for rotavirus – a gastric infection that causes thousands of hospitalisations each year but very few deaths in the US – was linked to an extremely rare but serious side-effect in 1999, the company withdrew it from the market. But in the developing world, where rotavirus causes up to 500,000 deaths a year and access to hospital care is less easy, the benefits have since been judged to outweigh the risks. That is one reason why GlaxoSmithKline sought regulatory approval first for its rival Rotarix vaccine in Mexico, in 2004” [Jack, Two Faces to Speedy Medicine Approval, 2007].

<sup>434</sup> In Tanzania, for the registration of new products TFDA first checks the ‘negative literature’, *ie* if the components of a product are known to be dangerous. Consequently TFDA studies the dossiers provided by the pharmaceutical company which reports on the trial conducted. Admittedly, this information is biased, even though the clinical trials are checked by government authorities. TFDA consequently commits to monitor the product once launched in the market through ‘pharmacovigilance’ [Interviews at TFDA July-August 2009, Dar es Salaam].

these countries.<sup>435</sup> It has to be noted however that delays in the registration can occur due to acts external to state action. Namely, pharmaceutical corporations may decide not to register new products in a country.<sup>436</sup> In sum, in order to protect the human right to medicines, the home states are expected to take binding decisions, but such exercise of power and biopower imposes problematic moral choices and can be practically challenging. The human right to medicines does not give precise prescriptions about the response of states to such contingencies.

### **5.3.2 Regulate promotion of access to medicines by third parties**

The CESC and the African Commission pinpoint some activities that states shall undertake to regulate third parties' behaviour to secure the promotion of access to medicines. Regulation on these matters is problematic in terms of power and biopower. For example, states can control the prices of medicines [AC Res. 141 (2008): para. 2(2)(iii)] and intervene on the territorial distribution of pharmaceutical outlets. Price controls can be implemented in the context of public purchasing and/or can be levied at the pharmacy retail level [Grace 2003]. Price controls at the producer level present a series of problems.<sup>437</sup> To begin with, the 'fair' price has to be determined, and this is contentious. Pharmaceutical products are not exchanged in classically competitive markets, and may deliver exceptional profits. It can therefore be suggested that those

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<sup>435</sup> See Chapter 6 sections 6.2.1.1 and 6.3 on the international action for the regulation and registration of medicines.

<sup>436</sup> Pharmaceutical companies for example can decide not to register new products in a country giving the lack of interest for a country's market, or can utilise this strategy in retaliation against a government's hostile policy (e.g. price controls or lack of protection of intellectual property). See Chapter 6 section 6.2.1.2. Lack of registration is unfortunate especially if generic equivalents are not available in the country. If the products are deemed to be safe, however, governments can issue special authorisations for importation. For instance, MSF had to request special authorisation for Merck's efavirenz, GSK's abacavir, Abbott's lopinavir/ritonavir, Cipla's lamivudine/stavudine/nevirapine and Gilead's renofovir in Cambodia, Uganda, Guatemala, Honduras, Laos, Ethiopia and other countries [MSF, *Untangling the Web of Price Reduction*, 2005: 7]. The effect to access to medicines in sub-Saharan Africa of delayed registration of antiretroviral generics in the US is presented in Chapter 6 section 6.2.1.1.

<sup>437</sup> See generally Tetteh reporting that African countries do not generally undertake price controls and analysing the options of price controls in this region [Tetteh 2008].

profits should be capped.<sup>438</sup> However, the pharmaceutical sector is also particularly risky and capital-intensive [Burns 2005] so the high returns on a product provide an incentive to research and develop new products [Grace 2003]. Different criteria can be adopted for the identification of the ‘fair’ price, although they all present problematic aspects.<sup>439</sup> Moreover, the price would have to be accepted by the manufacturer. The manufacturer holds a special bargaining position not only if the product in question is patented, but also if competition in the product’s therapeutic class is poor.<sup>440</sup> Indeed, there is no perfect generic competition in the pharmaceutical sector, and the pharmaceutical market is generally consolidated [Buse and Walt 2002:51; Chaudhuri 2005: 13; The Economist, Prescription for Change, 2005; Klimek & Peters 1995: 74; Levy 1999:196; OECD 2001: 33].<sup>441</sup> As a result, pharmaceutical corporations often have market power to retaliate to unfavourable state policies, for instance, by divesting, withdrawing from or not entering a market.<sup>442</sup>

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<sup>438</sup> As Evans and Padilla note, the competitive price is not the marginal cost in markets where competition is dynamic, significant economies of scale and/or scope, high fixed costs and low incremental costs [Evans and Padilla 2005]. See Chapter 2 section 2.3.2.

<sup>439</sup> Rietveld and Haijjer-Ruskamp identify the following options – and their relative drawbacks. ‘Cost plus calculations’ would be desirable considering that it is precisely the *uncompetitive* excessive price (as opposed to the price in competitive markets which theoretically corresponds to the marginal cost) that price controls ought to regulate. Yet it presents problems of: information on the real costs incurred by the manufacturer; allocating overhead and research costs to the single product; and attributing costs between parent firm and subsidiaries. Generally the methodology curtails incentives to efficiency. ‘Profit ceilings’ seek to control the profitability of a company as a whole rather than margins of individual products. It is again prone to difficulties with respect of the accounting of multinationals. This method is used for instance in the UK, through the Pharmaceutical Price Regulation Scheme, where there are domestically based producers. By ‘comparative pricing schemes’ (or external reference pricing), prices are set referring to the prices in other countries. African countries should have to consider applying a reduction given their financial situation. ‘Price negotiation models’ work better for generics and when the purchaser bargaining power is considerable. ‘Pharmaco-economic evaluations’ are interesting in identifying the clinical effectiveness of a medicine as compared to other treatments and thence establishing the willingness to pay for it. Problems rest in the uncertainty of the science underpinning such estimates and in the propensity to vested pressures from the pharmaceutical sector onto the politicians [Rietveld and Haijjer-Ruskamp 2002: 31-35]. See also OECD [2001].

<sup>440</sup> *Viz.* the so-called ‘rule-of-fives’: lowest prices are achieved in the market when at least five therapeutic alternatives are available from five competing producers [WHO and WTO Secretariats 2001: 16].

<sup>441</sup> See also Chapter 2 section 2.3.2.

<sup>442</sup> Lanjouw reports that in lower-income countries *extensive* price controls lowers the probability that new pharmaceutical products reach consumers quickly. *Moderate* price controls can also influence the introduction of new products in the poorest countries,

Prices may also be controlled at the distribution level, that is, at wholesaler and pharmacy retailing level, which can add conspicuous mark-ups [Madden et al 2003; Levison and Laing 2003].<sup>443</sup> Special caution shall be taken in fixing prices not to erode the economic viability of retailers which incur high operating costs and low sale volumes especially in marginal areas [OECD 2001: 50]. Regulation can guarantee revenues planning the number of pharmacies which a certain population should attend and setting minimum distances between shops [*id.*]. However, such approach does not make more appetising the African poorest and sparsely populated regions.<sup>444</sup> In sum, price controls can be another self-defeating policy tool: by eroding profits, they may also erode the incentive to provide medicines in the least appealing African markets.<sup>445</sup> In effect, African countries do not generally undertake price controls [Tetteh 2008].

States can protect the enjoyment of the human right to medicines through the regulation of intellectual property and competition law [AC Res. 141 (2008): para. 2(2)(v)]. Some problems regarding the operationalisation of intellectual property law have been analysed in section 5.2.1 above. The scope of competition law is broad, spanning the regulation of horizontal agreements, vertical agreements, abuse of dominance, intellectual property and mergers [Whish 2005]. Competition law is usually framed on the promotion of consumer welfare and economic efficiency.<sup>446</sup> This regulatory tool could however be informed and utilised for the human right to medicines. Competition policy instruments, for example, can proscribe excessive pricing (an abuse of market power). Yet, this concept is problematic to operationalise and enforce. An

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given these countries' less efficient regulatory procedures which slow price negotiations [Lanjouw 2005]. *See also* Chapter 2 section 2.3.2.

<sup>443</sup> Reportedly hidden costs, which include entry procedures, taxes, and allowable mark-ups increase the price of medicines by 70% on average in selected countries [Levison and Laing 2003].

<sup>444</sup> It has been noted that delivery costs are much higher in sub-Saharan Africa because of the low population density [Foster 1987]. OECD suggests using tendering for scattered areas while having price controls and free market where competition is possible [OECD 2001: 50]. However, this strategy if applied in sub-Saharan Africa would exacerbate the problems of affordability in rural areas. An alternative to product-oriented retail price setting are patient-oriented systems (based on capitation systems or fixed fees per prescriptions), applicable where medicines are covered by health insurance [*id.*], which is not common in sub-Saharan Africa. *See* Chapter 2 section 2.2.3.

<sup>445</sup> Reportedly Africa accounts for 1.2% of global pharmacy market (and the figure is even smaller for sales of patented medicines) [Friedman et al 2003: 341-343].

<sup>446</sup> *See also* the Tanzanian Fair Competition Act and the South Africa, Competition Act [Tanzania, Fair Competition Act 2003: art. 3; South Africa, Competition Act, as amended in 2001, preambular paras. 7-8, 10-11].

important case which has been presented at the Competition Commission in South Africa, *TAC v. GSK, BI and others*, shows such complexities. The case mainly regarded an allegation of excessive prices of some on-patent antiretrovirals.<sup>447</sup> Interestingly, the complaint explicitly referred to human rights and to the human right to health care. In a nutshell, the complainants proposed an algorithm for determining the reasonableness of the relation between a price charged for a good and the economic value of that good. The complainants suggested that attention shall be paid to the price of the good in a competitive market, including some allowances for research and development costs and profit, to the particular detriment to the consumers, and to the “the adverse impact of the high prices on constitutionally protected and internationally recognised rights”, namely, the rights to life, dignity and access to health care services [Tau et al 2002: para. 60]. The Commission consequently found that the respondents violated prohibitions against excessive pricing.<sup>448</sup> The episode has been concluded with a settlement agreement for the licensing of the patented products in question [South Africa Competition Commission 2003]. It has to be noted, though, that TAC’s reasoning if applied generally may annihilate the incentive of research-based pharmaceutical companies which arguably endure on the super-profits made from few blockbuster medicines.<sup>449</sup> We have seen few paragraphs above that the identification of a ‘fair’ price is in fact problematic.

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<sup>447</sup> The South African Competition Act prohibits a firm in a dominant position to charge excessive prices to the detriment of the consumer [South Africa, Competition Act, as amended in 2001, sec. 8(a)].

<sup>448</sup> The Commission also found that the respondent refused access to essential facilities and exclusionary acts that have an anticompetitive effect that outweighs technological, efficiency or other pro-competitive gains [South Africa Competition Commission 2003(b)].

<sup>449</sup> See Napp’s appeal to the UK Competition Commission Appeal Tribunal, arguing that pricing should be assessed with portfolio-based approach where prices and profitability for a range of different products are jointly assessed. The Appeal Tribunal did not yield such appeal [United Kingdom Competition Commission Appeal Tribunal, *Pharmaceutical Holdings v Director-General of Fair Trading*, 2002: paras. 357, 361; Evans and Padilla 2005: 107]. See generally, on the problems of finding a fair price, Evans and Padilla [2005].

## 5.4 Fulfil

Section 5.4 examines the obligation of African states to *fulfil* a human right to medicines. According to the CDESCR and the African Commission states shall ‘promote’, ‘facilitate’ and ‘provide’ access to medicines [CESCR 2000: para. 33; AC Res. 141 (2008): para. 2(3)]. Certain actions for the promotion and facilitation of access to medicines have been reviewed in the sections above, for example regarding the regulation of intellectual property, the promotion of research and development, the regulation of the quality of medicines, the provision of medical insurance by the private sector and the regulation of competition in the pharmaceutical sector.<sup>450</sup> This section focuses on the ‘provision’ by states of access to medicines. In particular, access to ‘essential’ medicines is deemed by the CDESCR, the African Commission and the Special Rapporteur to be a fundamental obligation of result that states shall satisfy immediately [CESCR 1990(b): para. 10; CDESCR 2000: 43, 47; AC Res. 141 (2008): 2(3)(a); Hunt 2006: para. 38]. Apparently, no resources shall be spared, as this injunction is not conditional on the available resources. Therefore, this obligation could be applied directly to the situation of access to medicines in sub-Saharan African countries where access to medicines is shortcoming. However, it has to be considered that the budget of African countries is limited.<sup>451</sup> This raises the question: to what extent shall more resources be collected and distributed for ‘essential’ medicines? To what extent shall other rights, interests, needs and liberties be overridden? Within the CDESCR framework itself, for example, there are other core needs “of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education” [CESCR 1990(b): para. 10]. Whereas those questions are pertinent, in the following sections I confine the enquiry to what is meant for provision of ‘essential medicines’ – thereby also asking whether access to medicines has the ‘legitimacy’ to be an overriding (‘*indispensable*’) minimum core obligation. Section 5.4.1 illustrates the problem of identifying ‘essential’ medicines and, more generally, priorities among health-care interventions. This section mainly refers to the ICDESCR and the ACHPR regimes. Section 5.4.2 elaborates on the doubts raised within the human rights framework presenting the ethical problems of setting priorities in health interventions. The contributions from other disciplines such as the philosophy of distributive justice and

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<sup>450</sup> See above sections 5.2.1 and 5.2.2.

<sup>451</sup> See Chapter 2 section 2.3.3.

medical ethics are analysed. Section 5.4.3 finally deals with the enforcement of the fulfilment of the human right to medicines.

#### **5.4.1 The identification of ‘essential’ medicines and health interventions prioritising according to the ICESCR and ACHPR regimes**

Access to ‘essential’ medicines is deemed by the CESCR, the African Commission and the Special Rapporteur on the right to health to be a fundamental obligation of result that states shall satisfy immediately [CESCR 1990(b): para. 10; CESCR 2000: 43, 47; AC Res. 141 (2008): 2(3)(a); Hunt 2006: para. 38].<sup>452</sup> According to the Special Rapporteur, nonetheless, the right to health encompasses ‘non-essential’ medicines as well [Hunt 2006: para. 38]. In effect, ‘essential’ medicines are typically a selection of prioritised medicines. The CESCR does not directly identify what essential medicines are, but it refers to the medicines “from time to time defined under the WHO Action Programme on Essential Drugs”, a document which corresponds to the WHO Model List of Essential Drugs [CESCR 2000: para. 43(d) and note 5]. The African Commission identifies essential medicines referring to the country’s essential medicines list and the WHO Action Programme on Essential Drugs AC Res. 141 (2008): 2(3)(a). In effect, the sources referred to by the CESCR and the African Commission are open-ended. As the WHO itself maintains, the WHO Model List of Essential Medicines is purely indicative and does not relate to the health problems of individual countries [WHO, *The Selection and Use of Essential Medicines*, 2003: 55]. WHO’s list is indeed meant to guide the development of national and institutional essential medicine lists

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<sup>452</sup> The Special Rapporteur makes clear that “the right to health encompasses access to non-essential and essential medicines. While a State is required to progressively realise access to non-essential medicines, it has a core obligation of immediate effect to make essential medicines available and accessible throughout its jurisdiction” [Hunt 2006: para. 58]. *See also* Chapter 3 sections 3.2.1.1 and 3.2.1.2.

(EMLs).<sup>453</sup> Fundamentally, WHO recommends states to identify essential medicines as:<sup>454</sup>

[...] those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost effectiveness... exactly which medicines are regarded as essential remains a national responsibility. [WHO, The Selection and Use of Essential Medicines, 2003: 54]

Once identified at the national level, essential medicines are to be set in a national essential medicines list [WHO, How to Develop and Implement a National Drug Policy, 2001: 7]. Most African states do compile EMLs.<sup>455</sup> The lists generally contain between 200 and 400 medicines and can serve as a guide for medicine supply in the public sector, medicine benefits within reimbursement schemes, medicine donations, local production and be linked to national clinical guidelines used for training and supervision [WHO and HAI 2008: 28, 34]. The aim of the lists is to concentrate resources and rationalise the use of medicines in a country, *ie* a use of ‘fewer drugs more effectively’ [*id.*: 28]. Moreover, generally the governments decide centrally which essential medicines are to be made available at the different levels of care (primary, secondary, tertiary level).

The very selection of essential medicines, therefore, exerts power and biopower, as it has considerable impact on access to medicines. Essential medicines are not simply the most cost-effective within their therapeutic class; they also represent a selection of

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<sup>453</sup> The UN Special Rapporteur sees WHO’s List as a default mechanism, maintaining that “[i]f a State declines to prepare its own national essential medicines list, the WHO model list will apply, subject to any obvious contextual revisions” [Hunt 2006: para. 57]. Hunt refers to the CESCR comment for backing this statement [*Id.*: footnote 42; CESCR 2000: paras. 12(1) and 43(4)].

<sup>454</sup> The comment refers to the Action Programme on Essential Drugs in the WHO Model List of Essential Drugs, revised December 1999, allegedly published in WHO Drug Information Vol. 13, No. 4, 1999 [CESCR 2000: endnote 5]. In WHO Drug Information I could not find the “Action Programme”, nor a definition of essential medicines/drugs (a document named “WHO Action Programme on Essential Drugs Collaboration between NGOs, Ministries of Health and WHO in Drug Distribution and Supply, 1999”, does not mention essential drug lists). I consequently refer here to the 2003 Technical Report Series 920, “The Selection and Use of Essential Medicines” [WHO, The Selection and Use of Essential Medicines, 2003]. Leach and colleagues as well, for the Millennium Task Force, utilise the definition proposed in “The Selection and Use of Essential Medicines” (they actually refer the definition to the “2004 World Medicines Strategy”, but I could not find the definition in that document) [Leach et al 2005: 151].

<sup>455</sup> Nearly all developing countries – 95% – have a published EML, 86% updated in the past five years [UN, Delivering on the Global Partnerships for Achieving the Millennium Development Goals, 2008: 36].

the health problems to be tackled. For instance, WHO has for long excluded treatment for HIV/AIDS from the lists, as vocally lamented by civil society groups [Laing 2004: 1725].<sup>456</sup> Antiretrovirals to treat HIV are not present in the EMLs of some of the African countries hardest hit by the AIDS pandemic, such as South Africa [South African Standard Treatment Guidelines and Essential Drugs List for Primary Health Care 2003].<sup>457</sup> Love also notes that on-patent medicines tend not to be included in the WHO EDL.<sup>458</sup> Love submits that this is a distortion as many patented medicines currently not on the EDL would be included, were they available at generic prices. For instance the most recent list includes no patented anti-cancer drugs, and the core list includes no anti-cancer drugs at all [Love 2006]. Therefore, Love asks the WHO to include in the EDL the somewhat paradoxical category of medicines “essential ‘if available at generic prices’” [*id.*]. In sum, ‘essential’ medicines are not to be confused with ‘vital’ medicines. The question is how to identify what WHO’s definition indicated as the ‘priority health needs of the populations’. For example, do those needs correspond to the most common conditions? To the most severe? To what a population itself identifies as priority? To the needs of the vulnerable and the marginalised?

The framework of the human right to health in effect does not give a precise answer about priorities in health care. To begin with, with regard to the object of the intervention, it sometimes refers to public health, prevention and primary health care, while other times it refers to a medical approach, curative, also supporting secondary and tertiary care.<sup>459</sup> Tomasevski for example remarks that “in defining the obligations of States that correspond to the human right to health, priority is accorded [by international human rights law such as that originating from the ICESCR] to *public* health measures” [Tomasevski 1995: 125, *emph. orig.*]. Public health is a discipline that has been defined as the “collective action for sustained population-wide health improvement” [Beaglehole

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<sup>456</sup> Some antiretrovirals, however, have been introduced in the most recent versions of the WHO EML, relaxing the requirements of cost-effectiveness [Laing 2004: 1725].

<sup>457</sup> South Africa’s government, notwithstanding the absence of antiretrovirals from its essential medicines list, has started to provide testing and treatment free in public hospitals – yet the take-ups remain low [Chopra et al 2006: Hadley 2008].

<sup>458</sup> Love recalls that only 14 (12 on the core list and two on the complimentary list) of the total 312 medicines on the [2005] EDL are under a US patent [Love 2006]. Reportedly, less than 5% of medicines of the WHO’s essential drugs list are subject to patent protection [Ghafele 2008: 16]. *See supra* section 5.2.1.

<sup>459</sup> Roughly, primary care is the first point of consultation, secondary care is specialist and tertiary care is specialised on referral.

and Bonita 2004: 174].<sup>460</sup> The very concept of the human right to health has been traced in the early public health measures [Toebes 1999: 8-14; Hestermeyer 1994: 111]. Three out of four steps sanctioned by the ICESCR can in effect be seen under the perspective of public health, namely, the concern for child and maternal health, for environmental and industrial hygiene, and for epidemic, pandemic, occupational and other diseases [ICESCR art.12(2)(a), (b) and (c)]. Furthermore, within medical interventions, the CESCR states that essential primary health care is a minimum core obligation that shall be realised immediately [CESCR 2000: para. 19, 43, note omitted]. Primary health care is often identified as a typical ‘public health’ policy [World Bank, Public Health and World Bank Operations, 2002: 5]. Primary health care however is *a* particular modality of health assistance to be implemented in the context of health systems.<sup>461</sup> Its

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<sup>460</sup> This definition is normative, as the authors advocate the reduction of health inequalities, the importance of sustainability, and the fit of policies in the supportive systems [Beaglehole and Bonita 2004: 174]. The American Public Health Association has synthesized the many definitions and perspectives on public health and identified six basic principles of contemporary public health theory and practice (APHA): a) emphasis on collective responsibility for health and the prime role of the state in protecting and promoting the public’s health; b) focus on whole populations; c) emphasis on prevention, especially the population strategy for primary prevention; d) concern for the underlying socioeconomic determinants of health and disease, as well as the more proximal risk factors; e) multi-disciplinary basis which incorporates quantitative and qualitative methods as appropriate; and f) partnership with the populations served [World Bank, Public Health and World Bank Operations, 2002: 5].

<sup>461</sup> Again, primary health care is not a clear concept, as also recognised by the CESCR [CESCR 2000: endnote 9]. Primary health care was originally meant to provide a route for the achievement of affordable universal coverage. However, it is arguably *a* health programme, to be implemented within health systems. As WHO contends in its World Health Report 2000, the implementation of primary health care has been problematic, also because its meaning is in fact ambiguous. The Alma-Ata declaration defines it as “essential health care based on practical, scientifically sound and socially acceptable methods and technology made universally accessible to individuals and families in the community through their full participation and at a cost that the community and country can afford to maintain at every stage of their development in the spirit of self-reliance and self-determination. It forms an integral part both of the country’s health system, of which it is the central function and main focus, and of the overall social and economic development of the community. It is the first level of contact of individuals, the family and community with the national health system bringing health care as close as possible to where people live and work, and constitutes the first element of a continuing health care process” [Alma-Ata Declaration, para. VI]. In effect, the term ‘primary’ “quickly acquired a variety of connotations, some of them technical (referring to the first contact with the health system, or the first level of care, or simple treatments that could be delivered by relatively untrained providers, or interventions acting on primary causes of disease) and some political (depending on multisectoral action or community involvement)” [WHO, World Health Report 2000: 13]. The Southern African Development Community (SADC) defines ‘Primary Health Care’ as “means essential

implementation, especially in developing countries, is not devoid of drawbacks [WHO, World Health Report 2000: 15]. Thus, the CESCRC seems to hold a penchant for public health. Attention to curative approaches is nonetheless sanctioned by the ICESCR. Indeed the steps referred by the ICESCR for the members to follow include the “[t]he creation of conditions which would assure to all medical service and medical attention in the event of sickness” [ICESCR art 12(2)(d)]. The wording is hesitant, but the same article also binds members to take steps for the treatment of different kinds of diseases [*id.* art 12(2)(c)]. Even more decisively, the ACHPR asks members to take measure “to ensure that they receive medical attention when they are sick” [ACHPR art. 16(2)].

Indeed, besides the problem of the object of such right – public health or medical care measures – lays the problem of the subject of such right, namely, if it is the individual, the population or groups. Tomasevski for instance remarks that international human rights law envisages two sets of norms relating to health. On the one hand, the human right to health creates entitlements for individuals and corresponding obligations for governments. On the other hand, the protection of public health constitutes legitimate grounds for limiting human rights [Tomasevski 1995: 125]. Thus, with regard to the latter aspect of the norm, public health often demands to limit human rights such as the right to privacy, autonomy, or even the human right to health of the individual, in favour of the collective interest [Beaglehole and Bonita 2004: 264-266; D’Oronzio 2001].<sup>462</sup> With regard to the former aspect of the norm, conversely, the ICESCR and the ACHPR respectively refer to the highest or best attainable standard of health, which seems to imply a personalised approach to health needs referring to the biological preconditions of the individual [ICESCR art. 12 para 1; ACHPR art. 16].<sup>463</sup> Toebees, indeed, argues that the human right to health is uncompromisingly private, therefore pertains to individuals or groups rather than the public. Thus it should not be a tool for states to take public health measures.<sup>464</sup> The CESCRC, instead, does not identify a conflict between the

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health care based on appropriate, acceptable methods and technology, made universally accessible through community participation” [SADC Protocol on Health art. 1].

<sup>462</sup> For instance, vaccinations may be imposed that could have side effects. O’Neill remarks that while (the new) medical ethics is centred on autonomy, it has “relatively little to say about public health, where interventions are often (and sometimes necessarily) compulsory” [O’Neill 2002: 36].

<sup>463</sup> See Chapter 3.

<sup>464</sup> Toebees also adds that perhaps [sic] the limitation clauses in civil and political rights are more suited to offer protection against public health threats [Toebees 1999: 275].

individual and the collective dimension stating that both dimensions are recognised by the human right to health:

[r]egardless of whether groups as such can seek remedies as distinct holders of rights, States parties are bound by both the collective and individual dimensions of article 12. Collective rights are critical in the field of health; modern public health policy relies heavily on prevention and promotion which are approaches directed primarily to groups. [CESCR 2000: para. 59 footnote 30].

Moreover, the CESCR identifies certain groups as deserving particular attention, and others as requiring less attention.<sup>465</sup> In particular, with regard to vulnerable and marginalised groups the Committee maintains, *inter alia*, that the ‘vulnerable members of society’ must be protected ‘even in times of severe resources constraints’, by the adoption of relatively low-cost targeted programmes [CESCR 1990(b): para. 12]. The African Commission and the UN Special Rapporteur on the human right to health also recommend special attention to the vulnerable and marginalised, even though falling short of demanding affirmative action.<sup>466</sup> Furthermore, the CESCR states that “investments should not disproportionately favour expensive curative health services which are often accessible only to a small, privileged fraction of the population, rather than primary and preventive health care benefiting a far larger part of the population” [CESCR 2000: para. 19, note omitted].

In conclusion, the ICESCR and the ACHPR regimes do not prescribe with precision the operationalisation of the fulfilment of the minimum core obligation to provide essential medicines. They do not establish clearly what ‘essential’ medicines are and do not set consistent instructions for the utilisation of resources for realising the human right to health. Such contingency should not be taken lightly. From a legal point of view it is paradoxical that *human*, subjective, rights may be concerned with and applied through collectivities (populations and groups).<sup>467</sup> From a normative point of view, as it is discussed in the following section, the biopolitics of priority-setting in health care is a sensitive matter rife with moral predicaments.

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<sup>465</sup> See also above section 5.2.2 on non-discrimination.

<sup>466</sup> See also above section 5.2.2 on non-discrimination.

<sup>467</sup> On the relationship between human rights, group rights, and people’s rights see Jones [2003].

#### 5.4.2 The prioritisation of health interventions: aggregate status of a population, individual need and equity

This section examines the ethical problems of biopolitical choices concerning which health interventions are to be prioritised and provided. It points out the decisions that have to be taken when choosing between the types of measures that will be administered and the recipients that will be served.<sup>468</sup> Indeed, three main principles/goals can be identified as informing choices of health interventions prioritisation: the health improvement of the aggregate status of a population, the response to individual needs, and the promotion of equity.<sup>469</sup> A focus on the aggregate health status of a population entails that greatest attention should be dedicated to the health conditions which are most prevalent and most threatening for a population. The benefits to a population can be measured in terms of reduction of the national ‘burden of disease’, for instance measured through aggregate disability-adjusted life-years (DALYs) or quality-adjusted life-years (QALYs).<sup>470</sup> Resources are then to be allocated on the basis of cost-effectiveness analysis, in order to discover the highest health impact per resource spent [Hammer and Berman 1995: 31].<sup>471</sup> This is the principle that WHO and the World Bank recommend for African and developing countries to adopt in health interventions prioritisations [CMH 2001; World Bank, World Development Report, 1993; WHO, The World Health Report, 1993; WHO, Tough Choices, 2006]. African countries, such as Tanzania, assess and consider the burden of disease and use it in articulating their policies [Tanzania’s MOH, Burden of Disease, The Morogoro District, 2001]. The criterion is also adopted in order

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<sup>468</sup> The section therefore focuses on the macro (*e.g.*, national) level. Cost containment decisions are usually implemented in health care both at the macro (national) and at the micro (individual) level [Kapiriri and Norheim 2004: 172; Laurie and Mason 2006: 414, 428].

<sup>469</sup> This account draws liberally from Hammer and Berman, who identify three goals and principles of public health policy in developing countries: improving aggregate health status, relieving equity/poverty, and improving individual welfare [Hammer and Berman 1995].

<sup>470</sup> DALYs are defined as “a measure of the future stream of healthy life (years expected to be lived in full health) lost as a result of the incidence of specific diseases and injuries”, *ie* a sum of “both premature mortality (years of life lost because of premature mortality or YLL) and disability (years of healthy life lost as a result of disability or YLD, weighted by the severity of the disability)” [World Bank, The Global Burden of Disease and Risk Factors 2006: 3]. QALYs, *ie* quality-adjusted life years, are the inverse form of DALYs [*id.*: 48]. *See also* Chapter 2 section 2.2.1.

<sup>471</sup> *See* Chapter 6 section 6.4.1.

to address the benefits of health interventions on development and economic growth, that is, the economic subsystem.<sup>472</sup>

Besides the technical difficulties of estimating DALYs or QALYs, such approach is prone to some criticism from an ethical point of view. For example, the emphasis on the aggregate health status of a population brought to the extremes suggests the concentration of public health interventions in densely populated regions, where economies of scale are probable and more ‘benefit’ is to be reaped given the greater number of individuals served at one time [Hammer and Berman 1995: 36]. Also, it may induce to exclude the elderly from health care, as their life expectancy is shorter and thence their life has lower value.<sup>473</sup> The emphasis on disease reduction as the only goal of health services, finally, ignores concerns of equity [Lilani Kumaranayake and Damian Walker 2002: 153]. In effect, the choice of burden of disease as the representation of population health needs derives most of its appeal from a prudential – as opposed to moral – stance. Sheaff argues that under a prudent course of action the individual, who is uncertain of what types of ill health might befall him, assumes that the relative size of different care groups indicates the relative probability that he will need that kind of care in future [Sheaff 1996: 176]. From this, ‘population health needs’ would be construed. However, the needs of the care groups composed by those exposed to particular risks, or whose risks cannot affect the ‘living’ others (such as genetic diseases) have to be elaborated from an impartial or objective standpoint, *ie* through an ethical approach, lest being neglected [*id.*: 169]. Sheaff also notes that “the assumptions built into cost-benefit analysis in general, and QALY analysis in particular, are simply false in respect of non-additive characteristics such as health and of entities such as populations” [*id.*: 170]. It is pointed out however that the elaboration of an ‘ethical approach’ is by no means straightforward.

In alternative to the ‘aggregate status of the population’, decisions for the prioritisation of medical interventions at the population level may be informed on

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<sup>472</sup> Thus, the cost-effectiveness of the provision of certain medicines with respect to other interventions may be based on the benefits for the economy or national wealth. Yamin reports that such were the concerns considered in the Costa Rican *Alvarez* case where the use of national resources was discussed [Yamin 2003: 136; Costa Rica Constitutional Court, *Alvarez*, 1997].

<sup>473</sup> Especially, if DALYs are considered [Hope et al 2002: 146].

considerations relating to ‘individual need’ or ‘equity’ [Hammer and Berman 1995].<sup>474</sup> These principles are more attentive to the individual. However, they are difficult to operationalise and implement. Philosophical perspectives of distributive justice have explored these issues. To begin with, the *ambit* of distribution has to be identified. Health can be seen as instrumental to other moral concerns (welfare, needs) or as a separate moral good, that thereby should be accorded a distributive route on its own [Hurley 2007: 318]. Dworkin argues that health care has to undergo resources prioritisation together with any other good [Dworkin 1993] while Daniels argues that health is special and cannot be factored into a resource-based theory of justice along with other resources [Daniels 1985]. For the sake of simplicity we confine to analyse the distribution of health resources – thereby overlooking the opportunity cost of the use of those resources for other aims in society.<sup>475</sup> The *object* of distribution has yet to be identified. The focus on welfare encounters some paradoxes, as the generation of welfare is subjective. With regard to health welfare (or ‘well-being’), a disabled or a sick may be happy yet ‘unhealthy’,<sup>476</sup> while people with so-called ‘expansive tastes’ may be miserable unless they get sophisticated treats [Hurley 2007: 315]. Alternatively, the object to consider can be ‘medical need’, or individual need, which occurs “when an individual has an illness or disability for which there is an effective and acceptable treatment” [Laurie and Mason 2006: 428].<sup>477</sup> As opposed to well-being considerations, this criterion is purportedly objective. Medical ethics generally prescribes to follow medical needs, at the micro level [Laurie and Mason 2006: 428]. At the macro policy level, however, researchers and professionals are not agreed whether non-medical needs should also be heeded [Kapiriri and Norheim 2004: 173]. Brauman, from MSF, eloquently contrasts the paradigm of health-care prioritising based on medical needs of the individual as opposed to the paradigm of public health. Brauman criticises the public health model for being too ‘rationalistic’ as it considers, in health decision-making, non-medical issues and long-

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<sup>474</sup> Hammer and Berman in fact refer to ‘individual welfare’ rather than ‘individual need’, but the latter terminology is preferred in light of the following discussion (‘individual need’ in fact encompasses both considerations of welfare and strict medical need) [Hammer and Berman 1995].

<sup>475</sup> See also the introduction to section 5.4.

<sup>476</sup> This occurrence is often referred to in health debates as ‘adaptability’. As Hurley presents it: “[p]eople who actually live with health conditions tend to regard them as less bad than do members of the public, of their own families, or of the health care professions. While at first a disability may reduce someone’s welfare dramatically, over time someone’s attitudes to his disability may adapt” [Hurley 2007: 311, note omitted].

<sup>477</sup> The definition of need for medical care is taken from Culyers [1976].

term medical outcomes. Moreover, the public health model presupposes the questionable exactitude and validity of epidemiological predictions.<sup>478</sup> Instead, he supports the ‘humanitarian’ model asserting as “primary obligation... to give direct medical treatment to people who require medical attention” [Brauman 2004].<sup>479</sup> However, it is noted that the health needs of a population can be infinite, and require operationalisation and ranking [Laurie and Mason 2006: 428].<sup>480</sup> DALYs and QALYs can also be utilised to estimate the benefits of a health intervention to individuals.

Further questions arise on the *algorithm* to follow if an equitable distribution of the chosen object of distribution – welfare, well-being or ‘medical health’ – is sought.<sup>481</sup> Utilitarians would efficiently maximise the amount of the object (utility) to be redistributed in society. In distributing welfare/well-being, they would not waste resources with the expensive tastes types, in distributing health care they would not heed to ‘worried wells’ or the expensive chronically ill. Egalitarians would distribute the object evenly. In the maximin version, yet, they would sanction inequality if it benefits the worse-offs.<sup>482</sup> Egalitarian theory can lead to paradoxical results as, if the welfare or the well-being are the objects to equalise, egalitarianism may require to satisfy the ‘spoiled’. If health is the good to redistribute, egalitarian policies would dissolve resources in ‘bottomless pits’ and reduce society to poverty, if given the chance [Daniels 1985: 44]. While utilitarians generally have scarce consideration for equity, the egalitarian theory – especially in the maximin version – is factually problematic to implement. Building on a criticism of the egalitarian maximin criterion, Daniels has conceived an influential theory based on the equality of opportunity [Daniels 1985: 44].<sup>483</sup> According to the philosopher, illness and disease are deviations from “the natural functional organization of a typical member of a species” [1985(a); 1985(b)]. As he sees

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<sup>478</sup> In fact, collecting epidemiological data can be extremely impracticable in some circumstances. See Chapter 2.

<sup>479</sup> Brauman is a doctor at MSF. In this article, he refers, in particular, to humanitarian work in health care [Brauman 2004].

<sup>480</sup> See also Bosanquet [2001].

<sup>481</sup> Again, there are different meanings that the term equity can take with regard to health and health care [Hammer and Berman 1995: 34].

<sup>482</sup> The maximin principle derives from Rawls’ ‘Difference Principle’ of justice which requires that the basic social and economic institutions of society be arranged so as to maximize the expectations of the worst-off representative group. According to Rawls, “the justice of a society can be seen in how it treats its least fortunate members” [Brock 2002].

<sup>483</sup> For the influence of Daniels in the field see e.g. the essays collected in “Medicine and Social Justice: Essays on the Distribution of Health Care” [Rhodes et al 2002].

it, the moral importance of meeting health-care needs is the moral objective impact on opportunity rather than the more subjective impact on happiness [Daniels 2002: 8]. So, *needs* should be met before other *benefits*, even if this leads to less welfare overall [Daniels 1980; 1985; Hope et al 2002: 146].

In fact, Daniels' theory is not easily practicable. Notwithstanding the best efforts to differentiate from maximin's shortcomings, his reasoning too would lead to a 'bottomless pit' for resources. Daniels has responded to such objection conceding that "the particular rights and entitlements of individuals to have certain needs met are specified only as a result of a fair deliberative process aimed at meeting population health needs fairly" [Daniels 2008]. Eventually, Daniels' theory is not conclusive; rather it refers to a public deliberative process. Besides, Daniels' construct expounds what I believe to be the typical vulnerability of the egalitarian reasoning: what is the point of opportunity after all, if not happiness? Sen, probably, provides a better approach to the problem of the good in his critique of the monolithic utilitarian accounts of either resources or welfare concepts of well-being (happiness). Sen sees functionings and capabilities/freedoms as both valuable goods to pursue, at the individual and societal levels and as end in themselves [Sen 1999]. Furthermore, Daniels' view may sanction eugenic considerations, identifying an ideal-type human being and possibly stigmatising those who are 'different', falling short of such description yet adapt to their conditions. It is also noted that Daniels' argument fits with what Foucault identifies as 'normalisation', as opposed to 'normation' and therefore can be politically transposed to the pursuit of 'security'.<sup>484</sup> Daniels' approach, moreover, lets down those who have already had their opportunities (or, as said in health debates, their 'innings'), such as the retired and the elderly or those whose normal state cannot be restored [Hurley 2007: 323, 326-7].

Those theoretical problems are well illustrated in a paper by Hope and colleagues specifically addressing the question whether a new health intervention (such as the provision of a new medicine) should be introduced. The authors propose to compare the

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<sup>484</sup> While according to 'normation' "there is an originally prescriptive character of the norm and the determination and the identification of the normal and the abnormal becomes possible in relation to this posited norm" [Foucault 2007: 57], according to 'normalisation' different immanent normalities are observed within the population as a whole and a norm is fixed on the basis of these normalities: "[t]he norm is an interplay of differential normalities. The normal comes first and the norm is deduced from it" [*id.*: 63]. See Chapter 1 section 1.4. See Newell calling for an inclusion in bioethics of the lived experiences of those who identify themselves as disabled, too often, instead rejected as 'emotional or anecdotal' [Newell 2006: 270].

cost of the QALY saved by the intervention with a ‘guide cost’, fixed nationally [Hope et al 2002]. If the cost is higher, they suggest assessing whether there are grounds for justifying paying more, and how much more.<sup>485</sup> Interestingly, they identify six grounds for exception, with undertones of ethical and human rights questions. First, they wonder whether treatments for the young should have a different priority from treatment for the old, as it would result using DALYs.<sup>486</sup> Rawls, for instance, argued in favour of such priority using the veil of ignorance [Rawls 1972]. Second, they ask whether the identifiable patients should be favoured over non-identifiable patients. According to the rule of rescue,<sup>487</sup> the identifiable patients have precedence on the ‘statistical people’, that which is counter QALY reasoning and prevention policies. Third, the authors acknowledge that QALY calculations deliver lesser importance to palliative care than that attributed by otherwise shared sensitivity. Fourth, particular attention may be morally required also to those who are particularly badly-off with regard to their health or, fifth, those for whom no alternative treatment is available, while QALYs forsake such concerns. Sixth, ‘double jeopardy’ has to be dealt with whenever other conditions subsist which otherwise impair the quality of life or that make treatment more difficult. Hope et al conclude that since each theory for allocation of health resources (welfare, needs and lottery theories) faces difficulties, it is more important to concentrate on the procedure [Hope et al 2002: 144].<sup>488</sup>

In sum, ethical reasoning points out the ethical problems encountered by the main principles of prioritisation and distribution of resources for health. No principle could be

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<sup>485</sup> Admittedly, Hope and colleagues draw from Daniels, utilising the needs theory which “suggest[s] that needs should be met before other benefits even if this leads to less welfare overall” [Hope et al 2002: 146; 1980; 1985].

<sup>486</sup> DALYs explicitly give different values for life at different ages – valuing young adulthood more than either old age or childhood.

<sup>487</sup> See McKie and Richardson [2003] for an interesting examination of the rule of rescue.

<sup>488</sup> So does also Daniels who has recently advocated to vet public agencies and private health plans making limit-setting decisions and hold them ‘accountable for reasonableness’, in order to solve the problems of legitimacy and fairness they face. Daniels also sets four conditions for procedure, namely: publicity, relevance, appeals and enforcement [Daniels 2002: 16; Daniels and Sabin 1997].

In fact, for example, WHO’s model lists of essential drugs have been long criticised by “incomplete and non-transparent reasoning”, feeding allegations of politicisation and concealment, as Richard Laing, a WHO Expert Committee on National Drug Policies, has recognised on the *Lancet*. The selection of the products was in effect done on a consensus basis. A more transparent procedure, revolving around considerations of public-health relevance, efficacy, safety, and cost-effectiveness, has been introduced in 2002 [Laing 2004: 1725].

found to be conclusively ‘moral’ and ‘just’. Most principles, furthermore, were also impossible to realise considering the limited availability of resources. In light of those considerations, some comment can be made with regard to the positions of the ICESCR and ACHPR regimes relating to priority-setting for the fulfilment of access to medicines. As seen in above section 5.4.1, the ICESCR and ACHPR regimes have shown to be vague and open to contradictions, especially when equality and individual dignity are seen in contrast. The CESCR seems to interpret the ICESCR with an inclination to equity, as in the egalitarian ‘maximin’ position. Views such as that “investments should not disproportionately favour expensive curative health services which are often accessible only to a small, privileged fraction of the population, rather than primary and preventive health care benefiting a far larger part of the population” reveal the concern for equity and non-medical considerations in the prioritisation of health interventions [CESCR 2000: para 19, note omitted]. Furthermore, the focus on public health and primary health care suggests a preference for the aggregate status of a population. The penchant for public health and the population or group interests, however, spurs some questions about the value of the human right to health as a subjective right. It may be decided for example that the human right to health care and medicines does not apply for those who suffer from rare or expensive conditions or belong to the ‘small, privileged fraction of the population’ [CESCR 2000: para 19]. Little is said by the CESCR about the gravity of the condition or suffering endured.<sup>489</sup> Remarkably, instances of the public health framework are at variance with the principles of medical, individual need. In sum, there is legal and moral uncertainty about the identification of entitlements to medicines. Furthermore, philosophical perspectives question why health should be prioritised separately from other moral goods. Thus not only the ‘essential’ medicines object of a minimum core obligation have not been defined conclusively; more generally, the operationalisation of priorities-setting required for the implementation of an ‘indisputable’ human right to medicines have revealed to be rife with problems of ‘ethics’ and ‘justice’. The next section will address, consequently the problems of enforcement of the fulfilment of the human right to medicines.

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<sup>489</sup> It may be suggested that a better (in moral terms) interpretation *could* reprove health-care interventions *intended* to favour a ‘privileged’ part of the population, but would not oppose interventions that *as a consequence* favour ‘privileged’ parts of the population. Thus, conditions which affect a higher proportion of the rich (such as cardiovascular diseases) shall not be discarded as such, and conditions which affect the marginalised, shall not receive favour by virtue of their target only.

### 5.4.3 Enforcement

This section presents the enforcement of the human right to medicines through judicial remedies. Judicial remedies are not demanded by either the ICESCR or the ACHPR. However, the CESCR demands, among the obligations to fulfil the human right to health, that judicial or other appropriate remedies for addressing violations of the right *should* be provided [CESCR 2000: 33; 59]. Some court adjudication has been analysed in sections 5.2 and 5.3 relating to the respect and protection of access to medicines. This section looks at the role of courts with regard to the obligation to fulfil/provide access to medicines. In particular, it is enquired whether and how the individual in sub-Saharan Africa can utilise the human right to medicines in domestic courts to obtain the medicines she needs. Inevitably, the contingencies emerged in sections 5.4.1 and 5.4.2 resurface in this section. Namely, uncertainties concern what is the object of the right – *e.g.* public health measures, primary health care, individual treatment – and who is the subject of the right – *e.g.*, the population, groups or individuals. This section studies how the judiciary can address those contingencies.

In effect, there is little jurisprudence in sub-Saharan Africa on the human right to medicines – as well as health care – as already seen in Chapter 3 section 3.3.5. The *Ministry of Health v. TAC* case at the South Africa's Constitutional Court is probably the only domestic court case dealing with the provision of medicines in sub-Saharan Africa [Hogerzeil 2006].<sup>490</sup> The case concerned the provision of nevirapine to pregnant women so that they could prevent the transmission of AIDS to their foetus. Nevirapine was offered to the government by the manufacturing companies free of charge for five years, but the government announced it would introduce the medicine only in certain pilot sites. The NGO Treatment Action Campaign (TAC) consequently launched a constitutional challenge, alleging a violation of the right to access health care.<sup>491</sup> In this case, the Court asserted its competence (subject-matter jurisdiction) on the realisation of the human right to health, which is a constitutional right [South Africa, Constitutional Court, *Ministry of Health v. TAC*, 2002: paras. 5, 25; South African Constitution arts.

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<sup>490</sup> See also Hogerzeil and colleagues [Hogerzeil et al 2006: 305]. International adjudication is explored in Chapter 6 section 6.4.3.2.

<sup>491</sup> For a background of the case see ESCR-Net, website, *Minister of Health v Treatment Action Campaign (TAC)*, last accessed July 2010.

27(1), 28(1)]. The Court refused to recognise individual entitlements, maintaining that the rights involved did not generally create an individual entitlement to any specific resources [*id.*: para. 32, 37].<sup>492</sup> Noteworthy, the Court did not endorse the view of the CDESCR and the African Commission in relation to the obligations of states to immediately realise a minimum core of the human right to health and medicines, ruling instead that it is not possible to give everyone access even to a ‘core’ service immediately [*id.*: para. 35].<sup>493</sup> The Court also stated that courts are not institutionally equipped to determine what the minimum-core standards should be [*id.*: para. 37]. Nonetheless, the identification of a core service was in fact acknowledged by the Court to be “possibly... relevant to reasonableness under section 26(2)”, as previously recognised in *Grootboom* [*id.*: para. 34]. In effect, the TAC case succeeded because the government’s action was deemed by the Court to be ‘unreasonable’:

[...] the policy of confining Nevirapine to research and training sites fails to address the needs of mothers and their newborn children who do not have access to these sites. It fails to distinguish between the evaluation of programmes for reducing mother-to-child transmission and the need to provide access to health care services required by those who do not have access to the sites [*id.*: para. 67].

Notably, I remark, while professing a limited role in public health policy decisions, the Court took a position with regard to technical and medical issues. For instance, it decided not to consider the problem of resistance to antiretrovirals or toxicity that the intake of nevirapine can generate.<sup>494</sup> With regard to the enforcement of the decision, the Court issued a mandatory – rather than declaratory – order [Bilchitz 2007:

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<sup>492</sup> In particular, the Court held that “[i]t is essential that there be a concerted national effort to combat the HIV/AIDS pandemic. The government has committed itself to such an effort. We have held that its policy fails to meet constitutional standards because it excludes those who could reasonably be included where such treatment is medically indicated to combat mother-to-child transmission of HIV. That does not mean that everyone can immediately claim access to such treatment, although the ideal, as Dr Ntsaluba says, is to achieve that goal. Every effort must, however, be made to do so as soon as reasonably possible. The increases in the budget to which we have referred will facilitate this” [South African, Constitutional Court, *Ministry of Health v. TAC*, 2002: para. 125].

<sup>493</sup> It is recalled that South Africa has not ratified the ICESCR [UNOHCHR 2008(b)]. It has however signed the Covenant [*id.*] and the Court does refer to the treaty in its ruling [South Africa, Constitutional Court, *Ministry of Health v. TAC*, 2002: paras. 26-33].

<sup>494</sup> On the toxicity and resistance generated Nevirapine see the medical research of Arrive et al [2007]; Connor et al [1994]; Guay et al [1999]; Jourdain et al [2004]; Mofenson and McIntyre [2000]. Cf. South Africa, Constitutional Court, *Ministry of Health v. TAC* [2002: paras. 59-60].

155].<sup>495</sup> ESCR-Net remarks that indeed nevirapine may have saved thousands of lives [*id.*]. Nevertheless, it has been pointed out that enforcement had been inefficiently managed both by the Court and by the executive. Indeed, the uptake of the programme has been slow, and the Court did not exercise supervision [Bilchitz 2007: 165]. The civil society had to exercise pressure for a follow-up, including a contempt of court action against one provincial authority [ESCR-Net, website, *Ministry of Health v. TAC*, 2009]. Furthermore, the Court had not ordered breast-milk substitutes to complement effectiveness of preventing mother-to-child transmission programme [*id.*].

In effect, the *Ministry of Health v. TAC* case is exemplary to identify the contingencies and paradoxes of decisions relating to the adjudication of a subjective human right to medicines. Allegedly, no individual entitlement has been recognised by the Court. Indeed Fitzpatrick and Slye note that the South African Constitutional Court has permitted the individual enforcement of specific socio-economic rights only in two, narrowly defined circumstances [Fitzpatrick and Slye 2003]. The first case is *Soobramoney*, where the claim was however not based on access to health care but on emergency medical treatment [South Africa, *Soobramoney v. Minister of Health*, 1998; Fitzpatrick and Slye 2003: 678].<sup>496</sup> The second case is *Grootboom*, where the Court accorded provision of shelter to homeless children [South Africa, *Government v. Grootboom*, 2000; Fitzpatrick and Slye 2003: 678]. However, the Court in *Grootboom* did not recognise a direct obligation of the state with respect to children who do not have shelter, but just with respect to the *group*, I remark, of those who had no parents or family members to care for them [*id.*].

The human right to health in *Ministry of Health v. TAC* was indeed purportedly awarded on the grounds of ‘reasonableness’. Normatively it could be argued that the criterion of ‘reasonableness’ – also referred to as ‘rationality’ – is too arbitrary and/or

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<sup>495</sup> Cf. the *Grootboom* case, where the Court issued a declaratory order. Most municipalities put in place ‘Grootboom allocation’ in their budgets to address those in most desperate need. Still, there was no consequent successful policies and implementation in Western Cape for the applicant community [Bilchitz 2007: 151; ESCR-Net, website, Government of the Republic of South Africa. & Ors v Grootboom & Ors 2000]. Further action was taken to enforce the remedy against the local government [*id.*].

<sup>496</sup> As per art. 27(3) of the South African Constitution: “[n]o one may be refused emergency medical treatment” [South Africa’s Constitution, art 27(3)]. The claim was then denied because the claimant suffered from a chronic disease [Fitzpatrick and Slye 2003: 678].

narrows the scope of courts in awarding human rights through judicial review.<sup>497</sup> Bilchitz for instance suggests that courts should look at overall budgets and focus on a minimum-core approach rather than on reasonableness [Bilchitz 2007: 233]. Indeed, Bilchitz favours an expanded role of the courts seeing human rights protection as the justification of judicial review. The problem is, however, how can courts award human rights – and take decisions on the appropriate operationalisation of human rights at all – amid the contingencies revealed above in this chapter. If a minimum-core approach were to be yielded, how could it be identified? Why is the minimum core more incumbent than any other intervention for health? What would the minimum core award? The notion of a minimum core in effect seems to be more related to an indicator of the state activity for the realisation of the human right to health of its ‘population’ rather than to the basic health needs – and individual right – of a person. Indeed it is recalled that, according to the CESCR, the lack of essential medicines in a country is a violation by states of their minimum core obligation if it affects ‘any significant number of individuals’ [CESCR 1990(b): para. 10; 2000: para. 43, *emph. add.*].<sup>498</sup> In the *Ministry of Health v. TAC* case the Court has, arguably, *in fact* granted an entitlement to a minimum core of the right to pregnant women.<sup>499</sup> However, nevirapine is not a perfectly self-standing cure – and can even be toxic for the individual. Thus the ‘health’ of the mother and the child may not be the result of the vindication of a minimum-core obligation in relation to the human right to health. In alternative, what could be comprised – or excluded – in an *individual*

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<sup>497</sup> See, e.g., Hogerzeil [2006] and Langford and Nolan [2006]. In the UK, for instance, judicial review traditionally relates to issues of illegality (unlawfulness), irrationality (unreasonableness) and procedural impropriety (unfairness) [Lord Diplock quoted in Horne and Berman 2006: 18]. Courts can decide about the compliance of the act of a public authority with human rights obligations in administrative law review. On the judicial review on health care in the UK see also Syrett [2000] and Tur [2002].

<sup>498</sup> See Chapter 3 section 3.2.1.1.

<sup>499</sup> Cf. Bilchitz arguing that in *Grootboom* the administrative law review would not have been sufficient to determine unreasonableness, as the problem was not unreasonable exclusion but inadequate provision, *ie*, the urgent need of shelter [Bilchitz 2007: 168]. Therefore, the issue was not discrimination, regarding who should be entitled to a benefit (scope), as per the ‘equality approach’, but an issue of what individuals are entitled to (content) [Bilchitz 2007: 167]. Bilchitz in effect maintains that “[c]ases that fall to be determined in accordance with the socio-economic rights of the Constitution ... are not essentially comparative: rather, they relate to defining the nature of the entitlements contained in these provisions and the corresponding obligations of the State. They are concerned primarily with what the State is required to do to realize the entitlements in question rather than with who is the beneficiary of the entitlements” [*id.*: 168]. Cf. *contra* Wesson [2004: 307]. See also Fitzpatrick and Slye [2003].

entitlement to health care and medicines in South Africa as part of the human right to health?

Furthermore, the case has revealed the practical limitations of judicial decisions, as the enforcement of the ruling by the executive has been shortcoming. The separation of powers conceals indeed the structural coupling of the legal and political subsystems and the evident conflict of interest of the executive in not enforcing certain sentences.<sup>500</sup> Noteworthy, discrepancies between decisions and enforcement have reportedly tainted most other cases relating to access to medicines in relation to human rights worldwide. Cases celebrated in Latin America for the award of expansion of benefits, for instance by Hogerzeil and colleagues, such as Venezuela's *Cruz del Valle Bermúdez* and Argentina's *Viceconte* case, have in fact been disappointing in terms of enforcement [Hogerzeil et al 2006].<sup>501</sup> We will see in Chapter 6 section 6.4.3 that the effects of the decisions by treaty-bodies on the provision of medicines and health care are also doubtful.

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<sup>500</sup> It is recalled that Luhmann describes the structural coupling of law and politics as follows: “[i]n order for law to be enforced it needs politics, and without the prospect of enforcement there is no stability to norms that are credible to (or which are expected by) everybody. Conversely, politics use law to diversify access to politically concentrated power” [Luhmann 2004: 162].

<sup>501</sup> With regard to the Venezuela' *Cruz del Valle Bermúdez*, Torres reports that “[t]he reality that the Venezuelan government ignores the Court's ruling in the Bermudez case with impunity only contributes to the widespread perception that the right to health is symbolic rather than vital to the life of the nation” [Torres 2002: 114; Venezuela, Supreme Court, *Cruz del Valle*, 1999]. With regard to the Argentinean *Viceconte* case, a discrepancy in the outcome can be noted. ESCR-Net for instance reports that the Court of Appeals has been remarkably active, monitoring compliance of the measures ordered within the framework of the decision, as well as controlling the management and execution of the budget allocations aimed at producing the vaccine. Production is currently in progress: the vaccine has already been tested in animals and is now being tested in humans [ESCR-Net, *Viceconte*, 2008]. However, Singh reported that “[a]s a result of this case the Argentine government developed a social plan to deliver basic medicines to those in need within 5 years of the ruling” [Singh et al 2007: 521. The case was decided in 1998 [Argentina, *Viceconte*, 1998]. See also Verma: “five years after the *Viceconte* case, a vaccine for haemorrhagic fever has not been produced despite close judicial supervisions” [Verma 2005: 2]. In effect, “[i]n spite of Argentina's strong positive decision on the right health case, *Viceconte* in 1998, implementation has not taken place. It was noted that the part of the problem in this instance was a lack of established procedure for implementation” [*id.*: 79].

## 5.5 Conclusion

Chapter 3 demonstrated that important instances of the international human right to health oblige African states to respect, protect and fulfil a human right to medicines. Chapter 5 has consequently explored the operationalisation, implementation and enforcement of the duties held by African states in relation to this human right. The utilisation of the human right to medicines to guide and redress the policies of home states influencing access to medicines, however, has appeared to be difficult. To begin with, often, the international human right to health does not set definite legal/illegal prescriptions with regard to the conduct or the results that states shall be liable for with respect to access to medicines. The right to health also admits margins of discretion. Or, for example, where the right to health accords an entitlement to essential medicines, it does not identify what ‘essential’ medicines are. From a normative point of view, furthermore, it was showed that the human right to medicines does not seem to solve the ethical predicaments involved in the design of policies for access to medicines which imply morally-sensitive biopolitical decisions concerning life as well as conflicts between other rights, needs, interests and liberties in society.

In summary this chapter has illustrated that, with regard to the duty to *respect*, problems are posed for instance by the selection of essential medicines for the national essential medicine lists (EMLs), the regulation of intellectual property and the operationalisation of substantive non-discrimination. In particular, the protection of patents can reduce the affordability of new medicines but can also promote pharmaceutical research and development, and be morally warranted by recognising the inventor’s efforts or fostering the economy. The prohibition of non-discrimination is problematic as formal non-discrimination does not solve the problem of inequality, while substantive non-discrimination is difficult to operationalise and implement. In relation to the duty to *protect*, problems are posed by the control of quality and safety, which may trade off wide and immediate access to medicines. Competition law presents problems of contingency for instance with regard to the assessment of ‘excessive prices’. The duty to protect is problematic to operationalise especially when it interferes with the role of the private in the distribution of medicines, for instance when dealing with health insurance and price controls. Finally, difficulties have been found in the operationalisation of the human right to medicines with regard to the *fulfilment* of the right in sub-Saharan Africa. In particular, the examination of public health and medical ethics revealed that the

identification of health-care priorities is controversial. Priorities are often subjective; different moral principles and values ultimately conflict.<sup>502</sup> A fundamental dilemma is ascertained in public health debates between attention to the aggregate health status of a population and to the individual health needs. With regard to adjudication, much uncertainty was revealed over the use of legal remedies to redress the lack of fulfilment of the human right to medicines. Given the resources constraints, courts are hesitant about recognising individual entitlements to medicines, even essential ones. When states are held to be in violation of access to medicines, furthermore, the judicial remedies have not necessarily been effective for the claimants' health needs. The objects of the awards are sometimes limited with respect to the health problems at stake. Moreover, the sentences may not be effectively enforced by the executive. The uncertainty of the enforcement of the right *de facto* generates contingency in the legal subsystem *de jure* as its legal/illegal communications are not in fact enforceable in courts with certainty. Interestingly, as mentioned above, judicial remedies are not demanded by the ICESCR and the ACHPR.

So “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. This chapter has shown the difficulties for the individual in sub-Saharan Africa to obtain redress for her situation utilising the human right to medicines. The reasons are not only to be attributed to judicial ‘inactivism’, but to a series of paradoxes which have been identified in this chapter. First and foremost, a subjective human right to medicines (or health care, health) faces the paradox of referring to an objective right, pertaining to collectivities, the ‘population’ or groups. Indeed the law showed some contradiction. Certain formulations by the ICESCR, the CESCR and the African Commission for example operationalised the human right to health and medicines as concerned with the aggregate health status of a population or with some groups and health problems. This indication clashes with the principle that everyone has equal importance and dignity.<sup>503</sup> More specifically, the focus on the aggregate population conflicts with the formulation of the human right to health according to which everyone is entitled to the maximum attainable standard of health [ICESCR art. 12(1); ACHPR art.

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<sup>502</sup> See also Evans J.H [2006] on the limits of public bioethics as technocracy.

<sup>503</sup> See, e.g., ICESCR preambular paragraphs 1 and 3 [ICESCR preambular paras. 1, 3] and ACHPR article 2: “Every individual shall be entitled to the enjoyment of the rights and freedoms recognized and guaranteed in the present Charter without distinction of any kind such as race, ethnic group, color, sex, language, religion, political or any other opinion, national and social origin, fortune, birth or other status” [ACHPR art. 2].

16]. Next, through structural coupling, powers are accorded to states in order to realise the human right to medicines. However, the human right to medicines, as demonstrated, cannot frame a political programme for access to medicines. Indeed, the ‘human rights subsystem’ rests on the notion of indisputable values of humanity/inhumanity which is in fact, often, a simplification. Such simplification can be positivised in the legal subsystem, which is also coupled to the political subsystem, only through indeterminacy. Thus, not all actions diminishing access to medicines violate the respect of the human right to medicines. Not all shortcomings in protection and fulfilment of access to medicines violate this right. States are conceded certain margins of discretion. In effect, the choices made by the state in its function of ‘fostering’ life in the name of law and human rights are sensitive and may not respond to medical needs, be practically limited in their steering and undermine other legitimate interests, rights and needs in society.

The next chapter will analyse the operationalisation, implementation and enforcement of the obligations held by ‘extra-governmental’ actors with respect to the human right to medicines. Indeed, this chapter pointed out that the shortcomings of the application of the human right to medicines vis-à-vis African home states is also generated by the actions of agents other than the state. We shall see how these actors can contribute to the realisation of the human right to medicines in Africa, also addressing violations of access to medicines by, inter alia, African home states. Again, the contingencies and possible instances of biopower that the human right to medicines can generate *de facto* will be highlighted.

## CHAPTER 6: THE OBLIGATIONS OF ‘EXTRA-GOVERNMENTAL ACTORS’ WITH REGARD TO THE HUMAN RIGHT TO MEDICINES *DE FACTO*

### 6.1 Introduction

Chapters 2, 4 and 5 illustrated that the realisation of the human right to medicines by home states also depends on the conducts of extra-governmental actors (foreign states and non-state actors). It was demonstrated in Chapters 3 and 4 that, in effect, the international human right to medicines attributes duties onto these actors. The duties are attributed both indirectly, as home states have to protect the enjoyment of the human right to medicines against third parties (Chapter 3), and directly (Chapter 4). Chapter 6 contributes to answering the research question of this thesis, “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”, by analysing and normatively evaluating the possible utilisation of this right with regard to the duties of extra-governmental actors.

The primary scope of this chapter is the critical analysis of the indications which human rights law gives for the operationalisation, implementation and enforcement of the human right to medicines with regard to the roles of extra-governmental actors. Among non-state actors special focus will be given to international organisations, NGOs and pharmaceutical companies, as they are most influent on access to medicines in sub-Saharan Africa. Part of the research will, moreover, enquire in what the legal subsystem does not prescribe but ‘expects’ about extra-governmental actors. It is noted, for example, that the international human right to health, like other international human rights (especially economic, social and cultural rights) rests on the idea that extra-governmental actors have a subsidiary role in the fulfilment of the human right to health [*e.g.* ICESCR art. 2(1), 12(1); ACHPR preambular para. 3]. For example the CESCR has maintained, when stating the minimum core obligations *that home states shall immediately realise*:

For the avoidance of any doubt, the Committee wishes to emphasize that it is particularly incumbent on States parties and other actors in a position to assist, to provide ‘international assistance and cooperation, especially economic and technical’ which enable developing countries to fulfil their core and other obligations indicated in paragraphs 43 and 44 above. [CESCR 2000: para. 45 *emph. add.*]

International cooperation and assistance by foreign states and other actors in a position to assist, apparently, is a premise for the *possibility* of the obligations befalling

on home states. Yet it is not an enforceable prescription: the law is structurally coupled to other social subsystems, including the subsystem of meta-positive human rights (it is recalled that structural couplings occur when subsystem need events to occur within their environment that they cannot achieve through their own operations [Luhmann 2004: 382]). Soft law and self-regulation, which can be seen as communications of the ‘human rights subsystem’, are indeed more prolific with regard to the (non-binding) duties of extra-governmental actors, as illustrated in Chapter 4. Thus the positive human rights law also builds on those meta-positive prescriptions. It will be asked whether and how extra-governmental actors can in effect respect and contribute to protect and fulfil the human right to medicines. This enquiry is pertinent in order to assess the utilisation of the human right to medicines, overall, to the problem of access to medicines in sub-Saharan Africa.

Generally, it will be shown that the operationalisation of the human right to medicines with regard to extra-governmental actors encounters several paradoxes. Some are analogous to those identified for the duties of home states. For example, not all actions committed by extra-governmental actors reducing access to medicines can be considered to violate the respect of the human right to medicines. Not all shortcomings in protection and fulfilment of access to medicines violate this right. Granted, access to medicines is complex, and this often makes problematic establishing the relevant nexus of causality for violations. Normatively, the actions of extra-governmental actors for access to medicines can touch upon indisputable values pertaining health as well as other rights, interests, needs and liberties in society. As a result, the action of extra-governmental actors, even if framed as in furtherance of human rights, may exert unwarranted power and biopower. Furthermore, from a practical point of view, it is recalled that the theory of autopoiesis in the social systems cautions that political action is generally prone to the limits of steering [Luhmann 1997: 44]. Organisations, more generally, are also autopoietic social systems which handle themes according to the actions of that system [Luhmann 1995: 196-197].

According to its broad scope, this chapter utilises a multidimensional and interdisciplinary methodology. To begin with, it deals with the legal analysis of the human right to medicines and health under: the ICESCR and the ACHPR, as they are the most comprehensive regimes of human rights obligations on access to medicines in sub-Saharan Africa; the comments and decisions of treaty bodies, focussing on the CESCR (the ICESCR treaty body), the African Commission (the ACHPR treaty body); the

decisions of international and national courts; the work of the UN Special Rapporteur on the human right to health, academics and other authoritative sources. Soft law and self-regulation of extra-governmental actors will also be studied, as mentioned above. The enquiry nevertheless expands on an interdisciplinary study, which spans the ethics, economics, politics and science involved in the realisation of access to medicines. Socio-legal studies, mainly drawing from Luhmann and Foucault, as well as my empirical work in sub-Saharan Africa (especially, in Tanzania) will be utilised.

With regard to the structure, this chapter is constituted by three main parts which follow the tripartite distinction of duties to respect, protect and fulfil the human right to health and medicines. Such tripartite classification is not adopted in human rights law and literature as systematically for extra-governmental actors as it is for home states.<sup>504</sup> However, it provides an immediate comparison with the duties of home states and permits a systematic analysis of the possibilities, problems and limits of the human right to medicines framework. Attention is dedicated to the most problematic aspects of regulation, policies and actions having an effect on access to medicine. With regard to the *respect* of the human right to medicines by extra-governmental actors in sub-Saharan countries, section 6.2 focuses on the design and utilisation of the international intellectual property regime; the policies of international financial institutions; and the predicaments of the operationalisation of the principle of non-discrimination. With regard to the *protection* of the human right to medicines from third parties violations in other countries, section 6.3 reviews the harmonisation of standards and regulations pertaining the safety and efficacy of pharmaceuticals. Section 6.4 analyses the role of extra-governmental actors in the fulfilment of the human right to medicines. Such investigation is particularly important considering the limited resources of African home states for the fulfilment of the human right to medicines. Sections 6.4.1 and 6.4.2 therefore analyse the problem of prioritisation and selection of the interventions of external aid for access to medicines, also presenting the debate in international public health between vertical and horizontal

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<sup>504</sup> With regard to the duties of home states, the distinction is enshrined by the ICESCR and ACHPR provisions on the right to health and has been adopted, among others, by the CESCR, the African Commission, and the UN Special Rapporteur on the right to health [CESCR 2000: paras. 33-36; AC Res. 141 (2008); Hunt 2006: paras. 59-60]. *See also* Chapter 3 section 3.2.1. The CESCR explicitly adopts the tripartite classification for the duties of foreign states [CESCR 2000: 39].

approaches.<sup>505</sup> Section 6.4.3 investigates the difficulties of the *enforcement* of the human right to medicines studying in particular the problematic evaluation of the fulfilment of the right, for instance through the utilisation of indicators of performance. Section 6.5 concludes the chapter commenting on the role and problems of the international human rights law in prescribing duties onto extra-governmental actors for the solution of the problem of access to medicines in sub-Saharan Africa.

## 6.2 Respect

The analysis of the operationalisation and implementation of the duties of extra-governmental actors to respect the human right to medicines is divided into two sections respectively dealing with duties not to harm (section 6.2.1) and not to discriminate (section 6.2.2). Each section considers separately foreign states and non-state actors. It is pointed out that failure to *respect* the human right to medicines can originate from activities undertaken by extra-governmental actors meant to *protect* and *fulfil* access to medicines.

### 6.2.1 No harm

#### 6.2.1.1 Foreign states and international organisations

Chapter 4 showed that foreign states have a duty to respect the human right to medicines. The duty originates from both treaty and customary international law.<sup>506</sup> This section explores how such duty can be operationalised. Apparently states shall avoid exerting a direct impediment to access to medicines in another country. In discussing the duty to respect the human right to medicines enshrined in the ICESCR, the CESCR for instance remarks that states shall refrain from embargoing medical equipment [CESCR 2000: para. 41]. Ascertaining whether sanctions violate the respect of the human right to medicines can be problematic, considering that sanctions not directly aimed at medicines

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<sup>505</sup> In the public health literature, horizontal programmes regard the health-care system at once, for instance through primary health care, while vertical programmes focus on one health problem at time. *See* Chapter 1 section 1.4.

<sup>506</sup> The CESCR, for example, unequivocally states that the respect of the right to health in other countries derives from the right to health enshrined in article 12 of the ICESCR [ICESCR art. 12; CESCR 2000: para. 39]. *See* Chapter 4 section 4.2.1.

can also undermine access to medicines.<sup>507</sup> Fluctuations or withdrawal of health care and other foreign aid programmes also impinges on peoples' access to health care.<sup>508</sup> Lack of respect can be the outcome of foreign states' policies to protect the human right to medicines in sub-Saharan African countries. For example, delays in the registration of pharmaceutical products for exportation or donation can damage access to medicines in African countries.<sup>509</sup>

Foreign states can also influence access to medicines in sub-Saharan Africa through international agreements and international organisations dealing with for example intellectual property rights, international health regulation or international finance. According to the CESCR, states are required to “ensure that the human right to health is given due attention in international agreements... States parties have an obligation to ensure that their actions as members of international organizations take due account of the human right to health” [CESCR 2000: 39]. With regard to agreements prescribing the protection of intellectual property, the UN Special Rapporteur on the human right to health, Hunt, has more specifically stated that “no rich state should encourage a developing country to accept intellectual property standards that do not take into account the safeguards and flexibilities included under the TRIPS Agreement” [Hunt 2006: para. 64]. As seen in Chapter 5 section 5.2.1 the patentability of pharmaceutical products in a country requires very sensitive and delicate decisions. It is therefore investigated here if foreign states violate the respect of the human right to medicines abroad by contracting with African states on intellectual property.

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<sup>507</sup> General public international law accepts the use of countermeasures for redressing another state's violation of international law obligations. Countermeasures can be otherwise unlawful actions but cannot, *inter alia*, “affect... obligations for the protection of fundamental human rights” [ILC 2001: art 50]. Yet it is controversial to establish what counts as an infringement of fundamental human rights. *See* Cassese [2005: 312-3].

<sup>508</sup> Foreign aid for health care can also be used as an instrument of foreign policy. For instance, in February 2007 the Italian government interrupted many cooperation projects in Eritrea in the context of souring bilateral relations with the African country. One of these projects, I learnt, was the Italian Cooperation/Red Cross health centre and training centre of Gash Barka, a remote region in Eritrea [Forti 2007]. I visited the project in 2004 and was enchanted by the contribution to health the centre made, with the full approval of the regional government. The literature on the political use of foreign aid is huge, *see e.g.* Adelman et al [1995]; Boone [1996]; Boulding [1981]; Easterly [2001, 2006]; Middleton and O'Keefe [1998]; Rugumamu (on Tanzania) [1997]; Streeten [1972].

<sup>509</sup> *See e.g.* The Economist, “From Bench to Bedside” [2007], Health Gap [2005], interviews [July-August 2009, Dar es Salaam]. Section 6.3 discusses in more detail the regulation of medicines by foreign authorities as a way to protect the human right to medicines abroad.

It is noted that there is a moral rationale for regulating intellectual property protection at the international level. Free riding intellectual property may damage the originators, depriving them of the return on their efforts. This occurs especially in certain cases of parallel trading.<sup>510</sup> If parallel trading is not permitted, the reward of the innovator and the consequent incentive to innovation are not undermined. A problem of ‘fairness’, yet, could be perceived among consumers in different countries, as products are more expensive where intellectual property is recognised, where most of the innovation happens and also the concomitant social costs are borne.<sup>511</sup> Thus, a worldwide regime of intellectual property protection would address such free-riding, promoting more innovation on a global scale and permitting national patent regimes of innovator countries to be laxer (for instance, on shorter terms).<sup>512</sup> Consequently, static access to medicines in the originator countries would be fostered and research for conditions affecting African countries may be stimulated as well.<sup>513</sup> Nonetheless, the consequences of the recognition of patents on medicines domestically can be considered too serious, especially in developing countries, for justifying anything short of the prohibition of re-exporting medicines into the innovator’s country through parallel trading.<sup>514</sup>

Most African countries, however, are bound by international obligations with respect to the protection of intellectual property on pharmaceutical products. While sub-Saharan African countries are not involved, until the moment of writing, in bilateral investment treaties (BITs) and regional free trade agreements (FTAs) contracting on

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<sup>510</sup> I am particularly referring to the parallel trading which occurs when a generic good is produced and marketed in a country without recognising intellectual property rights and then exported to the country where the original good is marketed (and likely protected by intellectual property rights). The imported good competes on an uneven playing field as it has been produced without incurring in the research and development costs.

<sup>511</sup> For instance, the cost of education.

<sup>512</sup> See Maskus and Reichman discussing global public goods and the optimal global jurisdiction [Maskus and Reichman 2004: 285]. See also International Task Force on Global Public Goods [2006: 13, 68].

<sup>513</sup> See Pascale and Velasquez, for WHO [Pascale and Velasquez 1999]. Some studies however show that pharmaceutical research remains mainly directed to the conditions of the people of developed countries. See Global Forum for Health Research [2000]. Cf. WHO’s “Diseases of Poverty and the 10/90 Gap” [2004: 3, 4] contending that neglected diseases constitute a small fraction of low income countries total disease burden and that there are only three diseases that are genuinely ‘neglected’: African trypanosomiasis, Chagas disease and leishmaniasis. Cf. UNAIDS on AIDS vaccines, objecting that the research for an AIDS vaccine is limited to the genetic subtype B, rather than A or C prevalent in developing countries [UNAIDS 2002: 105].

<sup>514</sup> See also WHO’s position [WHO 1999, Globalisation and access to drugs: 41; Van Thiel 2003]. See also MSF [2003; 2006(b)], Oxfam, Patent injustice [2001].

intellectual property, all major sub-Saharan countries except Ethiopia, Liberia, Somalia and Sudan are parties to the World Trade Organisation (WTO) and thereby the Trade Related Intellectual Property agreement (TRIPS) [WTO, website, Understanding the WTO, 2009].<sup>515</sup> Under the TRIPS, inter alia, the parties are legally bound to adopt a minimum twenty-year patent protection on all products and processes, including therefore medicines [TRIPS art. 27 and 33]. The WTO offers a binding dispute settlement mechanism for enforcing WTO law between members [Lowenfeld 2003]. Therefore, it can be argued that African states have been deprived of a notable portion of their discretion in setting their domestic regime of intellectual property. However, the TRIPS regime also provides for some flexibility. Apart from the fact that procurers can use parallel importation (of cheaper patented medicines)<sup>516</sup> and developing countries have been granted extensions in the deadlines for adopting patents on pharmaceutical products, some provisions are now available permitting countries to obtain generic versions of patentable products without the consent of the patent-holder.<sup>517</sup> In particular, a moratorium is in place sanctioning the freedom for states to issue compulsory licences (on domestic production and/or importation of generic medicines). The African Commission, the WHO and other authors recommend African countries to adopt and utilise such ‘flexibilities’ [AC, Res. 141 (2008): para. 8(1)(d); Baker 2004; Correa 2000, 2002; Lewis-Lettington and Munyi 2004; Lewis-Lettington and Banda 2004; Mercurio 2004; WHO 1999, Globalisation and access to drugs: 41].<sup>518</sup> But are these flexibilities appropriate?

In fact, the flexibilities are rarely adopted and used by African countries.<sup>519</sup> Thus, it is questioned whether these arrangements are effectively helpful. African countries may not need to use those provisions because pharmaceutical industries do not patent

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<sup>515</sup> The organisation has established a multilateral regime of intellectual property protection entered into force in 1995. The organisation is currently composed by 153 members (last figures available from WTO website, Understanding the WTO: The Organization. Members and Observers, 2008, last accessed 10 February 2009)

<sup>516</sup> Parallel importation (after exhaustion of rights in the exporting country) is sanctioned in TRIPS article 6 [TRIPS art. 6]. *See* Ferreira [2002: 1145-1146].

<sup>517</sup> The extension of a deadline for amending legislation is not particularly useful for sub-Saharan Africa considering that, substantively, almost all African countries provide for patents on pharmaceutical products. Only Angola and Eritrea do not currently observe patent protection on pharmaceuticals [Grace 2003: 53; CIPR: 46, 27; Thorpe 2002]. *See also* Chapter 5 section 5.2.1.

<sup>518</sup> For WHO’s position *see also* Pascale and Velasquez [1999] and Van Thiel [2003].

<sup>519</sup> Reportedly, most SADC countries have intellectual property laws that do not comply with or make use of flexibilities under TRIPS [Mushayavanhu 2007: 150].

their products in their jurisdictions.<sup>520</sup> Compulsory licenses may in fact become necessary for sub-Saharan Africa countries which commonly import pharmaceutical products from other countries,<sup>521</sup> such as India and China, where intellectual property protection on medicines is being gradually recognised for new products.<sup>522</sup> Or, again, flexibilities can be superfluous because African states negotiate the procurement prices of medicines and/or set the retailing prices. Such option, however, is effective if the state has bargaining power vis-à-vis the supplier, but African countries often represent small markets.<sup>523</sup> It is also often noted that less than 5% of medicines of the WHO's essential drugs list are subject to patent protection [Ghafele 2008: 16]. However, the list includes medicines, generally, on the basis of cost-effectiveness, and on-patent medicines can be more costly therefore not suitable for the list.<sup>524</sup> Remarkably, compulsory licences give a power to the state – which thereby increases its exposure to lacking respect of the human right to medicines. In effect, African governments may refrain from issuing the licences if that entails providing the medicine in question.<sup>525</sup> Alternatively, it can be argued that the TRIPS flexibility for compulsory licences is too cumbersome a procedure. Indeed, the provision of TriAvir by Canada Apotex Inc. for Rwanda is the only case to date in full compliance with the TRIPS regime procedure, also notifying the Council for TRIPS [WTO Doc. IP/N/10/CAN/1, 2007].<sup>526</sup> Furthermore, it is noted that the effects of intellectual property law are influenced by the conducts of pharmaceutical companies and foreign states which the law does not steer. The role of pharmaceutical companies is

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<sup>520</sup> See Attaran and Gillespie-White arguing that antiretrovirals are seldom patented in African countries even if patent protection is available by law [Attaran and Gillespie-White 2001]. The significance and accuracy of the study has been vivaciously rebutted by MSF [MSF, Doha Derailed, 2003: 6].

<sup>521</sup> To give an idea, in 1994 the World Bank reported that more than 90% of medicines in sub-Saharan Africa are imported [WB 1994: 67].

<sup>522</sup> Generally, products marketed before the implementation of TRIPS are instead not patentable in China and India. For more details *see* Grace [2005].

<sup>523</sup> Reportedly Africa accounts for 1.2% of global pharmacy market (and the figure is even smaller for sales of patented medicines) [Friedman et al 2003: 341-343]. *See also* Chapter 5 section 5.3.2.

<sup>524</sup> *See also* Chapter 5 section 5.4.1 on the selection of medicines for the essential medicines lists.

<sup>525</sup> In effect, as Love notes, compulsory licenses have followed foreign donors' initiatives to finance pharmaceutical products [Love 2007: 16]. *See also* Attaran and Granville [2004: 178] and Block [2001].

<sup>526</sup> Love recounts that compulsory licenses have otherwise been used successfully in Ghana, Guinea, Eritrea, Mozambique, Swaziland, Zambia and Zimbabwe. While the author conclude that compulsory licensing in Africa is now fairly common, even though often not widely publicised [Love 2007: 16], on the basis of similar evidence other authors conclude that compulsory are very rarely used [Bradford Kerry and Lee 2007].

discussed in *infra* section 6.2.1.2. With regard to foreign states, African states can be reticent for example about recurring to compulsory licenses to avoid external political pressures by other states that may support their industries exerting pressure on patent protection [Oh 2006: 31].<sup>527</sup> In effect, the consequences of the TRIPS on African states also depend on the actual enforcement of intellectual property law by pharmaceutical companies and foreign states.<sup>528</sup>

In order to appreciate the problems of operationalisation of the respect of the human right to medicines with regard to patent protection on medicines in sub-Saharan Africa I investigated the situation in Tanzania during my field work (July-August 2009). It is recalled – as also seen in Chapter 5 section 5.2.1 – that the Tanzanian government, the Tanzania Food and Drug Authority (TFDA) and WHO officials report that the country has not experienced ‘public health’ problems with patents on pharmaceutical products as of yet. Tanzania’s patent law does cover pharmaceutical products but according to my interviews about 99% of the medicines used in Tanzania is not under patent.<sup>529</sup> Nevertheless, the Tanzanian government has allegedly undertaken a three-fold

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<sup>527</sup> Support to a similar view can be found considering the experience of Thailand in issuing compulsory licenses. The reaction from Abbott has not been particularly philosophical. The American pharmaceutical firm indeed retaliated by withdrawing some of its products from the Thai market. The American Trade Representative stood behind Abbott’s behaviour [CPTech, website, Thailand, last accessed May 2010].

<sup>528</sup> Within the WTO/TRIPS framework, for instance, the US has initiated a case against Brazil alleging that the adoption by the latter country of local working requirements clause was incompatible with TRIPS [WTO, *Brazil – Measures Affecting Patent Protection*, 2000]. Unilaterally, outside the WTO Agreement, US Trade Act Section 301 obligates the US Trade Representative (USTR) to assess whether standards of intellectual property protection in other countries are consistent with the US preferred level of protection [Oxfam, *Patents Versus Patients*, 2006: 14]. If the country does not comply with US standards it can be placed on the ‘priority watch list’, thence it may face unilateral trade sanctions [Oxfam, *Patents Versus Patients*, 2006: 14]. In effect, for the African countries eligible to benefit from the Generalised System of Preferences (GSP) for developing countries, which include most African countries, the USTR’s reports can lead to sanctions or withdrawal of concessions. (*See Trade Act of 1974 [US, Trade Act of 1974, Subchapter V, Sec. 2462, para. C(5)] as amended by the ‘GSP Renewal Act of 1996’, which also requires the President to ‘take into account the extent to which such country is providing adequate and effective protection of intellectual property rights’ [US, Small Business Job Protection Act of 1996, Subtitle J, section 502 para c (5)].*) The threats are in fact rarely concretised, but it can be recalled that the USTR strongly sustained the *PMA v. South Africa* case, until civil society obtained its withdrawal from the dispute [South Africa, *PMA v. South Africa*, 2001; Klug 2008: 222-3].

<sup>529</sup> The originator pharmaceutical companies have not patented, for instance, the first-line antiretrovirals and the first line antimalarial (the artemether-lumefantrine ‘Coartem’) [Interviews with TFDA, Dar es Salaam, July-August 2009].

strategy on intellectual property and access to medicines.<sup>530</sup> First, Tanzania is working on the adoption of flexibilities to its patent law, which are not sanctioned in the 1987 Tanzania's Patents Act currently in force.<sup>531</sup> Secondly, the government is favouring local production of pharmaceuticals, for instance reserving in public tenders a 15% price advantage to local industries. Third, the government aims to comply with the Abuja Declaration and WHO Plan of Action by raising the national budget for health to 15%. According to WHO, the general government expenditure on health as percentage of total government expenditure in 2005 was 12.6% [WHOSIS, last accessed October 2009].

Some remarks nevertheless suggest that the situation of Tanzania with respect to global intellectual property protection is not unproblematic. The first element of the strategy will importantly enable compulsory licenses.<sup>532</sup> It has to be seen how the mechanism of compulsory licenses, issued by the importer and the exporter countries ad hoc by way of exception, will respond to possible systematic needs of patented medicines. Currently, reportedly, 70-85% of the medicines utilised in Tanzania are imported.<sup>533</sup> With the second element of the strategy the need of generic versions of new products could be tapped without using importations. In effect, the assembling of formulations of sophisticated patentable drugs, such as antiretrovirals, may not be technically prohibiting. However, the active pharmaceutical ingredients (APIs) have to be imported as they are

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<sup>530</sup> Interview with TFDA [Dar es Salaam, 17 August 2009]. TFDA is selected as the 'focus institution on intellectual property in Tanzania' [*id.*].

<sup>531</sup> Tanzania grants patents for both processes and products, without expressly excluding pharmaceutical products, since the Tanzania's Patents Act of 1987 [Tanzania's Patents Act, 1987: Art 7(1)]. Such legislation presents harsh provisions on compulsory licenses, parallel importation, and other exceptions to patent rights. For instance, an early working exception is not prescribed [Losse et al 8-14]. (Article 13 however authorizes the exclusion from patentability of 'certain kinds of products, or processes' for a maximum period of ten years [Tanzania's Patents Act, 1987: article 13].) Modifications can include the possibility of compulsory licenses, parallel importation, government use, Bolar exception, exemption in scope, patentability, and the exclusion of patents from pharmaceutical until 2016, as permitted according to the Doha Declaration [Doha Declaration 2001: para. 7; Decision of the Council for TRIPS of 27 June 2002: para. 1].

<sup>532</sup> With a worldwide tightening of intellectual property protection, parallel importation loses some of its attractiveness.

<sup>533</sup> According to an interviewee at the Medical Stores Department, 80-85% of the medicines procured by the department (the national procurer of pharmaceutical products) are imported [Interview, MSD, Dar es Salaam, July 2009]. According to an interviewee at the TFDA, 70% of medicines circulating in Tanzania are imported [Interview, TFDA, in Dar es Salaam, August 2009].

more technologically demanding and benefiting from huge economies of scale.<sup>534</sup> Finally, the trials required for the launch of new products are expensive.<sup>535</sup> The third strategy incurs in the reality that, by increasing from general government expenditure on health as percentage of total government expenditure 12.6% to 15%, the per capita government expenditure on health would shift from US\$ 23 to US\$ 27.4 [WHOSIS, website, 2005, my elaboration]. Notably, general expenditures on health already comprise external aid [WHO, website, WHOSIS – National Health Accounts, last accessed 10 November 2009]. By comparison, in France it is US\$ 2646, in Italy US\$ 1894, in the United Kingdom US\$ 2261, in the United States of America it is US\$ 2862 [WHOSIS: 2005, last accessed 30 October 2009]. It is spurious comparing the financial resources available for African least-developed countries with those available in developed countries.<sup>536</sup>

In sum it is not clear whether foreign states violate the human right to medicines by binding sub-Saharan African states – and the countries habitually exporting generics to them – to the TRIPS. On the one hand, the protection of intellectual property can be warranted under the human right to medicines and other ethical considerations. It can also be argued that African states were generally granting patentability of medicines before the TRIPS came into existence and that the emerging countries exporting generic medicines to Africa would have adopted patent protection anyway, following technological development.<sup>537</sup> On the other hand, the ‘flexibilities included under the

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<sup>534</sup> Trade in pharmaceuticals occurs because the pharmaceutical sector typically benefits from economies of scale at the international level and because the infrastructure in African countries can be challenging especially for technology-intensive products. Interviewees from pharmaceutical companies in Tanzania highlighted the problems of production in the country. The poor status of infrastructure and higher level education in Tanzania makes drugs production more expensive than in Asian countries from where most medicines are imported [Interviews with Shelys (the biggest manufacturer of pharmaceutical products in Tanzania), Salama (importer for generics) and others, Dar es Salaam, August 2009].

<sup>535</sup> For some products, especially for antiretrovirals, WHO requires bioequivalence trials which cost about US\$ 100,000 [Interviews with Shelys (the biggest manufacturer of pharmaceutical products in Tanzania), Salama (importer for generics) and others, Dar es Salaam, August 2009].

<sup>536</sup> In effect, the medicine budget in Tanzania for year 2003/04 was US\$ 28.5million, *ie* US\$ 0.75 per capita [The United Republic of Tanzania, Survey of the Medicines Prices in Tanzania: 2004: 3, my elaboration].

<sup>537</sup> See Mushayavanhu noting that at the time of the entry into force of the TRIPS agreement only three African countries excluded the patentability of pharmaceutical products [Mushayavanhu 2007: 150]. Many countries in effect have inherited intellectual property legislation from colonial times [Druce 2004: 15]. See also Chapter 5 section 5.2.1.

TRIPS', to borrow Hunt's expression, may not be sufficient for avoiding patents and getting access to cheap generic medicines [Hunt 2006: para. 64]. The effect of the TRIPS, moreover, does not follow linear and immanent causality; rather, it is much contingent, depending on the health systems of the sub-Saharan countries and on how the intellectual property rights are utilised by foreign states and pharmaceutical companies. Foreign states can influence the implementation and enforcement of intellectual property in African countries. Decisive is also the promptness of foreign states to issue compulsory licenses for exporting generic products to African countries, as they are under no compulsion from the TRIPS to do that. Foreign states can also contribute to purchasing patented medicines in poorer African countries through aid and cooperation. The practice by pharmaceutical companies will be studied in following section 6.2.1.2.

Always with regard to the actions of states in international organisations, some WHO programmes meant to protect access to safe medicines worldwide are sometimes too inefficient and therefore a barrier to access to medicines.<sup>538</sup> The activity of WHO in recommending lists of 'essential drugs' can also be problematic. In particular, the WHO Essential Drug List which, following cost-effectiveness considerations, identifies medicine that states shall keep available in public health facilities, has been criticised until recently for having excluded treatment for HIV/AIDS [Laing 2004: 1725].<sup>539</sup> Other instances of international selection and prioritisation of health interventions in sub-Saharan Africa are further analysed in section 6.4.1 below.

Lastly, this section deals with the impact on access to medicines that foreign states have by influencing the public policies and social welfare systems of African states in the context of development aid, development finance and debt reduction. This influence occurs through bilateral cooperation or by participating to international financial institutions such as the International Monetary Fund (IMF), the World Bank and regional development banks. African countries are particularly prone to the intervention of those agencies given the scarce availability of public finances and their high levels of public debt.<sup>540</sup> It has been contended however that the intervention of

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<sup>538</sup> See *infra* section 6.3.

<sup>539</sup> Some antiretrovirals have been introduced in the most recent versions of the WHO EML, relaxing the requirements of cost-effectiveness [Laing 2004: 1725]. See, e.g., WHO, WHO Model List of Essential Medicines, 16<sup>th</sup> List [2009]. See also Chapter 5 section 5.4.1.

<sup>540</sup> Under the World Bank classification of Highly Indebted Poor Countries (HIPCs) 33 out of 40 countries are African [World Bank, HIPC At-A-Glance Guide, 2009].

international financial institutions, for instance when encouraging liberalisation and privatisation of hitherto public enterprises, has had a negative effect on economic, social and cultural rights in several states.<sup>541</sup> It is argued here that it is not straightforward to identify liability for such policies under the framework of the human right to medicines. In its comment on the human right to health the CESCR demands explicitly that parties to these institutions “should pay greater attention to the protection of the human right to health in influencing the lending policies, credit agreements and international measures of [international financial institutions and regional development banks]” [CESCR 2000: 39]. In a previous comment on technical assistance and cooperation the CESCR did however recognise that, considering the amount of debt of some countries, adjustment programmes may be unavoidable and that these can involve austerity – yet basic economic, social and cultural rights must be protected even in those circumstances [CESCR 1990(b): para. 9]. In effect, it can be difficult to assess the level of a ‘basic’ right to medicines, or what ‘austerity’ really means. As seen in Chapter 5, the operationalisation of the concept of ‘essential’ medicines and the prioritisation of health-care needs is not certain.<sup>542</sup> In addition, the nexus of causality has to be established. It can be asked how direct the consequences of the policies shall be. Policies with no focus on access to medicines can have negative effect on access to medicines. The temporal horizon for the assessment shall also be set out. Policies which interfere with access to medicines today may mean more access at another time or by other subjects. Furthermore, availability, affordability and quality can in effect be traded off. For example, price controls can increment availability to detriment of affordability whereas user fees and cost sharing for medicines can decrease the affordability but increase the availability.

The recommendation of the imposition of user fees for health services by the World Bank and the IMF, which had also been supported by WHO and UNICEF,<sup>543</sup> in particular, has raised considerable criticism against those institutions.<sup>544</sup> It has to be

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<sup>541</sup> See Ssenyonjo [2008: 740].

<sup>542</sup> See section 5.4.1.

<sup>543</sup> UNICEF and WHO have also supported rolling funds for sub-Saharan African countries with the 1987 Bamako initiative [Paganini and Jarrett 1993].

<sup>544</sup> The lending institutions insisted on user fees for health services during the 1980s as part of the structural adjustment programmes [Mamdani B. 2007: 139]. Later on, the World Bank adopted a more flexible approach. In 2004, the World Bank claimed a ‘no blanket policy on user fees’, in effect recommending that fees be evaluated within each policy context [World Bank, World Development Report 2004, 2004]. Indeed the foreign states most in favour of the imposition of user fees changed their position. The US now

asked if user fees and cost sharing on medicines are totally inappropriate. Fees are not only relevant for revenue collection. User fees are ‘output-based payments’ that foster quality of care, responsiveness to users and efficiency because the health facility gains if services are delivered [Mamdani B. 2007]. Fees also stem overconsumption of health-care services and moral hazard by the public. The case of Tanzania is quite representative. With the 1967 Arusha Declaration, the Tanzanian Government became the major provider and financier of health services, putting emphasis on the free provision of primary health-care services. Health services were expanded to rural areas. However, Tanzania was not self-sufficient in its social policies.<sup>545</sup> In 1994 user fees (cost sharing and drug capitalization) were introduced with a view of “generat[ing] additional resources to compliment government budgetary allocations” [The United Republic of Tanzania, Baseline Survey of the Pharmaceutical Sector in Tanzania 2002, 2002]. The reported user fee income proportion for the district health budget was on average 10.5% [Laterveer et al 2004: v]. In Tanzania, user fees are used at the local level that which safeguards decentralisation and local accountability. Fees collection offers incentive against waste and irrational use of medicines which are otherwise rife in Tanzania [Yudkin 1999; Tanzania MoHSW/UNICEF 1987]. Exemptions from payments are prescribed for mothers, children under five years of age, the elderly and patients suffering a series of chronic and epidemic diseases including for instance tuberculosis and AIDS [Tanzania MOH, 2003, National Health Policy]. The implementation of the fee system has, however, been quite distinct from the policy announced by the government. The

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officially opposes the utilisation of user fees as condition for loans by the IMF and the World Bank. The 2000 US Foreign Aid Bill prohibits the US government from supporting future programmes of international financial institutions or the IMF that include the introduction of fees as a loan condition. In particular: “[t]he Secretary of the Treasury shall instruct the United States Executive Director at each international financial institution (as defined in section 1701(c)(2) of the International Financial Institutions Act) and the International Monetary Fund to oppose any loan of these institutions that would require user fees or service charges on poor people for primary education or primary healthcare, including prevention and treatment efforts for HIV/AIDS, malaria, tuberculosis, and infant, child, and maternal well-being, in connection with the institutions’ lending programs” [US Public Law 106-429, Section 596]. *See also* CHER [2002: 3].

<sup>545</sup> Since the 1960s Tanzania utilised massive amounts of aid and accumulated massive amounts of debt. Attempts to restructure the economy indeed took place before the intervention of the international financial institutions. However, the health-care system of Tanzania collapsed during the 1980s and medicines in particular became overall unavailable. With regard to medicines, for instance Havnevik et al report that in 1988 most hospitals in the country reported to be practically empty of drugs [Havnevik et al 1998: 168]. *See also* Yudkin [1999]; Tanzania MOH [National Health Policy 2003: 27].

international NGO Save the Children for instance studied the access to primary health care in the Lindi region and reported that exemptions were accorded more as a favour than as a right. The use of exemptions for the poorest households, pregnant women and children under-five was overall low [Save the Children 2005: 21-22]. My personal observation of the dispensaries in the Sumbawanga municipal area and Ulanga (July 2009) is that the fees for cost sharing of medicines were indeed variable.

In sum, the policy undertaken by international financial institutions of demanding user fees for health services are not permitted or prohibited outright according to the human right to medicines. The CESCR pronounces on this matter but its comments are tentative and vague. The analysis provided in this section has shown that user fees can reduce the affordability of health care for the individual but also have benefits as they collect revenues for health systems and avoid overconsumption of health-care assistance. In effect, the outcomes of such policies much depend on the context and on how they are implemented.

#### *6.2.1.2 Pharmaceutical companies and intellectual property rights*

Chapter 3 showed that the international human right to medicines imposes duties on states to protect access to medicines from noxious actions by third parties. Chapter 4 illustrated that soft law and self-regulation do directly assign duties and responsibilities on non-state actors to respect – more or less explicitly – a human right to medicines. Section 6.2.1.2 focuses on the problem of whether and when pharmaceutical companies fail to respect the human right to medicines by holding patents on their pharmaceutical products in sub-Saharan Africa. The policies of pharmaceutical companies can have decisive influence on the effects of intellectual property rights on access to medicines. Pharmaceutical companies decide whether to apply for patent protection of innovative products;<sup>546</sup> whether to grant licenses; and whether to enforce patent rights. For a notorious example in Africa, the Pharmaceutical Manufacturers' Association of South Africa took action against the provision of parallel importation and compulsory licenses

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<sup>546</sup> See Attaran and Gillespie-White arguing that antiretrovirals are seldom patented in African countries even if patent protection is available by law [Attaran and Gillespie-White 2001]. The significance and accuracy of the study has been vivaciously rebutted by MSF [MSF, Doha Derailed, 2003: 6].

in the South Africa's Patent Act [South Africa, *PMA v. South Africa*, 2001].<sup>547</sup> The pharmaceutical companies can also put pressure on the governments of developed countries about the implementation and enforcement of intellectual property abroad.<sup>548</sup> In fact, major pharmaceutical companies are now pledging to embrace 'friendly' patent policies. However, such actions are generally not systematic, concentrating on some geographic regions and a selection of products on a case-by-case basis.<sup>549</sup> After all, it can

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<sup>547</sup> For an account of the case *see* Klug [2005], Pugatch [2004: 216-17] and CpTech [website, Court Case Between 39 Pharmaceutical Firms and The South African Government].

<sup>548</sup> *See* Drahos and Braithwaite [2002]; May [2000]; Oxfam, *Patents Versus Patients* [2006: 14]; Sell [2003]; Pfizer, 2007 Corporate Responsibility Report [2007: 92]; and Pugatch [2004].

<sup>549</sup> I have reviewed the policies of a sample of pharmaceutical companies. The selection, presented in alphabetical order, is based on a combination of factors. The companies are among the 20 biggest pharmaceutical companies for sale and revenue, vastly exporting to sub-Saharan Africa. GlaxoSmithKline and Boehringer Ingelheim have also been involved in the notorious case *TAC v. GSK, BI and others* at the South Africa Competition Commission [Tau et al 2002]. The same selection has been examined, *ceteris paribus*, in Chapter 4 section 4.3.2.3. Boehringer Ingelheim is renouncing patents on Viramune® (nevirapine) and Aptivus® (tipranavir) for HIV/AIDS. With regard to Viramune® (nevirapine), "[i]n the past Boehringer Ingelheim granted Voluntary Licenses to several companies in Africa enabling them to produce generic nevirapine for low income countries as per World Bank classification. In order to further improve and facilitate access to nevirapine, Boehringer Ingelheim will not enforce its patents and offers interested manufactures listed on the WHO prequalification list non-assert declarations allowing them to supply nevirapine-containing medicines for Eligible Countries. These Eligible Countries are defined as all low income countries according to the World Bank classification of economies, all countries classified as Least Developed Country (LDC) according to the United Nations and all African states which are not classified as low income of LDC like South Africa, Botswana" [Boehringer Ingelheim, 2009(b): 2]. With regard to Aptivus® (tipranavir), "[a] policy in equivalent terms shall apply to Aptivus®. At the moment, wherever there is a medical need with patients who are highly treatment experienced with virus resistance to multiple protease inhibitors, the product is available for those patients in form of a Compassionate Use Programme" [*id.*]. GlaxoSmithKline has identified as part of its responsibilities in access to medicines "[b]eing more flexible on intellectual property" [GSK, website, 2009(b)]. Since 2009 GlaxoSmithKline launched a LDC (Least-Developing Countries) Neglected Tropical Disease patent pool and has implemented price reductions on patented products in Least-Developing Countries. The commitment is that "all GSK patented products in these countries will now cost less than 25 per cent of their price in the referenced developed countries... GSK reduced prices for seven patented brands (110 individual product lines and formulations) by an average of 45 per cent" [*id.*]. Other firms like Novartis also proclaim attention to providing access to patented medicines to developing countries. Novartis acknowledges that "the price of patented, life-saving medication plays an important role in the attainment of treatment for poor people from developing countries" and the firm pleads to contribute to solving this problem "for example by issuing medication against leprosy free of charge, providing the anti-malaria drug Coartem for

be commented, pharmaceutical companies are concerned with the economic return of access to medicines policies:<sup>550</sup> showcase approaches are instrumental to the reputation of pharmaceutical companies and therefore more convenient than comprehensive undertakings. From an ethical point of view, nonetheless, it is not clear whether pharmaceutical companies shall relinquish patents in sub-Saharan Africa altogether. Questions can be raised about which countries should be permitted not to respect intellectual property rights on medicines, and for which parts of the population and sectors (public, private not-for-profit and/or private for-profit). The issue is complicated considering the other factors influencing access to medicines apart from the protection of intellectual property. As seen in Chapter 2, the capacity of health systems to deliver medicines depends on a combination of supply and demand elements.<sup>551</sup> Such complexity weakens the causation nexus between patents on pharmaceutical products

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developing countries at cost price...” [Novartis, website, The Right to Health and Access to Treatment, last accessed 2 November 2009]. Some companies are instead less keen. Pfizer, for instance, does not seem to adopt flexibilities for its patents policy in developing countries. Indeed, in its “Corporate Responsibility Report”, Pfizer only stresses that “[w]e believe that strong patent laws, when balanced with reasonable times of exclusive marketing rights, lead to more medicines and, ultimately, less disease. There is a view that patent rights limit access to medicines because they prohibit the unauthorized manufacture and sale of a patented medicine. We disagree that patents are a primary cause of limited access to medicines” [Pfizer, 2007 Corporate Responsibility Report, 2007: 90].

<sup>550</sup> The pharmaceutical sector is increasingly compelled to help access to medicines in sub-Saharan Africa because this policy ‘makes business sense’. Shareholder groups for instance note that friendly policies boost the favours of the procurers and consumers of emerging countries’ markets, employees’ satisfaction and recruiting, and overall the companies’ reputation. *See, e.g.*, the Pharmaceutical Shareowners Group [2004: 1] and the Ethical Investment Research Services [EIRIS 2005: 7]. In effect, the *PMA v. South Africa* case was dropped before a verdict was issued by the South African High Court because of the pressure from the civil society [Pugatch 2004: 216-217; South Africa, *PMA v. South Africa*, 2001].

<sup>551</sup> It can be recalled for example that some pharmaceutical products remain out of reach of African health systems even in their generic formulations. As a journalist from the Wall Street Journal reports, quite scornfully, regarding the initiative of a generic pharmaceutical company to obtain from the South African government a compulsory license: “[t]he South African government has been tossed a hot potato by Indian drug maker Cipla, which asked Wednesday for legal permission to supply the country with low-cost generic copies of patented AIDS medicines... Officials privately say they are worried that should Cipla win its bid to supply the country with cheap AIDS drugs, the government will not have the budget to buy them or distribute them. ‘We are in real danger that Cipla could open the door on the AIDS drugs barrier in this country and we will not be able to walk through,’ said one health-ministry official” [Block 2001]. Also *see* Attaran reporting that “[t]he government of Zimbabwe, which also accounted that it would break patents in order to provide HIV/AIDS medicines... never bought the medicines and never treated the patients” [Attaran and Granville 2004: 178].

and access to medicines in Africa, thereby diminishing the responsibility of the patenting pharmaceutical companies. Such remark applies all the more to the lack of access to medicines for the poorest who may not afford generic formulations anyway.

## 6.2.2 Non-discrimination

### 6.2.2.1 Foreign states

The ICESCR obligation to respect the human right to health, and thence the human right to medicines, contains the prohibition of discrimination [CESCR 2000: 34, 50]. In its basic formula, the prohibition relates to discrimination founded on race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.<sup>552</sup> Foreign states can exercise discrimination for instance when offering international aid for providing or facilitating access to medicines. With regard to international agencies, in particular, the CESCR maintains that “the international agencies should scrupulously avoid involvement in projects which... promote or reinforce discrimination against individuals or groups contrary to the provisions of the Covenant” [CESCR 1990(a): para. 6]. Furthermore, the CESCR advances the principle of substantive non-discrimination when stating – but falling short of prescribing – that: “[p]riority in the provision of international medical aid, distribution and management of resources, such as... food and medical supplies... *should* be given to the most vulnerable or marginalized groups of the population” [CESCR 2000: 40, *emph. add.*]. Substantive equality – *e.g.* the favour for the vulnerable and the marginalised – is however also problematic to operationalise, as seen in Chapter 5 section 5.2.2.

For example, people living with AIDS are identified by the Special Rapporteur as ‘vulnerable’ and ‘marginalised’.<sup>553</sup> Still, the numerous foreign aid programmes which focus on HIV/AIDS may raise doubts with respect of those who are not supported by

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<sup>552</sup> From ICESCR art. 22 [ICESCR art. 22]. The ACHPR provides for a similar list, adding the categories of ethnic group and replacing property with fortune [ACHPR, art. 2]. *See* Chapter 5 section 5.2.2.

<sup>553</sup> As seen in Chapter 5 section 5.2.2 the CESCR is silent on the identity of the ‘vulnerable’ and ‘marginalised’ people. The Special Rapporteur instead, when investigating home states duties, does identify ‘vulnerable individuals’ and ‘disadvantaged groups’ as including “women and girls, ethnic minority and indigenous populations, people living in poverty, people living with HIV/AIDS, internally displaced people, the elderly, people with disabilities, prisoners and others” [Hunt 2006: para. 52].

them. Nguyen for instance studies the impact of the US President's Emergency Plan for AIDS Relief (PEPFAR) in Ivory Coast. Nguyen notes that triage is both used to decide who gets treatment and to "exclude[e] others either because they are HIV-negative or not considered 'vulnerable'", such as children orphaned by the war rather than AIDS [Gerrets and Rottenburg 2008: 70]. Nguyen interestingly elaborates identifying the phenomenon of 'therapeutic citizenship' whereby "the only meaningful form of citizenship comes from belonging to a program such as US President's Emergency Plan for AIDS Relief which not only offers treatment, but also identity papers, nutritional support, and schooling for one's family" [*id.*]. The favour for the vulnerable and the marginalised, thus, can be disputed under the very principle of non-discrimination. However, the concentration of resources can be required to deliver quality care to people. In effect quality assistance does not only entail medical care but also food supplements, financial support and other implements. Arguably, such considerations are sanctioned by the moral principles of individual need or individual welfare.<sup>554</sup>

Central coordination at the national level could address the 'unequal' impact of vertical foreign aid programmes, provided that it succeeds in being implemented in an 'egalitarian' way. Some developing countries now collect foreign aid in 'basket funds'. In Tanzania a basket fund and other coordination mechanisms have been established for some diseases.<sup>555</sup> The US however does not participate to the fund arguing that it prefers acting instead as a distinct safety net. The USAID officials I interviewed (Dar es Salaam, August 2009) in effect report that USAID had to play as 'fallback' in several occasions, when bottlenecks occurred throughout the Tanzanian national medicines distribution system.

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<sup>554</sup> Those problems are further explored in section 6.4.1 relating to the fulfilment of the human right to medicines by foreign states. *See also* Chapter 5 section 5.4.2.

<sup>555</sup> *See* for instance the work of the Development Partners Group [DPG website].

### 6.2.2.2 Non-state actors

International law does not hold NGOs, international funds and public-private partnerships accountable for violations of non-discrimination directly. States however have to protect against discrimination on prohibited grounds by third parties.<sup>556</sup> Furthermore, those entities can self-regulate on non-discrimination.<sup>557</sup> It is more difficult to operationalise the *de facto* component of formal non-discrimination, for instance with regard to the selection of a region/country where the entity would operate. NGOs in particular usually act out of ‘vocation’ in certain parts of the world and they can hardly be expected to dedicate their efforts equally worldwide. The actualisation of *substantive* non-discrimination poses further hurdles. As mentioned in section 6.2.2.1 above with regard to international organisations and NGOs the CESCR states (but does not prescribe) that “[p]riority in the provision of international medical aid, distribution and management of resources, such as... medical supplies... *should* be given to the most vulnerable or marginalized groups of the population” [CESCR 2000: para. 65 *emph. add.*].<sup>558</sup>

The Global Fund on AIDS, Tuberculosis and Malaria can be used to illustrate the problems of non-discrimination with regard to the conduct of non-state actors for the facilitation of access to medicines.<sup>559</sup> The Global Fund was launched in 2001 as a financing mechanism for country-level efforts to combat AIDS, tuberculosis, and malaria. Admittedly, the Global Fund collects and distributes vast financial resources for tackling “three of the world’s most devastating diseases and to channel the money to areas of greatest need” [GFATM, website, Fighting AIDS, Tuberculosis and Malaria, last accessed 9 November 2009].<sup>560</sup> Thus, it is apparent that the fund only focuses on the

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<sup>556</sup> See Chapter 3, Chapter 4 section 4.3.2 and Chapter 5.

<sup>557</sup> As seen in Chapter 4 section 4.3.2.2 for instance, international NGOs with the “INGO Accountability Charter” pledge not to discriminate [INGO Accountability Charter, 2003: Principles, para. 5].

<sup>558</sup> Alternatively, the CESCR’s paragraph could be interpreted as indicating the priority for the vulnerable and marginalised only in ‘times of emergency’, considering the first part of the paragraph which refers to those circumstances. However, noting the analogy with paragraph 40 of the same document, I understand that the CESCR meant to recommend a more general priority to the vulnerable and marginalised [CESCR 2000: para. 40].

<sup>559</sup> The Global Fund for AIDS, Tuberculosis and Malaria is an independent entity, governed by a board of directors that includes representatives from donors, the UN, civil society, and the private sector [Leach et al 2005: 44-5]. To note, however, 98% of the funds are pledged by governments [Feachem and Sabot 2006].

<sup>560</sup> “Since its creation in 2002, the Global Fund has become the main source of finance for programs to fight AIDS, tuberculosis and malaria, with approved funding of US\$

conditions of certain patients. From the point of view of substantive non-discrimination it could be argued that the Global Fund does address the needs of the ‘marginalised’ or the ‘vulnerable’ if these are identified as the AIDS, malaria and tuberculosis patients, and that it intervenes where the need is the greatest. However, overall, the worse-offs in health or income are not necessarily those who receive the Global Fund’s attention. The Global Fund states that “[i]n making its funding decisions, the Fund will support proposals which... Give due priority to the most affected countries and communities, and to those countries most at risk” [GFATM, Framework Document, 2002: Section III(H)(9)], and finances proposals originated by governments as well as civil society organisations.<sup>561</sup> In fact, as Sabot and Feachem (former Executive Director of the fund) themselves note, there is tension between the empowerment of local groups to determine the disease-control priorities and strategies in their countries on the one side and the need to ensure that those priorities and strategies are the most effective use of resources on the other side [Feachem and Sabot 2006]. Furthermore, the fund dispenses money according to the performance of the recipients. Consequently, it is less likely that poor health systems will facilitate outcomes attractive enough for the fund’s board.<sup>562</sup> Even if the fund adopts procedures equally open to all countries for selecting the recipients of their recipients, the outcome may be still differ depending on the ability of the applicants to formulate and manage the proposals.

In sum, section 6.2.2 has shown that the prohibition of non-discrimination is particularly problematic to operationalise. It seems established that the enjoyment of the human right to medicines shall not be affected by intentional discrimination under the internationally prohibited grounds. Such prohibition, however, refers to – but does not deal with – the paradox of equality in the ‘human rights subsystem’, as also discussed in

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15.6 billion for more than 572 programs in 140 countries” [Global Fund for AIDS, Tuberculosis and Malaria, website, About the Global Fund, last accessed 9 November 2009].

<sup>561</sup> Also, “[t]he Fund will balance its resources by giving due priority to areas with the greatest burden of disease, while strengthening efforts in areas with growing epidemics” [GFATM, Framework Document, 2002: Section IV (A)].

<sup>562</sup> Thus, the fund can actually increase rather than decrease the inequality of the health status of the worse-offs. As Bluestone et al put it, “[t]he temptation for JPPIs [joint public-private initiatives] is to target countries or parts of countries where health systems are already strong and can deliver quick results” [Bluestone et al 2002: 17]. About GAVI *see also* Starling et al [2002]. The Global Fund indeed recognises those limitations, and calls on other donors to contribute to systematic, long-term development of fundamental health infrastructure [GFATM, Partners in Impact – Results Report 2007, 2007, para. 18].

Chapter 5 section 5.2.2. The principle of special attention to the vulnerable and the marginalised tries to obviate such paradox. However, this attempt of prohibiting substantive discrimination is not positivised by the legal subsystem and, as demonstrated, is of difficult application. It can be argued, more simply, that some *de facto* and substantive discrimination are unavoidable in extra-governmental interventions for the fulfilment of access to medicines. From a legal point of view, in effect, I am not aware of cases awarded against extra-governmental actors on the grounds of *de facto* and substantive non-discrimination. From an ethical point of view, it is noted, *de facto* and substantive non-discrimination are germane to the moral principles of equality and equity in the distribution of health-care resources. The importance and limitations of these principles are studied in the ethical analysis of the biopolitical choices concerning access to medicines, which has been presented in Chapter 5 with regard to the policies of home states and is further explored in section 6.4 with regard to extra-governmental actors.<sup>563</sup>

### 6.3 Protect

The CESCR describes the obligation to protect the human right to health internationally as follows: “[t]o comply with their international obligations in relation to article 12, States parties have to... prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law” [CESCR 2000: para. 39]. As seen in Chapter 4 section 4.1 the identification *de jure* of violations of the right with regard to access to medicines by non-state actors is problematic. I hypothesise here that, for example, foreign states may be required to regulate pharmaceutical companies on the quality and safety of medicines in sub-Saharan Africa. Such initiative could be seen as an ideal response to the problems of sub-Saharan African regulatory authorities in registering and controlling, especially, new and sophisticated pharmaceutical products.<sup>564</sup> However, it should not be overlooked that

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<sup>563</sup> Those principles, together with the other principles are analysed in Chapter 5 section 5.4.2.

<sup>564</sup> See Chapter 5 section 5.3.1.

these initiatives are also subject to cognitive limitations in the subsystem of science, ‘deficits of execution’, and exert important biopower.<sup>565</sup>

There are different problems related to the use of foreign standards or the international harmonisation for the regulation of the safety, quality and efficacy of pharmaceutical products. To begin with, there may be country or population-specific issues that need to be taken into account, such as those concerning the ‘metabolic pathway’ of the product [Hill and Johnson 2004: 14]. Next, clinical practice varies from country to country. Thus, what may be a reasonable indication for a product based on the data in one country may not fit with the style of clinical practice in another [*id.*]. The balance between, on the one side, the penchant in public health for prescribing regulation mandatory for all and, on the other side, the autonomy of professionals and patients to choose what product to use may not be universal. Furthermore, safety standards vary across countries which are supposed to weigh the balance of risks and benefits according to their health needs, for instance considering different burdens of disease and level of medical resources available [Jack 2007].<sup>566</sup> Moreover, issues of safety and efficacy are not definitely settled in the science.<sup>567</sup> In effect, it is not possible to determine *a priori* with clinical trials all the consequences of a medicine’s intake. Continuous empirical observation of the medium and long term – drugs surveillance and post-marketing monitoring are also needed. Thus, adverse reaction reporting has to be as widespread as possible. In effect, international networks are rather usefully undertaken in which drug regulatory authorities can exchange information between themselves or with international bodies such as the WHO.<sup>568</sup> Problematic has been instead the attempt of the WHO to exercise global regulation through the WHO Pre-Qualification Programme regarding pharmaceutical products for AIDS, tuberculosis and malaria. The programme has been responsible for serious inefficiencies.<sup>569</sup> This is unfortunate considering that the

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<sup>565</sup> Deficits of implementation are one of the practical limits of the steering of the political subsystem [Luhmann 1997: 44].

<sup>566</sup> See Chapter 5 section 5.3.1.

<sup>567</sup> See Chapter 5 section 5.3.1.

<sup>568</sup> WHO manages several programmes for sharing information on the safety, quality and efficacy of medicines. See WHO, How to Develop and Implement a National Drug Policy [2001: 57].

<sup>569</sup> The Prequalification Programme for HIV/AIDS, malaria and tuberculosis pharmaceutical products has been criticised by Dr Gillies, president of MSF’s International Council, as becoming “a barrier to, rather than a tool for, expanding access to medicines” [MSF, WHO Leadership Failed to Scale Up Prequalification 2005]. See

approval of medicines to be distributed in African countries, both by African regulatory authorities and by foreign donors, considerably relies on the programme.<sup>570</sup> It is also noted that exporting countries may take responsibility for controlling the safety and quality of the medicines exported. However, delays in the registration of pharmaceutical products for exportation or donation can damage access to medicines in African countries.<sup>571</sup>

#### 6.4 Fulfil

The role of extra-governmental actors in fulfilling the human right to medicines is of particular relevance considering the limited financial and technical resources of African countries for realising access to medicines.<sup>572</sup> For certain projects and diseases, especially those related to AIDS, external funds cover the greatest part of expenses in sub-Saharan Africa. In Tanzania, for example, the US President's Emergency Plan for AIDS Relief (PEPFAR) provides second-line, alternative first-line and children treatment for AIDS. Other states are involved in bilateral cooperation on access to medicines.<sup>573</sup> The Global Fund for AIDS, Tuberculosis and Malaria provides funding for all for first-line antiretrovirals. The Global Fund also provides all funding for the procurement of artemisin-based combination therapy (ACT) in the public sector. Many international NGOs contribute to access to health care and medicines in Tanzania. For example the Clinton Foundation, among other things, participates to AIDS and malaria programmes [Clinton Foundation 2008; Haonga 2007; Kwitema 2007; Hutton 2004]. Faith-based organisations provide 40% of health care [Tanzania, Survey of the Medicines Prices in Tanzania, 2004]. International pharmaceutical corporations are participating to partnerships for several health problems in Tanzania.<sup>574</sup> Novartis for example sells

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*also* Lancet, The important World of Drug Prequalification [2004]; Health Gap [2005].  
*See also supra* section 6.2.1.1.

<sup>570</sup> Interviews at TFDA [July-August 2009, Dar es Salaam].

<sup>571</sup> The US Food and Drug Authority (FDA), for example, has been criticised for such delays. *See e.g.* The Economist, From Bench to Bedside [2007], Health Gap [2005], interviews [July-August 2009, Dar es Salaam].

<sup>572</sup> *See* Chapters 2 and 5.

<sup>573</sup> The Danish (DANIDA), Finnish (FINNIDA), Norwegian (NORAD) and Swedish (SIDA) international development agencies have all collaborated on access to health-care and medicines in Tanzania. *See e.g.* Havnevik et al [1998].

<sup>574</sup> For example, Boehringer-Ingelheim, Abbott, Merck & co., Pfizer collaborate on AIDS; Novartis, Sanofi-Aventis collaborate on malaria; Bayer, Merck, Sanofi-Aventis

Coartem, the artemisin-based combination therapy selected by the Tanzanian state for distribution in the public sector, for a non-profit price to the country. Thus, the possibility of exercise of biopower ‘to *foster* life or *disallow* it to the point of death’ by extra-governmental actors in access to medicines is apparent. Sections 6.4.1 and 6.4.2 analyse the operationalisation and implementation of the contributions of, respectively, foreign states and non-state actors to the fulfilment of access to medicines. In particular, it investigates for whom, for what and how much extra-governmental should intervene in access to medicines. Section 6.4.3 deals with the enforcement of the human right to medicines with regard to extra-governmental actors.

#### **6.4.1 Foreign states**

There are no obligations of foreign states to immediately realise the provision of ‘essential drugs’, one of the core domestic obligations of the states parties to the ICESCR [CESCR 2000: para. 43(d)]. Nonetheless, the CESCR does identify duties of facilitation and cooperation for the realisation of ICESCR rights abroad, also referring to other international commitments, namely the UN Charter, the UN General Assembly Declaration on the Right to Development [UN GA Res. 128 (1986)] and the ‘well-established principles of international law’ [CESCR 1990(b): para. 14].<sup>575</sup> The CESCR operationalises such prescriptions for health indicating that foreign interventions should give priority to the vulnerable and marginalised groups of the population [CESCR 2000: para. 40]. In addition, drawing from the Alma Ata Declaration, the CESCR advances another parameter, namely, the difference in health status of people within and between countries [*id.*: para. 38]. The amount of aid to be distributed, according to the CESCR, should depend on the availability of resources of the donor country [CESCR 2000: para.

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collaborate on tropical diseases; Novo Nordisk, Sanofi-Aventis collaborate on chronic diseases [IFPMA, website, Health Partnerships: Developing World – 2009, Tanzania, 2010]. Novartis also delivered nearly 250,000 tuberculosis treatments to Tanzania between 2005 and 2008. With a 2009 Memorandum of Understanding, Novartis committed to extend the donation, delivering another 250,000 treatments over the 3-4 years. This donation is worth about US\$ 6 million and aimed to treat an estimated 60,000 patients per year [Novartis, website, Novartis Extends Tuberculosis Drug Donation to Tanzania, 2009].

<sup>575</sup> In the General Comment on the right to health, the CESCR refers to UN Charter art. 56, ICESCR arts. 12, 2(1), 22 and 23 and the Alma Ata Declaration to maintain that “[s]tates parties *should recognize* the essential *role* of international cooperation and comply with their commitment to take joint and separate action to achieve the full realization of the right to health” [CESCR 2000: para. 38, *emph. add.*].

39]. Nonetheless, in cases of emergency, each state “should contribute to this task to the maximum of its capacities” [*id.*: para. 40].<sup>576</sup> The Special Rapporteur on the human right to health also reported on the duties of international assistance and cooperation with similar position to those of the CESCR.<sup>577</sup>

In practice, foreign states traditionally provide aid for health abroad as part of their foreign policies. Furthermore, they are increasingly rationalising their interventions within programmes and plans in the name of development – which often also refer to human rights. In the following paragraphs I analyse these latter type of undertakings. It will be shown that the biopolitical decisions concerning help for health abroad entail momentous practical and moral problems. It will therefore be asked whether these interventions in effect fit with the fulfilment of the human right to health and medicines, and if such fit can be a normative model. As an example, I analyse the WHO’s Commission on Macroeconomics and Health (CMH) report “Macroeconomics and Health: Investing in Health for Economic Development” [CMH 2001]. The report of the Commission on Macroeconomics and Health gives recommendations for the utilisation of resources domestically in developing countries and for the disbursement of aid by extra-governmental actors. The report is very specific, quantifying the amount of resources that states ‘should’ donate for health in developing countries at US\$ 22 billion per year by 2007 and US\$ 31 billion per year by 2015 [CMH 2001: 11]. Importantly for our discussion the report is influential with regard to access to medicines. The report, for instance, is referred to by the “WHO Medicines Strategy 2004-2007” [WHO, WHO Medicines Strategy 2004-2007, 2004: 13, 58, 60, 62].<sup>578</sup> It is recalled that the CESCR sanctions the authority of WHO’s normative activity, recommending states to use

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<sup>576</sup> For emergencies the CESCR names “disaster relief and humanitarian assistance in times of emergency, including assistance to refugees and internally displaced persons” [CESCR 2000: para. 40]. Again, the CESCR refers to normative sources other than the ICESCR. In particular, the CESCR refers here to the UN Charter, relevant resolutions of the UNGA and of the World Health Assembly [*id.*].

<sup>577</sup> Like the CESCR, Hunt recommends the collaboration of developed states calibrated to the available resources and encourages priority for the disadvantaged groups [Hunt 2005: para. 64]. Hunt furthermore refers directly to the international aid for access to medicines envisioning that developed states should, *inter alia*, “help developing countries establish... health systems that include reliable medicine supply systems delivering quality affordable medicines for all...” [Hunt 2006: para. 64].

<sup>578</sup> The report is also having operational consequence as, for instance, approximately 40 countries (14 in sub-Saharan Africa, including Tanzania) have undertaken national follow-up to the Commission on Macroeconomics and Health’s recommendations [WHO, Tough Choices, 2006: 23].

WHO's works to formulate and implement strategies to realise the human right to health.<sup>579</sup> To note, the Commission on Macroeconomics and Health recognises health as human right, thereby it subscribes to the 'human rights subsystem' [CMH 2001: 21]. However, it also uses the communications of economics (incidentally, the Commission has been chaired from 2000 to 2001 by economist Sachs, who subsequently became the head of the UN Millennium Project). In fact, the report can be questioned as simplifying in its rationalisations a variety of complex issues, including economics, medicine and the moral concern for poverty and health care.

The 'investment for development' is purportedly aimed at favouring the poor. This should occur both directly, by relieving the poor from morbidity – although the Commission on Macroeconomics and Health recognises that the interventions it identifies also affect the better-offs<sup>580</sup> – and indirectly, through the economic benefits of a stimulated country's economy [*id.*: 23]. In particular, by 2010, around eight million lives per year would be saved "mainly in the low-income countries" through the aid provided by foreign states [*id.*: 11]. This amount equals to 330 million disability-adjusted life-years (DALYs) [*id.*: 12].<sup>581</sup> Consequently, attributing the economic benefit of US\$ 563 to one DALY they calculate that "the direct economic benefit of saving 330 million DALYs would be [US]\$186 billion per year, and plausibly several times that" [CMH 2001: 12]. Speaking the language of the economic subsystem, with regard to the stimulus to the country economy, the use made by the commission of DALYs to grasp the economic benefits is disputed.<sup>582</sup> Furthermore, in order to reduce the burden of

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<sup>579</sup> The CESCR attributes special relevance for the realisation of the right to health to the development of health programmes by WHO [CESCR 2000: paras. 1, 63].

<sup>580</sup> *Sic*, CMH [2001: 42].

<sup>581</sup> On the definition of DALYs *see* Chapter 2 section 2.2.1 and Chapter 5 section 5.4.2.

<sup>582</sup> The economic benefit of a health intervention cannot be really grasped by the DALYs saved. Attaran and Granville for instance argue that the proposed interventions should be evaluated on the long-run health and macroeconomic benefits [Attaran and Granville 2004: 182]. Accordingly, for example, they recommend treatment for (adults suffering from) malaria even though "the immune system cost nothing and saves life 99.8 per cent of time" because it saves the overall cost of malaria which includes the individual's out-of-pocket expenses and long-term disability, the worker's in lost wages, the enterprise's lost output and the state's lost income [Attaran and Granville 2004: 181]. Attaran and Granville also work on the assumption that "improving the delivery of essential medicines and producing good health is part of the more general agenda of development policy" [Attaran and Granville 2004: 189]. *See also* Kumaranayake and Walker [2002] and Brock and Wikler [2006] for a critique of the calculation of DALYs undertaken in the report of Commission on Macroeconomics and Health. In addition I note that the

disease, the Commission on Macroeconomics and Health promotes disease-oriented vertical health programmes on identifiable targets.<sup>583</sup> The commission assumes that vertical programmes are more efficient.<sup>584</sup> Lele et al, who are nonetheless critical towards vertical approaches, have indeed noted that “[t]he long history of management of vertical programmes resulted in the development of strong skills, extensive networks, and the basic infrastructure necessary for efficient and effective implementation of program activities” [Lele et al 2005: 21].<sup>585</sup> The efficiency of vertical approaches, however, is the object of a prolonged debate among public health specialists. In practical terms, considering the environment’s contingencies, it has been remarked that the integration of health interventions consents economies of scale in improving systems for a number of communicable diseases rather than attempting to strengthen systems disease by disease. Furthermore, integration also avoids the transaction costs of dealing with each disease – and vertical programme – separately [Lele et al 2005].<sup>586</sup> Always from a practical perspective, Kumaranayake and Walker point out that factors determining effectiveness vary from context to context, and such global approaches ignore context. Moreover, shifting resources is not costless, while these approaches ignore very critical investment on basic infrastructure of a health system, which may vary [Kumaranayake and Walker 2002].

Certainly, vertical programmes raise the profile of a specific problem or solution [Buse 2006]. Reportedly, the WHO/UNAIDS ‘3 by 5’ initiative sanctioned a change in thinking about how to tackle the global AIDS epidemic according to which not only prevention but also treatment are important [The Economist, 1.3 by 5, 2006]. The

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utilisation of lives saved as the only input for the DALYs saved seems to be erroneous as it neglects all the morbidity (short of mortality) saved.

<sup>583</sup> In the public health literature, horizontal programmes regard the health-care system at once, for instance through primary health care, while vertical programmes are disease-oriented.

<sup>584</sup> One of the principles inspiring the report is that of spending more efficiently. Indeed, the Commission on Macroeconomics and Health take part in the debate among global health experts on how development assistance for health should be used more effectively. For the debate over the most efficient uses of development assistance for health *see e.g.* Ravishankar [2009: 2113]. Also, there is an assumption that donor funds will flow if it is demonstrated that they will be used efficiently [CMH 2001: 97; Brundtland 2001].

<sup>585</sup> Lele et al write for the International Task Force on Global Public Goods, undertaking a study on “Health System Capacities in Developing Countries and Global Health Initiatives on Communicable Diseases” [International Task Force on Global Public Goods, Terms of Reference, 2002].

<sup>586</sup> *See also* Söderlund [1998: 205-6]; World Bank, World Development Report, 1993 [1993].

programme in effect fell short of its goal but it has been argued that “there is little doubt that, without the initiative, the number of people on treatment would not have tripled in just 2 years, or increased eight-fold in Africa” [Schwartlander et al 2006].<sup>587</sup> However, vertical programmes can ‘displace’ other health interventions.<sup>588</sup> In effect, in recent years, HIV/AIDS has received most of the attention from the international community while the volume of general health-system support that are not linked to specific programmes or diseases have remained low [Ravishanker et al 2009: 2118].<sup>589</sup> For the US, for instance, in 2003 HIV/AIDS constituted nearly half of all US health funding while health sector development funding had ‘virtually vanished’.<sup>590</sup> In Tanzania, the funding from the US and the Global Fund are strongly skewed in favour of AIDS.<sup>591</sup> Notably, the fact that

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<sup>587</sup> UNAIDS and WHO worked as catalysers of funding aimed to distribute antiretrovirals to three million people by 2005. In fact, only 1.3 million HIV positive patients obtained the antiretrovirals [The Economist, 1.3 by 5, 2006]. *See* the scathing critique pronounced by Bate and Mooney: “[t]he ‘3 by 5’ initiative cut corners on drug quality exposing thousands of patients to drugs of unknown quality (all over Africa); it over-strained poor countries’ fragile health systems, potentially undermining small-scale but successful treatment programs (notably Sierra Leone and Lesotho); failed to maintain dialogue or even consult with some countries that disagreed with its targets and methods (notably South Africa); furthermore, it failed to promote good clinical practice, so it is unknown how many patients are failing treatment (all over Africa)” [Bate and Mooney 2006].

<sup>588</sup> The resources displaced can be financial as well as human, technical etc. For instance, it has been reported that the best medical talents are diverted to ‘trendy’ causes and away from basic medicine such as against diarrhoea and respiratory infections – the chief killers of children [The Economist, More Money than Sense, 2007]. *See* also Lele [2005], Walt and Buse [2006], Brown et al [2006].

<sup>589</sup> This notwithstanding the arguments made by donors emphasising the importance of funds providing general health support [Ravishanker et al 2009: 2118]. *See generally* Ravishanker et al for an account of global health development assistance for health from 1990 to 2007 [Ravishanker et al 2009].

<sup>590</sup> Jeremy Shiffman [Presentation at annual meeting of American Public Health Association, November 7th, 2006]. A similar remark has been expressed by USAID officials in Tanzania [Interviews, US Embassy, Dar es Salaam, August 2009].

<sup>591</sup> The 2010 Congressional Budget Justification for Tanzania reveals that roughly US\$ 280 ml have been requested for AIDS, while US\$ 52 for malaria, US\$ 8 for maternal and child health, US\$ 3.7 for tuberculosis [United States of America, 2010, FY 2010 Congressional Budget Justification for Foreign Operations, 2010]. A senior USAID official in Tanzania also hinted at a 67% increase in US funds for AIDS from 2008 to 2009 [Interviews, 2009, US Embassy, Dar es Salaam]. Analogously, the maximum grants approved by the Global Fund for AIDS, Tuberculosis and Malaria, the other major donor for medicines in Tanzania, are also skewed in favour of HIV/AIDS projects, considering that they are divided as follows: for HIV, US\$ 507,536,271; for HIV/tuberculosis, US\$ 83,466,904; for malaria, US\$ 275,300,919 (plus US\$ 76,050,523 pending request from round 9); for tuberculosis, US\$ 16,498,948 [GFATM website, Tanzania and the Global Fund, last accessed 25 November 2009]. Worldwide, to compare, most funding of the

more international resources are flowing to the AIDS cause does not necessarily entail that at the domestic level less resources are dedicated to other health problems. The international resources, indeed, can be merely additional rather than fungible. In the case of global health initiatives for AIDS in Tanzania however Hutton, in a thought-through review of the “Global Health Initiatives in HIV/AIDS in Tanzania”, maintains that “it is becoming clear that funds for HIV/AIDS will not contribute significantly to general capacity development, and therefore will not benefit control of other diseases. It is likely that other major killer diseases will not be addressed sufficiently, leading to gross inefficiencies in resource allocation” [Hutton 2004: 15-16]. Hutton specifically points out that “the HIV/AIDS Public Expenditure Review (November 2003) already showed that donor projects do not all address government priorities” [*id.*]. Furthermore Hutton reports that the annual budget of Tanzania (including external support) for the AIDS Care & Treatment Plan dwarfed the entire Health Sector budget including external support – in 2004 the former stood at US\$ 100 million while the second amounted to US\$ 200 million.

The contentions of the Commission’s report are in effect questionable when arguments regarding medicine and the moral concern for health are taken into consideration. Separating patients in vertical programmes according to the specific disease they suffer is problematic considering their very health. Patients often suffer from a combination of health conditions at the same time which can afflict them with impairing synergies.<sup>592</sup> Also, the health problems need not be medical strictly speaking. For example malnutrition has devastating effects on health.<sup>593</sup> The World Bank as well recognises the importance of horizontal programmes, primary health care and continuity as opposed to vertical, ‘cut and run’ projects [World Bank 1994: 51]. Therefore immunisation, maternal and child care must be integrated in health facilities providing steady and ongoing care [*id.*]. Unger et al also remark that “the number of diseases requiring clinical intervention makes it impossible to consider vertical programmes as the gold standard template for disease control organisation” [Unger et al 2006: 3]. Unger et al even contend that the favour of international aid for policies of health-care

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Global Fund (56%) is devoted to fighting AIDS, whereas tuberculosis, the disease with the smallest financing gap, has the smallest share (17%) [Feacham and Sabot 2006]. The role of the Global Fund in the fulfilment of access to medicines is analysed *infra* in section 6.4.2.

<sup>592</sup> Interviews with physicians, Tanzania and Kenya, July-August 2009.

<sup>593</sup> Interviews at KEMRI-Wellcome Trust, Kilifi District Hospital [August 2009, Kilifi, Kenya]. On the effects of malnutrition on health *see also* Chapter 2 section 2.2.2.

fragmentation and privatisation strained first line public health care delivery [Unger et al 2006: 4].<sup>594</sup> Admittedly, furthermore, the costing estimates of the Commission on Macroeconomics and Health do not include “some key categories that will need to be part of any operational health system, such as trauma and emergency care...; tertiary hospitals; and family planning...beyond the first year after birth” because they are not cost-effective [CMH 2001: 55-56].<sup>595</sup>

From the perspective of the ethics of distribution of health care, issues of equality arise country-wide and worldwide for the patients who have not been selected to obtain assistance from the international vertical programmes.<sup>596</sup> For instance Daniels noted with regard to the ‘3 by 5’ programme that out of the six million people who would potentially enjoy the benefits of the programme only three millions would have been chosen [Daniels 2005].<sup>597</sup> These issues also arise for the population who does not suffer from the condition addressed by the vertical programme. Furthermore, it is noted that the Commission on Macroeconomics and Health proclaimed to pursue the equity principle, prioritising the poor, also by relieving them from morbidity. However this principle is challenged by the medical principle of need which demands to look solely at health needs.<sup>598</sup> Moreover, in fact, the Commission founds its calculations on the improvement of the aggregate health status of a population. Noteworthy, burden of disease and cost-effectiveness calculations correspond to a prudential, rather than moral, approach.<sup>599</sup>

It is asked what indications originate from the report of the Commission on Macroeconomics and Health specifically for the action by extra-governmental actors on access to medicines. With particular regard to pharmaceutical products it has been noted

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<sup>594</sup> This occurred through “pressure exerted by disease control managers, by multiplication of disease-specific divisions in (inter) national administrations, by ill-defined priority-setting and increasing opportunity cost, unrealistic costing, inadequate budgets, and financial overruns, failure to make clear the line of command; tension between health care professionals over income disparity, treatment discrepancy and opportunity costs and problems with sustainability...” [Unger et al 2006: 4].

<sup>595</sup> Indeed, with regard to the essential health system envisaged, it is “a rather minimal health system, one that can attend to the major communicable diseases and maternal and perinatal conditions that account for a significant proportion of the avoidable deaths in the low-income countries” [CMH 2001: 55].

<sup>596</sup> For a discussion of the principles of health interventions prioritisation *see* Chapter 5 section 5.4.1.

<sup>597</sup> Daniels specifically argues that the criteria for rationing were not discussed, therefore the decision was not a ‘just decision’ [Daniels 2004].

<sup>598</sup> *See* Chapter 5 section 5.4.2.

<sup>599</sup> *See* Sheaff [1996: 169]. *See* Chapter 5 section 5.4.2

that, if they are to follow vertical programmes, the parallel delivery of medicines may lead to duplications (*e.g.*, in transport costs), distortions (as staff is depleted from other functions, and demotivated if it sees higher pays in other sectors), disruptions (as health workers are taken from other jobs, re-training), and distractions (for example the uncoordinated reporting requirements) [Travis et al, 2004: 902]. In Tanzania, vertical programmes for essential drugs distribution have been attempted by donors in the past but have not been sustainable [Kanji 1992: 671]. Prioritisation is also needed within the disease focus in order to select the modality of intervention.<sup>600</sup> In our case, it can be asked how much should be spent on pharmaceutical products as opposed to, say, non-pharmacological prevention. The cost of saving from AIDS one DALY by different interventions, for instance, has been estimated as: US\$ 8 via blood safety, US\$ 13 via sexually transmitted diseases (STDs) control, US\$ 18 via voluntary counselling and testing (VCT), US\$ 19 via preventing mother-to-child transmission (PMTCT), and finally US\$ 3502 via HAART [Marseille et al 2002]. Moreover, as Hutton remarks for Tanzania, the “large differences between the cost-effectiveness of prevention and treatment are further heightened by the different population sizes that can be affected by prevention and treatment activities, at 88% and 1% of the population, respectively” [Hutton 2004: 18]. In light of the ethical considerations seen in the paragraphs above and in Chapter 5, however, arguments of cost-effectiveness are not conclusive against treatment. In particular it is recalled that medical need rather than DALYs can be used to decide the adoption of a certain health intervention. Or, it can be argued that triage should be based on the identifiable patient rather than on the ‘statistical people’.<sup>601</sup>

In sum, at this stage we can try to answer the questions posed at the beginning of this section, whether the rationalisation of foreign aid for health in developing countries proposed by the WHO Commission for Macroeconomics and Health fits with the fulfilment of the human right to medicines, and if such fit can be a normative model. The report of the Commission, it can be argued, by and large fits with some instances of the human right to medicines. For example, the report prioritises the poor, also by relieving them from morbidity. This is possibly in line with the recommendations of the CESCR and Special Rapporteur on the vulnerable and marginalised [CESCR 2000: para. 40; Hunt 2005: para. 64]. Or, it focuses on certain conditions, again arguably affecting

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<sup>600</sup> In effect, the Commission on Macroeconomics and Health’s ‘primary targets’ are indeed numerous.

<sup>601</sup> See Chapter 5 section 5.4.2.

vulnerable and marginalised groups [*id.*]. The report also focuses on a “minimal health system, one that can attend to the major communicable diseases and maternal and perinatal conditions that account for a significant proportion of the avoidable deaths in the low-income countries” [CMH 2001: 55]. This idea is arguably akin to the satisfaction of minimum core obligations of the right to health [CESCR 1990(b): para. 10; 2000: para. 43]. Yet, it is recalled that the human right to health also sanctions other injunctions, including the prescription that everyone is entitled to the maximum attainable standard of health [ICESCR art. 12(1); ACHPR art. 16]. Therefore, the international human right to medicines prescribes international cooperation; however, it is not clear how cooperation should be implemented. The indications from the human right to medicines are often paradoxical, contradictory and not framed as legal/illegal prescriptions. Thus, the interventions of foreign states in pursuit of the ‘indisputable’ access to health care and medicines entail considerable power and biopower to ‘foster life or disallow it to the point of death’, influencing the health as well as other rights, interests, needs and liberties in sub-Saharan Africa [Foucault 1976: 138].

In effect, it is reckoned from a normative point of view, the algorithm proposed by the WHO Commission for Macroeconomics and Health proposes undue simplifications of the complexities and contingencies of medicine, ethics as well as economics and development. Overall, I express caution with regard to the elaboration of special principles and programmes for the prioritisation of health interventions in developing countries. In fact, as demonstrated in Chapter 5 section 5.4.2, the prioritisation of health interventions poses sensitive, knotty, practical and ethical dilemmas which do not seem to be solved by the programmes undertaken by foreign states. Furthermore, they are affected by the limits of steering. I am therefore critical about similar international attempts to setting priorities in developing countries,<sup>602</sup> such as the 1993 World Development Report [World Bank, World Development Report 1993], the WHO’s World Health Report 1999 [WHO, The World Health Report, 1999], which also recommend cost-effectiveness analysis in investment for development, and the Millennium Development Goals (MDGs), with their philosophy of target-setting and vertical programmes. With specific regard to the Millennium Development Goals I share

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<sup>602</sup> Cf. the Commission’s 2005 report “Tough Choices” which stresses the fact that “[t]here is no ‘one way’ to approach the planning and advocacy needed for scale-up. Preservation of a ‘bottom-up’ approach translates into very different priorities, sequencing, and capacity needs” [CMH, Tough Choices, 2006: 54].

the appraisal of Horton, who aptly pointed out that: "...what is missing from these Goals – e.g., any mention of chronic illnesses, such as heart disease, cancer, and stroke – has damaged the overall credibility of the MDG programme" [Horton, 2006: 1793].

#### 6.4.2 Non-state actors

International human rights law does not prescribe obligations to fulfil the human right to medicines directly onto non-state actors. States can nonetheless regulate the promotion and fulfilment of access to medicines by non-state actors.<sup>603</sup> Furthermore, soft law and self-regulation may demand to non-state actors to help realising the human right to medicines. Trends of global health financing illustrate an increasing role of the voluntary contribution of non-state actors in global health initiatives.<sup>604</sup> This section looks at the activities for the fulfilment of access to medicines undertaken by: public-private partnerships such as the Global Fund for AIDS, Tuberculosis and Malaria or partnerships for bulk purchasing; NGOs; and pharmaceutical companies.

The Global Fund for AIDS, Tuberculosis and Malaria is the largest health-related global public-private partnership [Leach et al 2005: 44-5], among those collecting and disbursing more resources for access to medicines;<sup>605</sup> indeed its achievements for AIDS, tuberculosis and malaria are tremendous.<sup>606</sup> However, with a view to the *fulfilment* of a

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<sup>603</sup> Also, states can be acting in cooperation with non-state actors. On the *casus specialis* of conduct of non-state actors imputable to states and influencing the right to health see Clapham and Rubio [2002]. See the UK Human Rights Joint Committee's report "Any of our business? Human Rights and the UK private sector" on the application of the UK Human Rights Act 1998 to businesses performing public functions [Human Rights Joint Committee 2009: Section 6, Protect].

<sup>604</sup> For example Ravishankar et al report that the Global Fund for AIDS, Tuberculosis and Malaria and the Global Alliance for Vaccines and Immunization (GAVI), two public-private partnerships, have attracted a growing share of funds and the role of NGOs in terms of spending funds from the public and private sectors has expanded massively in low-income and middle-income countries [Ravishankar 2009: 2121-22]. On the charitable contributions of the private see also CMH [2001: 95], Commission on Macroeconomics and Health Working Group 6 [2002]; Claeson and Wagstaff [2004]; Friedman et al [2003].

<sup>605</sup> According to Kazatchkine, executive director of the Global Fund, in 2007 the fund sponsored some two-thirds of all tuberculosis treatment worldwide, 45% of malaria treatment and nearly 30% of programmes against AIDS [AFP 2007].

<sup>606</sup> Reportedly, as of 30 November 2009, the Global Fund has performed outstanding achievements for AIDS, tuberculosis and malaria. For AIDS: 2.5 million people were receiving antiretroviral treatment, 105 million HIV counselling and testing sessions were

human right to medicines and to ethics some points should be raised. As seen in section 6.2.2.2 above, it is not necessarily the worse-offs in health or income who receive the Global Fund's attention. Next, these results only concern three diseases, constituting a discrepancy with other conditions.<sup>607</sup> The effects of the fund, furthermore, vary according to the context. The Global Fund's interventions can also displace national priorities and are in effect volatile, deployed on time-limited projects. Leach et al for instance remark that the fund imposes short-term horizons that can be counterproductive: "[e]ven if actual allocations are yearly and subject to regular review and evaluation, sustainability is enhanced when resource commitments are known and driven by health needs" [Leach et al 2005: 57].<sup>608</sup> In the practice, furthermore, the fund's model has shown 'deficits of execution' with regard to slow disbursement of the sums committed, low oversight, transparency, accountability and efficacy of the projects.<sup>609</sup> In Tanzania, the Global Fund

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conducted; 4.5 million orphans were provided with medical services, education and community care; 790,000 HIV-positive pregnant women have received HIV prevention from mother to child transmission (PMTCT) treatment. For tuberculosis: 6 million additional cases of infectious tuberculosis were detected and treated; 48% of the 2009 estimated international targets for detection of tuberculosis cases and treatment using DOTS were contributed by Global Fund supported programs. For malaria: 104 million bed nets were distributed to protect families from transmission; 108 million malaria drug treatments were delivered [Global Fund for AIDS, Tuberculosis and Malaria Website, Fighting AIDS, Tuberculosis and Malaria, last accessed 3 December 2009]. On the Global Fund *see also supra* section 6.2.2.2.

<sup>607</sup> AIDS, tuberculosis and malaria funds can be additional to African health system resources. But they can also distort the countries' political priorities. *See also supra* section 6.4.2.

<sup>608</sup> The same criticism can be applied to GAVI [Leach et al 2005: 57]. The Global Fund, again, recognises those limits acknowledging that "the Global Fund cannot achieve sustainable results on its own" [Global Fund for AIDS, Tuberculosis and Malaria, Partners in Impact – Results Report 2007, 2007, para. 18].

<sup>609</sup> *See*, for instance, Lancet's Editorial "A Call for Transparency at the Global Fund" [2006] and previous articles in the Lancet, *e.g.*, Attaran et al, "WHO, the Global Fund, and medical malpractice in malaria treatment" [2003], Nantulya and Lidén "Response to Accusations of Medical Malpractice by WHO and the Global Fund" [2004], Kokwaro et al, "WHO, the Global Fund, and Medical Malpractice in Malaria Treatment" [2004]. *See also* Jones [2003].

is not exempt from complaints of lack of accountability<sup>610</sup> and displacement of resources.<sup>611</sup>

Other international institutions facilitate access to medicines in sub-Saharan Africa by undertaking procurement of medicines via international bulk purchasing. Current initiatives in this field are for example the Global Alliance for Vaccines and Immunization (GAVI) for vaccines, the Global Drug Facility for generic medicines to treat tuberculosis, the Green Light Committee for multi-drug resistant tuberculosis, the UN Population Fund for contraceptives [Grace 2003]. Again, some practical and ethical considerations run against a universal extension of such initiatives. In general, aggregated procurement is a cumbersome procedure that needs regularity in demand and distribution of the product lest running into shortages or oversupply of the good [Bate 2007]. Importantly, the monopsony of aggregate procurement may stifle competition [Grace 2003]. Public-private partnerships are also engaged in research and development for diseases affecting sub-Saharan Africa. Such institutions however may not replace patents as an incentive to pharmaceutical innovation. Patent pools or prizes for certain inventions suffer two major shortcomings: first, in order to be economically manageable, they are set for specific goals and diseases. Therefore, they select between conditions. Next, they are not likely to provide incentive for ‘incremental’ innovation, *ie* the improvement of existing products.<sup>612</sup>

NGOs cover different roles in access to medicines spanning the provision of health care in sub-Saharan Africa, procurement of medicines as non-profit wholesale suppliers, negotiation of discounted medicines with pharmaceutical companies, research on the supply chain, research and development of pharmaceutical products and

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<sup>610</sup> On the lack of accountability and control *see* the Global Fund’s “Audit Report on Global Fund Grants to Tanzania” [Global Fund for AIDS, Tuberculosis and Malaria 2009]. The criticisms are confirmed in my interviews with participants to the Country Coordinating Mechanism (CCM) [Interviews, USAID, Dar es Salaam, July-August 2009].

<sup>611</sup> Most health policies at the national level in Tanzania tend to emphasise their contribution to the fight against AIDS, tuberculosis and malaria in order to attract the Global Fund’s resources. For example, a senior official at the National Tuberculosis and Leprosy Program (a department of the Tanzanian Ministry of Health and Social Welfare) admitted that some national health programmes had been reconfigured in order to include schemes on ‘AIDS and TB’, as such label increases the chances of getting funds from the Global Fund [Interviews, Dar es Salaam, July 2009].

<sup>612</sup> *See, e.g.,* Lyles [2006]. *See generally* the comprehensive report by WHO’ Expert Working Group [Expert Working Group 2010]. On patent pools *see also* Duxbury and Page [2008].

advocacy.<sup>613</sup> In Tanzania, 40% of health care is provided by faith-based organisations [Tanzania, Survey of the Medicines Prices in Tanzania, 2004]. The quality of care offered by those institutions is generally better than that provided by the public sector. Some concerns about the equity of such arrangements are raised considering that the cost sharing they collect is generally higher than that requested by the public service [*id.*]. NGOs indeed can provide a big contribution to access to medicines. However, typically NGOs act according to their vocation and mandate, focussing on a region or a cause, rather than out of a systematic plan for the fulfilment of the human right to medicines.<sup>614</sup> Furthermore, NGOs can undertake research projects on access to medicines in sub-Saharan African countries. Those programmes raise further questions about their impact on the certainty and stability of a health system. Publications and advocacy by NGOs can be very interesting, as NGOs can be independent from governments and based in the field. However, often NGOs generalise and simplify themes according to their goals.<sup>615</sup>

As Chapter 4 showed, many prescriptions concerning the fulfilment of access to medicines in sub-Saharan Africa are being formulated on the role of the pharmaceutical industry by the UN Special Rapporteur on the human right to health, other international soft law and the industry itself.<sup>616</sup> The question here is what should these actors do, and how should they do it, in order to fulfil the human right to medicines. The UN Special Rapporteur Hunt, in the “Draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines” identifies recommendations for the formulation and implementation of access to medicines initiatives by pharmaceutical companies [Hunt 2007(a)].<sup>617</sup> Namely, the company should:

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<sup>613</sup> See, e.g., Leach et al [2005]. NGOs are here understood, broadly, as non-profit companies. See Chapter 5 section 5.3.2.3 for the definition of NGO.

<sup>614</sup> Operational NGOs in particular can offer selective care, avoiding certain medical practices out of moral or religious objection.

<sup>615</sup> See also Dar [2004]. See Luhmann’s critical remarks on organisations: organisations are identified as a type of autopoietic social systems which handle themes according to the actions of that system (they also self-describe themselves as ‘action system[s]’) [Luhmann 1995: 196-197]. Thus, “[o]rganizations are not goal-realizing but goal-seeking systems. They are constantly involved in interpreting (observing) their own operations and seek goals, or even new goals, that make what happens or has happened understandable and determinable” [Luhmann 1998: 105]. Cf. Knudsen contending that organisations structurally couple to different subsystems to deal with contingency [Knudsen 2007: 114].

<sup>616</sup> See Chapter 4 section 4.3.2.3.

<sup>617</sup> The Guidelines do not identify a duty of providing medicines as such but in the introductory paragraphs they recall that “many States have emphasised the profound

- (i) give particular attention to disadvantaged individuals and communities, such as those living in poverty;
- (ii) give particular attention to gender-related issues;
- (iii) give particular attention to the needs of children;
- (iv) give particular attention to the very poorest in all markets;
- (v) be transparent;
- (vi) encourage and facilitate the participation of all stakeholders, including disadvantaged individuals and communities.

The criteria seem favouring the poor and marginalised, in line with other prescriptions of the Special Rapporteur on the realisation of the human right to medicines, but are quite broad and indicative, as they cannot be all pursued at the same time.<sup>618</sup>

I have consequently analysed the practice of implementation that pharmaceutical companies generally undertake in order to facilitate and provide access to medicines in sub-Saharan Africa.<sup>619</sup> Mainly, those actions are tiered pricing and donations for

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impact – positive and negative – of pharmaceutical companies on the ability of governments to realise the right to the highest attainable standard of health for individuals within their jurisdictions” [Hunt 2007(a): preambular para. E].

<sup>618</sup> On the attention for the poor and marginalised in the work of the Special Rapporteur *see e.g.* Hunt [2005: para. 64; 2006: para. 52].

<sup>619</sup> I have reviewed the same companies whose self-regulation I have analysed in Chapter 4 section 4.3.2.3 (more initiatives relating to the collaboration of pharmaceutical companies for access to medicines can be found at the IFPMA data base on health partnerships online [IFPMA, website, Health Partnerships: Developing World – 2009, 2010]). Boehringer Ingelheim participates to the Global Compact and donates Viramune® (nevirapine) to ‘the countries most in need’ [Boehringer Ingelheim, website, Viramune Donation Programme, last accessed 7 December 2009]. The Viramune® Donation Programme has provided the non-nucleoside reverse transcriptase inhibitor Viramune® (nevirapine) to target the prevention of mother-to-child transmission (pMTCT) of the HIV-1 virus during birth in the countries most in need. By 2008, this programme extended to 169 schemes in 59 countries in Africa, Asia, Latin America and Eastern Europe [Boehringer Ingelheim, website, Viramune Donation Programme, 2009(c)]. I could not find such type of commitments at Cipla’s website. GlaxoSmithKline commits to work to address global health care challenges through action in four areas: preferential pricing, research and development, partnerships and health-care services [GSK(c), website, Our Approach and Contribution, 2009]. In practice GlaxoSmithKline for example has announced that “[o]n 1 April 2009 we implemented price reductions on our patented products in the Least Developed Countries (LDCs). Our commitment is that all GSK patented products in these countries will now cost less than 25 per cent of their price in the referenced developed countries. We reduced prices for seven patented brands (110 individual product lines and formulations) by an average of 45 per cent. In some countries prices were not reduced immediately due to regulatory processes such as needing to obtain government authorisation, however the price reduction process was initiated. We also cut prices in some non-LDC markets in East Africa and Francophone West Africa to reduce the risk that products would be diverted from the LDCs and sold in these wealthier countries, thereby reducing their availability in the LDCs” [GSK, website, The Future, 2009]. Novartis is, for instance,

developing countries (or other countries ‘in need’). It is asked whether those actions do in effect contribute to the fulfilment of the human right to medicines. With regard to differential pricing, a problem resides in the fact that price reductions by pharmaceutical companies are often individually-negotiated on a case-by-case basis.<sup>620</sup> As a consequence, those policies can be volatile and unreliable as there may not be guarantees that price offers will continue and the range of products on offer may not be predictable [Bluestone et al 2002: 12]. Also, one-off price reductions can “discourage long-term health planning in developing countries” [*id.*].<sup>621</sup> An alternative can be globally regulated tiered pricing system, but this can be problematic to design and implement in principle and in practice.<sup>622</sup> Furthermore, pharmaceutical companies generally oppose such forceful interventions in the market.<sup>623</sup>

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“[w]orking with WHO to help eliminate leprosy by offering free treatment to patients worldwide; supplying our antimalarial drug Coartem without profit through multilateral institutions and public-private partnerships [such as the Global Fund for AIDS, Tuberculosis and Malaria in Tanzania]; [developing medicines and vaccines to combat diseases in the developing world]; Providing discounts and assistance programs to low-income patients in the developed world” [Novartis, website, Patients, 2009]. With specific regard to pricing, Novartis is also committed to ‘access-to-medicines programs’ [Novartis, website, Drug Pricing, 2009]. Pfizer recognises ‘threefold’ responsibilities to improve access to medicines, which include research and development to benefit patients in developing countries, support to the development of health-care systems and, for the distribution of existing medicines, tiered pricing and donations [Pfizer, website, Access to Medicines, 2009]. Ranbaxy has policies on corporate social responsibility which include research on anti-malarials and other medicines for developing countries’ diseases, and the distribution of cheap antiretrovirals and anti-infectives for opportunistic infections [Ranbaxy, website, Anti malaria project, 2009; Ranbaxy website, Anti HIV/AIDS].

<sup>620</sup> See footnote 620 above.

<sup>621</sup> See also MSF reporting on the technical difficulties of utilising, for example, antiretrovirals under differential price schemes from Abbot and Roche [MSF, Untangling the Web of Price Reduction, 2005: 7].

<sup>622</sup> For example, the Accelerating Access Initiative aims to negotiate antiretrovirals prices according to each targeted country’s socioeconomic condition. The initiative was launched in 2000 and includes UN agencies and several pharmaceutical companies. However, the roll-out of the initiative has been slow and hindered by individual countries having to negotiate prices and conditions [Schwartzländer et al 2006]. The originator companies participate voluntarily and reportedly have often been shy in making their price offers for certain countries. In 2003, for example, originator companies made price offers only to least-developed countries or to sub-Saharan countries [Hellerstein 2003]. Only three offers were publicised for medium-income countries. See generally Grace [2003]. See also Act up Paris [2002]; MSF, Reports and Publications [2002]; Mossialos and Dukes [2001] and WHO and WTO Secretariats [2001].

<sup>623</sup> Bluestone et al report from interviews with the industry that companies oppose such system mainly citing two concerns: parallel importing and reference pricing [Bluestone

With regard to the donations of medicines there is little doubt that they constitute “a valuable tool in specific circumstances, such as when the disease dynamics require only one-off treatment or vaccinations” [PSG 2004: 15]. However, as Bluestone et al critically point out, donations can also distort the national procurement systems [Bluestone et al 2002: 17]. Moreover, “donations on the scale needed to address the health crisis are not a commercially sustainable, long-term solution” [*id.*: 13]. Donations in effect also serve marketing purposes for the donating company, which can penetrate a market or win the loyalty of the national procurer. Those practices can be detrimental to the patients of African countries in so far as they have the effect of crowding out the products of other pharmaceutical companies.<sup>624</sup> Finally, it has to be mentioned that even partnerships in research activities for developing countries’ diseases<sup>625</sup> raise issues of independence and conflicts of interests.<sup>626</sup>

In sum, the ‘human rights subsystem’ formulates meta-positive communications about the roles and responsibilities of non-state actors to fulfil the human right to

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et al 2002: 13]. Yet, those features can be avoided with appropriate regulation. *See, e.g.*, Bluestone et al [2002: 12]; WHO and WTO Secretariats [2001]. Pfizer nonetheless remarks that “[e]ven discounted medicines will often remain unaffordable for patients in poor countries...” [Pfizer, website, Access to Medicines, 2009]. For this reason Pfizer has claimed to prefer donating medicines in the context of partnership programmes [*id.*]. Novartis, while claiming that for some products it does participate to differential price schemes, also states that generally pharmaceutical companies should be free to set prices for their products [Novartis, website, Drug Pricing, 2009]. Certainly pharmaceutical companies have a vested interest in ad hoc negotiations which can serve as bargaining chips to entrench their market power in a country.

<sup>624</sup> Novartis for instance is well established in Tanzania, where it contributes to fund the prestigious Ifakara research centre, donates tuberculosis drugs, and sells Coartem (artemether-lumefantrine, the first-line malaria therapy) at cost. It will be interesting to see whether Coartem will be designed as the national artemisin-based combination therapy in the next request for support to the Global Fund for AIDS, Tuberculosis and Malaria, even though a cheapest Indian generic equivalent (Lumerax, produced by Ipca Laboratories Ltd.) is now registered in Tanzania.

<sup>625</sup> Actions of pharmaceutical companies other than donations and tiered pricing which can be framed as ‘fulfilling’ the human right to medicines include research and development of new products; charitable actions other than medicines donations. *See* footnote 620 above.

<sup>626</sup> In the case of Novartis in Tanzania, for instance, research outcomes from the Ifakara Health Institute, partially funded by the Novartis Foundation for Sustainable Development, include studies on the efficacy of artemether-lumefantrine that led to the change of first-line treatment of malaria from sulphadoxine-pyrimethamine to artemether-lumefantrine, and thence Coartem, the Novartis proprietary-branded artemether-lumefantrine [Mugittu et al 2005]. Other studies include social marketing to raise awareness of malaria and encourage its treatment with artemether-lumefantrine [Hetzl et al 2007].

medicines. However such communications avoid the conflicts between ‘indisputable values’ and the contingencies of the environment. Certainly, the actions of these non-state actors can be agile, responsive to local needs and effective. Indeed the amount of help provided by these actors to increasing access to medicines and the welfare of – selected – groups of individuals is tremendous. However, such initiatives can be dubious in terms of equity, non-discrimination, effectiveness, predictability, coordination with health systems overall and reliability. Thus, the actions of non-state actors relating to the realisation of access to medicines can be problematic, wielding power and biopower to foster or disallow life. Such powers are exacerbated by the fact that non-state actors (like foreign states) are generally poorly accountable to the subjects of their influence in sub-Saharan Africa.

### **6.4.3 Enforcement**

Section 6.4.3 analyses some critical issues concerning the enforcement of the duties of extra-governmental actors and the role of foreign states in enforcing a human right to medicines. In particular, this section reviews: the enforcement of transboundary violations of the human right to medicines committed by a foreign a state (section 6.4.3.1); the enforcement by foreign states of violations of the human right to medicines committed by the home African states in their jurisdictions (section 6.4.3.2); and the enforcement of violations of the human right to medicines committed by non-state actors (section 6.4.3.3). Particular attention is dedicated to the enforcement of the *fulfilment* of the human right to medicines, bearing in mind the research question “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”.

#### *6.4.3.1 Transboundary violations of the human right to medicines*

States can be held internationally responsible for the transboundary violations of human rights.<sup>627</sup> In order to redress such torts, the foreign state where a violation has occurred – or a third state with legal interest in the matter – can use diplomatic or economic retortions, peaceful countermeasures or recur to international adjudication, for

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<sup>627</sup> See generally Skogly and Gibney [2002].

instance through the International Court of Justice (ICJ) or the treaty-based semi-judicial procedures where applicable.<sup>628</sup> None of these measures of redress has been much forthcoming for transboundary violations of the human right to health or medicines. With regard to international adjudication, I could not find a case of transboundary violation of the human right to medicines (or, access to medicines within the human right to health) to be addressed by the ICJ<sup>629</sup> or African Commission in its intra-state semi-judicial complaint procedure.<sup>630</sup> Nonetheless, within the CESCR state-reporting procedure, states have occasionally reported about the influence of their action on access to medicines in other countries. For example India reported to the CESCR that it has been actively pursuing the implications of the implementation of the TRIPS regime on health for developing countries in various multilateral forums and in the WTO ministerial conferences [CESCR, E/C.12/IND/5, 2007: 137, para. 520]. However, the CESCR does not enquire systematically on the impact of intellectual property protection on access to medicines abroad.<sup>631</sup>

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<sup>628</sup> See generally Cassese [2005: 241-310]. State responsibility is part of customary law, albeit not fully settled. See Chapter 4 section 4.3.1.

<sup>629</sup> The right to health, as well as other human rights, are not habitual subjects of ICJ disputes. In recent years however a few cases have been filed regarding adverse effects on health of transboundary activity. In particular, in *Aerial Herbicide Spraying (Ecuador v. Colombia)*, the applicant makes explicit reference to health and human rights [ICJ, *Application of Ecuador*, 2008: paras. 26, 38]. The case is pending. See also the ICJ case, *Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, where the applicant makes reference to health but not to human rights [ICJ, *Application of Argentina*, 2006]. In the judgment of 20 April 2010, as well, there is no mention to the human right to health [ICJ, *Pulp Mills on the River Uruguay*, 2010]. Furthermore, the right to health has been clearly recognised by the ICJ as matter under protection in international law in the 2004 advisory opinion on the *Legal Consequences of the Construction of a Wall in the Occupied Palestinian Territory* [ICJ, *Wall in the Occupied Palestinian Territory*, 2004]. Namely, “the Court is of the opinion that the construction of the wall and its associated regime...also impede the exercise by the persons concerned of the right to work, to health, to education and to an adequate standard of living as proclaimed in the International Covenant on Economic, Social and Cultural Rights and in the United Nations Convention on the Rights of the Child” [*id.*: para. 134]. Israel is part to both Conventions [*id.*: para 103].

<sup>630</sup> Baderin has noted however that, until 2007, the African Commission had received only one interstate communication, that is, the 1999 *Democratic Republic of Congo v. Burundi, Rwanda and Uganda* [Baderin 2007: 149].

<sup>631</sup> With regard to India’s reporting on patents, I could not find mention of the issues of patents or intellectual property in the accompanying documents, namely, in “List of issues to be taken up in connection with the consideration of the second to fifth periodic reports of India concerning the rights covered by articles 1 to 15 of the International Covenant on Economic, Social and Cultural Rights (E/C.12/IND/5)” [CESCR,

#### 6.4.3.2 Violations of the human right to medicines by home states

International law provides for two procedures which can in principle be used by foreign states to enforce other states' domestic obligations with regard to the human right to medicines:<sup>632</sup> the action for obligations *erga omnes* and the action via human rights treaty bodies. All members of the international community have a legal interest, under international customary law, to redress violations of *erga omnes* obligations, by invoking the state responsibility of the wrongdoer.<sup>633</sup> A violation of obligations *erga omnes* occurs, inter alia, when another state is responsible for a 'gross' and 'large-scale' violation of any internationally recognised human right [Cassese 2005: 59; 394].<sup>634</sup> This procedure presents the problem of identifying a properly so-called *violation* of the human right to medicines. The lack of fulfilment of the human right to medicines is particularly difficult to judge as a violation. To begin with, the provision of medicines ultimately depends on the availability of resources – the fulfilment of the duty is to great extent subject to progressive realisation. The identification by the CESCR of a core obligation to immediately provide access to 'essential medicines' could be used as a criterion, but it has not been adopted generally outside the CESCR regime.<sup>635</sup> Furthermore, this criterion is relative, as the identification of 'essential medicines' is ultimately made by the national authorities.<sup>636</sup>

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E/C.12/IND/Q/5, 26 May 2006] and the previous concluding observations [CESCR, E/1990/23, 1990; CESCR, E/C.12/IND/CO/5, 2008: para. 73].

<sup>632</sup> The possibility of (forcible) 'humanitarian intervention' falls outside the scope of this thesis. Also, I will not deal with the case of violations of the human right to medicines as part of international crimes, such as genocide, war crimes, ethnic cleansing and crimes against humanity.

<sup>633</sup> Cassese sees breaches of *erga omnes* obligations as entailing 'aggravated responsibility' whereby, unlike 'ordinary' state responsibility, accountability is not demanded for material or moral damages to another state, as "[w]hat matters is that the breach results in the infringement of a State's right to compliance by any other State (or contracting State) with the obligation" [Cassese 2005: 263]. Therefore foreign states can intervene through diplomatic or economic retortions, peaceful countermeasures or recur to international adjudication, for instance through the ICJ [Cassese 2005: 394]. See Chapter 4 section 4.3.1.

<sup>634</sup> See Chapter 4 section 4.3.1.

<sup>635</sup> See Chapter 3 section 3.2.1.1. For example, the South African Constitutional Court rejected the idea of a state obligation to fulfil immediately access to a core of medical services [South Africa, *Ministry of Health v. TAC*, 2002: para. 35].

<sup>636</sup> See Chapter 5 section 5.4.1.

I have examined a few proposals in the literature in order to assess the realisation of the duty to fulfil. Kinney for example proposes three tools for holding states internationally accountable for the realisation of the right to health: 1) the definition of universal outcomes; 2) the establishment of a comparative reporting system to international bodies to monitor progress and compliance with international human rights obligations; and 3) the identification of civil rights violations, such as discrimination against protected groups [Kinney 2001: 1471-4]. The establishment of international reporting systems is illustrated in the following paragraphs. It is interesting to discuss beforehand the use of indicators as a gauge of fulfilment of the human right to medicines, also in relation to the enforcement of the right outside international bodies. The use of indicators is problematic. To begin with, a problem in using targets and indicators is the trade-off between, on the one side, standardisation, comparability and simplicity and, on the other side, accuracy, depth and contextualisation. Economic, social, political and cultural circumstances are very different worldwide, and standardised indicators may fail to appreciate such diversity. Indeed Tomasevski notes that international law accepts that government obligations should be divided into obligations of conduct and obligations of result but “this important legal difference does not easily translate into indicators” [Tomasevski 1995: 400].<sup>637</sup> Furthermore, indicators are aggregative, overlooking individual situations. An emphasis on aggregative dimensions skews the human right to medicines to a collective – as opposed to subjective – right.

Furthermore, it is noted that the procedure for the enforcement of obligations *erga omnes* may not be capable of providing substantial redress to the holders of the subjective right to medicines. In fact, reparations from state to state under state responsibility can be inconsequential for those whose rights have been violated in a gross and large-scale manner.<sup>638</sup> Moreover, isolated instances of violation of the human right to medicines are not considered. In fact the rationale of obligations *erga omnes* is the idea that certain violations of international law, even if happening internally to a state,

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<sup>637</sup> Nonetheless, Tomasevski maintains that “[t]he purpose of indicators is to capture two key factors: the *willingness* and the *capacity* of a government to protect and promote human rights” [Tomasevski 1995: 390 *emph. orig.*].

<sup>638</sup> But, according to Cassese, “one may envisage the possibility that the responsible State may pay compensation to the victims, or to the relatives of the victims, of those gross breaches” [Cassese 2005: 273].

damage all other members of the international community [Cassese 2005: 262].<sup>639</sup> Indeed, the members are not obliged to take action; they have a legitimacy to do so. In effect, as far as I am aware, to date states have not enforced internationally the human right to medicines by denouncing state responsibility for the international human right to medicines.<sup>640</sup>

Consequently, I look at the enforcement procedures offered by the human rights treaty bodies. International treaties sanctioning the human right to medicines offer alternative mechanisms for addressing the international compliance with the right sanctioned therein, as seen in Chapter 4. Particular cases of violations can be referred to the CESCR and the African Commission through the *complaints procedures*. Until recently the CESCR had no power to redress situations and did not hear complaints from individuals or groups.<sup>641</sup> Some parties to the ICESCR have however become parties to an ‘Optional Protocol’ which provides the CESCR with the capability to hear individual complaints, order ‘interim measures’ and establish an inquiry procedure, although the Protocol is not operational as of yet [ICESCR-OP, art. 5, 11].<sup>642</sup> The African Commission examines violation complaints (‘communications’) also hearing individual and group cases [ACHPR: art. 30, 55-59, 62].<sup>643</sup> Some African Commission cases relating to access to health care and medicines originated from the violation of non-discrimination in health care.<sup>644</sup> The lack of provision of medicines has been expressly recognised by the African Commission as a violation of the human right to health in one case concerning Zaire.<sup>645</sup> However, the compliance with the decision remains

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<sup>639</sup> The responsibility for *erga omnes* human rights obligations originating from treaty law nonetheless, according to Cassese, is extended to minor or sporadic breaches of these obligations – thus it is not confined to the gross and serious breaches of the corresponding obligations originating from customary international law [Cassese 2005: 276].

<sup>640</sup> As Skogly points out, “... whether or not a foreign state may have a legitimate legal interest in the case based on obligations *erga omnes* is only half the story. The other half... is whether there are any corresponding obligation on the foreign state to take action” [Skogly 2002: 13].

<sup>641</sup> See CESCR Revised General Guidelines [1991] and ECOSOC Resolution 17 (1985).

<sup>642</sup> See Chapter 4 section 4.2.1.

<sup>643</sup> See also Odinkalu [2001: 351].

<sup>644</sup> See the *Mauritania* [AC, *Mauritania*, 2000] and the *Media Rights Agenda and Others v. Nigeria* cases [AC, *Nigeria*, 1998] in Chapter 5 section 5.2.2.

<sup>645</sup> In the *Zaire* case, the Commission found that “[t]he failure of the Government to provide basic services such as safe drinking water and electricity and the shortage of medicine... constitutes a violation of Article 16” [AC, *Zaire*, 1995: para. 47].

doubtful.<sup>646</sup> In effect, the African Commission remained vague not making clear what Zaire positively had to do in order to remedy the shortage of medicines [AC, *Zaire*, 1995]. Indeed, from a procedural point of view, the commission does not issue binding judicial decision and is not endowed with powers to enforce compliance with its pronouncements [Murray 2000: 22].<sup>647</sup> To note, the aim of the communications procedures at the African Commission is an ‘amicable resolution’ to the controversies.<sup>648</sup> Interestingly, however, in 2006 the African Court on Human and Peoples’ Rights has been instituted [AfCHPR, website, 2010].<sup>649</sup> The Court, as opposed to the Commission, is set to deliver binding judgments and to provide remedies [Protocol to the ACHPR: art. 30].<sup>650</sup> So far the Court has only delivered one judgment in December 2009, not related to the human right to health and medicines.<sup>651</sup>

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<sup>646</sup> See for example the scepticism expressed by ESCR-Net, considering the state of civil war which has struck Zaire (notwithstanding the peace deal reached on 23 January 2008) [ESCR-Net, website, Free Legal Assistance Group and Others v. Zaire, Comm. No. 25/89, 47/90, 56/91, 100/93, last accessed 2010]. Doubts have also been expressed with regard to the redress of the *Mauritania* case on non-discrimination [ESCR-Net, *Mauritania*, last accessed September 2008]. Reportedly, even after the decision of the African Commission, the physical and mental health of political prisoners and the treatment of prisoners in pre-trial detention have continued to be worrying. Slavery and forced labour have also continued. The human rights situation in Mauritania has however apparently improved following a non-violent military coup in August 2005 [*id.*]. See also Baderin criticising the inaction of the Commission in cases of non-compliance with the recommendations, also noting that the purpose of naming and shaming with which the Commission findings are published on the website is betrayed by the fact that the website is not regularly updated [Baderin 2007: 149].

<sup>647</sup> On the compliance of judicial decisions relating to economic, social and cultural rights see the tracking provided by ESCR-Net [ESCR-Net website].

<sup>648</sup> As reminded by the African Commission in the *Zaire* case, “[t]he main goal of the communications procedure before the Commission is to initiate a positive dialogue, resulting in an amicable resolution between the complainant and the State concerned, which remedies the prejudice complained of” [AC, *Zaire*, 1995: para. 39].

<sup>649</sup> As per the 1998 Protocol to the African Charter on Human and Peoples’ Rights on the Establishment of an African Court on Human and Peoples’ Rights [OAU, Protocol for Establishment of an African Court, 1998].

<sup>650</sup> According to Article 30 of the Protocol, “[t]he States Parties to the present Protocol undertake to comply with the judgment in any case to which they are parties within the time stipulated by the Court and to guarantee its execution” [Protocol to the ACHPR: art. 30].

<sup>651</sup> The African Court on Human and Peoples’ Rights gave its first judgment in the matter of *Yogogombaye v. The Republic of Senegal* in December 2009. The applicant, Yogogombaye, a Chadian national, brought the action to prevent the government of Senegal from conducting the trial of the former Chadian head of state, Hissene Habre in Dakar, Senegal [AfCHPR, *Yogogombaye v. The Republic of Senegal*, 2009; AfCHPR, website, 2010].

Some international procedures are also in place for *monitoring* the realisation of the human right to health and other social rights. The Special Rapporteur on the human right to health presents annual reports to the Human Rights Council and to the UN General Assembly on the activities and studies undertaken in the view of the implementation of the mandate, communicating with states and other concerned parties with regard to alleged cases of violations of the human right to health [UNOHCHR website, Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, 2010]. Since the first session of the Human Rights Council in 2006 the Rapporteur has reported on the communication of sub-Saharan Africa countries only once, on Angola [Hunt 2008]. Both the CESCR and the African Commission monitor the realisation of, respectively the ICESCR and the ACHPR. These procedures are similar. The CESCR receives regular reports from the states parties and produces lists of issues for these states to respond to. Next, the CESCR considers the states' responses and issues 'concluding observations' [UNOHCHR, website, Committee on Economic, Social and Cultural Rights – Monitoring the economic, social and cultural rights, 2010]. The African Commission as well receives reports on the measures taken by states for realising the ACHPR rights [ACHPR: art. 62]. Since 2001 the African Commission has also started to issue concluding observations regarding the states' reports [Bulto 2006: 84].

With regard to access to medicines the CESCR, in its general comment on the human right to health, recommends that in order to monitor, at the national and international levels, a state party's obligations under article 12, national health strategies should identify appropriate right to health indicators and benchmarks [CESCR 2000 para. 57]. The new 2009 reporting guidelines in effect ask to "[p]rovide information on the measures taken... To ensure affordable access to essential drugs, as defined by the WHO, including antiretroviral medicines and medicines for chronic diseases" [CESCR, Reporting Guidelines, 2009, para. 57, 57(f)]. As opposed to the 1991 guidelines, the 2009 guidelines do not require states to report on the fulfilment of standard indicators on access to medicines.<sup>652</sup> The African Commission does not ask to report explicitly on access to medicines but access to medicines should naturally be part of the information

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<sup>652</sup> With the 1991 guidelines the CESCR envisaged national indicators (rather than international standards). The 1991 guidelines specifically requested to use as indicator the "[p]roportion of the population having access to trained personnel for the treatment of common diseases and injuries, with regular supply of 20 essential drugs, within one hour's walk or travel" [CESCR, Reporting Guidelines, 1991: art. 12, para. 4(f)].

that should be provided on the “[c]omprehensive schemes and specific measures, including vaccination programmes to prevent, treat and control epidemic, endemic, occupational and other diseases and accidents in urban and rural areas... [and] [t]he main features of existing arrangements for the provision of medical care and methods of financing them” [AC, 1988-89: para. 36 (d), (f)]. The guidelines thus do not demand precise qualitative or quantitative data. Both CDESCR and African Commission guidelines are therefore indicative and vague, not suitable for comparisons between countries and on the progress made within countries on the realisation of the human right to medicines.

In practice, both commissions are quite selective about the issues they comment on. In particular, access to medicines does not receive systematic attention by the committees and is rarely addressed as an issue on its own. The sub-Saharan countries considered in the last five years (2004-2009) by the CDESCR have been the Democratic Republic of Congo, Angola, Kenya and Zambia [UNOHCHR, website, 2010(c)]. Out of those CDESCR works, the only direct reference I could find on access to medicines was about antiretrovirals in Zambia.<sup>653</sup> Issues indirectly affecting access to medicines, such as the use of user fees have been addressed other times.<sup>654</sup> The African Commission has commented on access to medicines more frequently. Among the last four concluding considerations of state reports on Democratic Republic of Congo, Cameroon, South Africa and Uganda, access to medicines was mentioned for South Africa, Uganda, and indirectly for Cameroon. The feedbacks are however brief remarks or notes of compliment.<sup>655</sup>

Therefore, the analysis of the international enforcement of the human right to medicines illustrates how the human rights, the legal and the political subsystems are ultimately structurally coupled. The positivisation in the legal subsystem of human rights – both at the domestic and international level – confers legitimacy and power to governments. In turn, human rights undertakings are produced by the political initiative. However, such coupling also embeds the contingency of human rights law. The vague substance of the rights and the weak procedures render the enforcement of the rights contingent. At the international level, in effect, the realisation of the human right to

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<sup>653</sup> See CDESCR, List of Issues to Zambia [2003: para. 32-33]; CDESCR, Concluding Report on Zambia [2005, E/C.12/1/Add.106: para. 30].

<sup>654</sup> See e.g. Kenya [2008: paras. 20, 32, 33].

<sup>655</sup> See AC, Concluding Observations – South Africa [2005: para. 13]; AC, Concluding Observations – Uganda [2006: para. 19], AC, Concluding Observations – Cameroon [2005: para. 11(g)].

medicines is seldom assessed in international adjudication, let alone through binding decisions. Most procedures do not directly redress the situation of the subjective right-holders; overall international enforcement (spanning prosecution, adjudication, remedy) is a political process between states.

#### *6.4.3.3 Violations of the human right to medicines by non-state actors*

This section reviews the implementation and contingencies of the enforcement of the duties of international organisations, NGOs and private actors (in particular, pharmaceutical companies) with respect to the human right to medicines. States parties to international organisations can be prosecuted individually for the actions they take within the organisations. Therefore, they can be subject to the procedures seen in sections 6.4.3.1 and 6.4.3.2 above. Next, as seen in Chapter 4 section 4.4.2 international organisations and NGOs arguably have a duty to respect the human right to health under international customary law. However, I am not aware of any domestic claim against international organisations and NGOs for the lack of fulfilment of the human right to medicines (or health care, or access to medicines) in a country. Furthermore, it is recalled that non-state actors, normally, are not subject to the jurisdiction of international courts. Moreover, in furtherance to self-regulation, human rights violations could be redressed by semi-judicial means through monitoring and complaint procedures within the organisations.<sup>656</sup> For example, the World Bank's Inspection Panel, as mentioned in Chapter 4, has addressed complaints regarding the alleged responsibility of the World Bank in cases concerning the health of people who received the bank's assistance – although the cases have been presented in terms of damage or harm rather than as violations of the human right to health.<sup>657</sup> Perusing the reports for the Human Rights Council sessions, nevertheless, I noted that the Special Rapporteur on the human right to health has in one instance investigated the alleged violations of the human right to health

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<sup>656</sup> On self-regulation of international organisations *see* Chapter 5 section 5.3.2.1.

<sup>657</sup> *See, e.g.*, the case relating the “Arun III Hydroelectric Project Nepal” reported by Toebes. Toebes remarks that “[a]lthough the right to health was not explicitly invoked in this case, governmental obligations involving resource allocations were addressed which are similar to the obligations protected by the right to health” [Toebes 1999: 180]. On the same case *see also* Skogly [2001: 182-5]. *See* the review by FIAN of the work of the Inspection Panel and the response of the World Bank to the case of the ‘Coal Mining Project Parej-East, India’ [FIAN 2006]. *See also* the Inspection Panel investigation in the Ghanaian ‘West African Gas Pipeline Project’ [Inspection Panel 2008: para. 276, footnote omitted].

by ‘other actors’. Namely Hunt exchanged communications with the Global Fund for AIDS, Tuberculosis and Malaria on the withdrawal from Myanmar and with the United Nations Interim Administration Mission in Kosovo on the contamination of refugee camps [Hunt 2007(b): paras. 51-55]. The episode, however, is so far isolated.

With regard to private for-profit actors, most duties concerning the human right to health and medicines can be prescribed and enforced indirectly, without mentioning access to medicines as a human right, by the home states through legislation which addresses the behaviour of these actors.<sup>658</sup> Direct reference to the human right to health in order to decide in private law cases is rare.<sup>659</sup> Furthermore, as seen in section 6.3, the CESCR identifies a duty of foreign states to prevent violations of the human right to medicines by third parties abroad. Extra-territorial jurisdiction concerning violations of health and access to medicines (even short of explicit reference to the human rights to health and medicines) by companies abroad is however exceptional. The literature concerning the extra-territorial adjudication of human rights violations by non-state actors usually refers to the uncommon example of the US Alien Tort Claims Act (ATCA) relating to torts committed in violation of international law abroad.<sup>660</sup> US courts have accepted jurisdiction under ATCA for certain violations of human rights by corporations but not for the human right to health or medicines.<sup>661</sup> For the UK, Jägers identifies the 1995 case *Ngcobo & Others v. Thor Chemicals Holdings Ltd. & Others* as ‘landmark’, as it held that British-based companies can be sued in English courts for harm to health caused abroad [Jägers 1999: 268]. However, in the case there was a nexus in the UK with the damage occurred in South Africa [United Kingdom, High Court, *Ngcobo & Others*,

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<sup>658</sup> Violations of the right to health and medicines can also be redressed, indirectly, by international courts deciding of international crimes. For example, the International Criminal Court has subject-matter jurisdiction on ‘inhumane acts’ causing serious injury to health [ICC Statute art. 7(k)]. These violations, however, are special cases, falling outside the scope of this thesis.

<sup>659</sup> Toebe for instance reports that the Italian Constitutional Court held that the right to health applies in both public law and private relations, ruling that safeguarding health also imposes on individuals the duty to refrain from injuring or endangering by their behaviour the health of another person [Toebe 1999: 210]. The right to health has also been cited in the successful application to the South African Competition law case on the excessive pricing of medicines in South Africa [Tau et al 2002: para. 60]. See Chapter 5 section 5.3.2.

<sup>660</sup> See Chapter 4 section 4.3.2.3.

<sup>661</sup> See Chapter 4 section 4.3.2.3.

1995].<sup>662</sup> No mention was made throughout the case to the human right to health or human rights in general.<sup>663</sup>

It is normatively doubtful whether the extra-territorial adjudication of the human right to medicines should be expanded in order to redress the behaviour of pharmaceutical companies in relation to access to medicines. Extra-territorial jurisdiction is an attractive option if the assets of the respondent are based abroad or if part of the action with adverse effects originates abroad [Joseph 2005: 4]. In effect, pharmaceutical corporations providing medicines to African countries are mostly based in a foreign country. However, the adjudication of cases of violations of the human right to medicines is undermined by technical/procedural and substantive factors. To begin with, transnational corporations have a dispersed structure whereby parent companies are shielded through the separation of legal identity, and the courts are notoriously reluctant to lift the ‘corporate veil’.<sup>664</sup> Next, the costs for the plaintiffs may be discouraging [Jägers 1999: 268-9]. Finally, according to the *forum non conveniens* doctrine, the state with the closest connection to the action has jurisdiction [*id.*]. Technical problems also relate to ‘enforcement jurisdiction’, for instance in gathering information abroad [Whish 2005: 430].<sup>665</sup> Substantively, in effect, as seen in chapters 3 to 6, there is no clarity regarding the prescriptions originating from the human right to medicines onto companies.

In sum, uncertainty and unpredictability, in both substance and procedure, have been found concerning: the enforcement of transboundary violations of the human right to medicines committed by foreign states; the enforcement of the duties of home states by foreign states and treaty-bodies; and the enforcement of the duties of non-state actors, by home and foreign states. The subjective human right to medicines of African people, overall, is not effectively redressed through these procedures.

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<sup>662</sup> The UK High Court examined the principle of *forum non conveniens* and allowed the suit to proceed in England, in fact holding that negligence occurred in England, therefore the plaintiffs may have had difficulty in presenting their case in South Africa [United Kingdom, High Court, *Ngcobo & Others*, 1995].

<sup>663</sup> The case was about tortious liability.

<sup>664</sup> See also Joseph [2004:131].

<sup>665</sup> Some international agreements are in place on the matter. See e.g., Hague Convention on the Taking of Evidence Abroad (Cmnd 3991, 1968) and the UK/US Mutual Assistance Treaty to criminal infringements of competition law (UK/US Mutual Assistance Treaty Cm 5374, 2001) [Whish 2005: 430-1]. See also Whish [2005: 449] on other international cooperation agreements.

## 6.5 Conclusion

This chapter has critically analysed the possible operationalisation and implementation of the duties of extra-governmental actors in relation to the international human right to medicines. It has also made reference to the pertinent non-binding law, as the legal subsystem structurally couples to the meta-positive subsystem of human rights. Human rights law (*e.g.* treaties and national constitutions), often attributes ‘roles’ and ‘responsibilities’ to non-state actors, which are ‘expected’ to collaborate to the realisations of these rights. Moreover, non-binding human rights duties appear, enthusiastically, in the soft law and self-regulations concerning the extra-governmental actors more relevant for the provision of medicines, that is, foreign states, international organisations, NGOs and pharmaceutical companies. Many paradoxes and uncertainties have however been found. To begin with, the ‘human rights subsystem’ appeals to goals, ‘programmes of humanity’ which *actually* require the collaboration of actors other than the states [Luhmann 1995(b): 231]. However, duties originally formulated for home states are not ‘textually’ applicable onto extra-governmental actors unless a watered-down, ‘minimum common denominator’ approach is adopted. Luhmann, in effect, saw human rights as institutions for the functional differentiation of society, thereby keeping distinct in society the state bureaucracy and its function [Luhmann 2002/1965: 59-61, 290; 2004: 135-6]. Therefore, human rights are meant to apply vertically between the state and the individual. Nevertheless, subjective human rights refer to the human rights ‘utopia’, which does not consider the contexts and does not, to elaborate, confer perfect duties [Luhmann 1995(b): 231; 2004: 416-7]. Furthermore, as Luhmann noted, human rights cannot be realised as indisputable values, as values, interests, needs, and rights can clash [Luhmann 1997(b): 992-3]; the context is complex, contingent and rife with ethical dilemmas. The legal and ‘human rights subsystem’, in their autopoiesis, avoid those paradoxes. Rather, these subsystems adopt uncertainties, contradictions and therefore contingencies.

In particular, the analysis of the duties to respect, protect and fulfil the human right to medicines has revealed that, with regard to the *respect*, it is not clear which intellectual property international agreements and actions violate the respect of the human right to medicines in African countries. A univocal condemnation could not be expressed of the international financial institution's structural adjustments programmes demanding restraint of the social welfare policies in African states (for example, through the imposition of cost sharing for health care and medicines). The operationalisation of non-discrimination is morally problematic, for example considering the frequent trade-off between the observance of formal equality (whereby all have to be treated in the same way) and substantive equality (whereby different situations have to be treated differently). Furthermore, the provision of quality health services by extra-governmental actors is at odds with the possibility of the provision of these services to all. Some instances of international human rights law (and its commentaries) recommend attention to the vulnerable and the marginalised but such provision suffers from legal, practical and ethical flaws. With regard to *protection*, the international standardisation and control of the safety of medicines was found to be problematic given medical, scientific, contextual and operational contingencies. Major problems subsist in the operationalisation of the role of extra-governmental actors for the *fulfilment* of the human right to medicines. In effect, extra-governmental actors are not capable to fully realise the human right to medicines in sub-Saharan Africa, as their resources are limited. The human right to medicines does not set clearly what priorities should be enacted. Legally speaking, certain prioritisations can conflict with the duties to respect and not to discriminate, but there is no certainty about the operationalisation of these injunctions in the law. In ethical terms, the interdisciplinary analysis has shown that prioritisation imposes contingent and morally sensitive biopolitical choices concerning which lives to foster and disallow to live. If isolated approaches can be at odds with equity and equality, some attempts to rationalise globally the interventions of extra-governmental actors arguably pay questionable attention to the aggregate status of a population.

The uncertainty of the human right to medicines is epitomised by the weakness of its *enforcement*. Little practice could be found with regard to the enforcement of the duties held directly by extra-governmental actors and the enforcement by home states of the duties of foreign states. The enforcement by foreign states of the duties of (African) home states to fulfil the human right to medicines at home encounters the relevant substantive problem of identifying 'violations' of the right, considering that the

implementation of the right is supposed to be progressive and conditioned on the availability of resources – which are particularly limited in sub-Saharan Africa. The utilisation of targets and indicators is aggregative and has to cope with the trade-off between, on the one hand, standardisation, comparability, simplicity and, on the other hand, accuracy, depth and contextualisation to the economic, social, political and cultural circumstances. In effect, the international procedures most frequently utilised to defend the human right to medicines do not produce legally binding decisions; decisions are in fact seldom complied with. Furthermore, the individual right-holder does not benefit directly from most of those procedures, which generally concern the aggregate dimension, *ie* group (or ‘gross’ and ‘large-scale’) violations. Some institutions and procedures have been recently created to address such shortcomings but, until now, they have not been very productive with regard to the human right to health and medicines.<sup>666</sup> The subjective right to medicines of African people, therefore, is not consistently adjudicated either internationally or nationally. With regard to the monitoring of implementation of human rights treaties, the guidelines of the CESCR include access to medicines and the guidelines of the African Commission include vaccination and medical care. In practice, however, the monitoring has not been systematic – notwithstanding, for example, the prescriptions formulated by both bodies that states shall immediately realise access to essential medicines.<sup>667</sup> Thus it is evident how the legal subsystem and the political subsystem are ultimately coupled both at the domestic and at the international level. International enforcement (spanning prosecution, adjudication, remedy) is ultimately a political process between states. Law is also created by the political system. The indeterminacy of the law in identifying precisely legal/illegal situations *a priori* reverberates with the procedural uncertainties for its enforcement.

So, “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?” Can and shall the framework of the human right to medicines be utilised to guide and adjudicate the realisation of the human right to medicines in sub-Saharan Africa? It can be contended that, on the one hand, the human right to medicines does not seem to have the power *de facto* to obtain the realisation of access to necessary medicines. The ‘expectation’ that extra-governmental actors would fill the gap in the shortcoming realisation of the right by African states is not satisfied –

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<sup>666</sup> See the ICESCR Optional Protocol, the African Court on Human and Peoples’ Rights and CEDAW Optional Protocol. See section 6.4.3.2 and Chapter 4 section 4.2.3.

<sup>667</sup> See Chapter 3 sections 3.3.1.1 and 3.2.1.2.

although extra-governmental actors certainly do contribute to access to medicines in sub-Saharan Africa. The human rights framework instead revealed conspicuous paradoxes: not all actions of extra-governmental actors diminishing access to medicines violate the respect of the human right to medicines; and not all shortcomings in the protection and fulfilment of access to medicines violate this right. In effect the autopoietic legal subsystem and ‘human rights subsystem’ code the environmental contingencies, complexities and uncertainties through generalisations and simplifications. Uncertainty is ultimately mirrored in the hesitant adjudication of the right. On the other hand, the prescriptions of the human right to medicines may legitimate the power and biopower of extra-governmental actors, which are generally very poorly politically accountable to the subjects of their power. Indeed, the human right to medicines and the meta-positive ‘human rights subsystem’ can attribute roles and responsibilities onto the extra-governmental actors. However, by communicating on indisputable norms, they de-problematise sensitive biopolitical predicaments. So is the human right to medicines a desirable feature? Should it be reinforced or dismissed? Chapter 7 will propose some tentative answers to those normative questions.

## CHAPTER 7: CONCLUSION

### 7.1 Introduction

This concluding chapter reports on the four contributions to knowledge that the thesis sought to achieve.<sup>668</sup> The first contribution concerns the identification and analysis of the human right to medicines in international law, *de jure*. Indeed the international law literature is rather undeveloped with regard to the duties that international human rights law formulates in relation to access to medicines. I have mainly addressed this issue in Chapters 3 and 4, and I shall summarise my findings in section 7.2 below. The second contribution regards the study of the possible implementation of a human right to medicines, *de facto*, in sub-Saharan Africa. This thesis therefore researched broader questions of human rights, health care, public health and development in sub-Saharan Africa. In effect, several contingencies relating to practical as well as ethical problems were found which challenged the identification of a ‘right’ operationalisation of the human right to medicines in sub-Saharan Africa. Such analysis has been mainly undertaken in Chapters 5 and 6, and is summarised in *infra* section 7.3.

The third contribution relates to socio-legal studies. The thesis builds on Luhmann’s theory of social systems, contributing to the critique of human rights by examining autopoiesis and contingency in the legal and political subsystems. Such framework is moreover utilised in order to analyse the exercise of power and biopower to control issues of life in a population through the use of law (including the human right to medicines) and politics. These themes have been presented throughout the thesis and will flow into section 7.4, which provides my response to the research question: “can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?”. The response will highlight two main limitations of the utilisation of the human right to medicines to solve the problem of access to medicines in sub-Saharan Africa noting that: first, the human right to medicines has limited capacity to realise the need of medicines in sub-Saharan Africa; second, the right can in fact entrench power and biopower. It will be argued that a human right to medicines is in effect a second best with regard to other types of policies and regulation.

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<sup>668</sup> See also Chapter 1 section 1.7.

## 7.2 The international human right to medicines *de jure*

Chapters 3 and 4 demonstrated that an international human right to medicines can be identified as a short-hand expression for “fundamental component of the international human right to health regarding access to medicines”. The positive law I analysed, in effect, does not name a self-standing human right to medicines. Nevertheless, the law does enshrine human rights obligations with regard to access to medicines. In particular, important formulations of the international human right to health comprise access to medicines as a fundamental component. The expression ‘human right to medicines’ has consequently started to be used in the last decade by, among the others, soft law, the UN Special Rapporteur on the right to health, and publicists.<sup>669</sup>

The main recipients for obligations under human rights law are home states. **Chapter 3** has consequently analysed the obligations, *de jure*, of sub-Saharan African states. *Treaties* widely accessed by African states such as the UN International Covenant on Economic, Social and Cultural Rights (ICESCR) and the African Charter on Human and Peoples’ Rights (ACHPR) [ICESCR art. 12; ACHPR art. 16] enshrine a human right to health which states are obliged to *respect, protect* and *fulfil*.<sup>670</sup> Access to medicines is deemed to be a fundamental component of this right. In particular the CESCR and the African Commission (respectively, the treaty-bodies overseeing the ICESCR and the ACHPR) have identified the provision of ‘essential’ medicines as a minimum core obligation that states shall immediately realise in relation to the human right to health [CESCR 2000: para. 43 and note 5; AC Res. 141 (2008): para. 2(3)(i)]. It was also showed that many human rights such as the right to life and the right not to be subject to torture, inhuman and degrading treatment can support a case against states for the recognition of the right to access to medicines. Furthermore, it was established that *customary international law* sanctions the *respect* of the human right to health and thereby medicines. I could not identify, instead, duties to *protect* or *fulfil* the human right to medicines as part of customary international law. Instead, several instances of soft law were found whereby states pledged for the realisation of access to medicines also referring to the human right to health, or pledged to realise human rights which arguably included the realisation of access to medicines.

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<sup>669</sup> See also Chapter 1 section 1.3.

<sup>670</sup> Most African countries are parties to the ICESCR and all African countries are parties to the ACHPR. See Chapter 3 sections 3.2.1.1 and 3.2.1.2.

**Chapter 4** demonstrated that the human right to medicines also prescribes duties onto extra-governmental actors (*ie* foreign states and non-state actors such as international organisations, NGOs, pharmaceutical companies, individuals). With regard to the obligations of *foreign states* concerning the enjoyment of the human right to medicines in other (sub-Saharan African) countries, widely-accessed human rights *treaties* obligate states to internationally *respect* and *cooperate* for the realisation of the human right to health, and thence medicines. Foreign states are instead not responsible for the full realisation/ fulfilment of this human right abroad. In effect foreign cooperation and assistance are prescribed in vague terms. The ICESCR regime, according to the CESCR, also demands states to *protect* the right internationally from third parties violations. With regard to the role of foreign states in the *enforcement* of the human right to health and medicines abroad, the treaties examined set up treaty-based bodies in order to monitor the conduct of the parties with regard to the human rights sanctioned therein. However, most treaty-based bodies do not exercise a judicial function proper. Procedures to redress the complaints of individuals are not envisaged by several treaties, included the ICESCR regime (the Optional Protocol redresses this shortcoming but is not in force as of yet). Reparations for individual situations are not envisaged by the treaties analysed. Furthermore, not all the bodies receive inter-state complaints. Even those who receive such complaints rarely have the power to issue actionable interim measures,<sup>671</sup> and have no policing capacity.<sup>672</sup> Under *international customary law*, which binds all states, foreign states have to *respect* access to medicines in other countries. A customary duty to internationally *protect* the human right to medicines instead could not be established. With regard to international *fulfilment*, it is hard to identify what states would be specifically prescribed to do under a potential customary duty to cooperate for realising the human right to medicines. ‘Paper practice’ and ‘factual practice’ were not consistent. It was noted that states are keen to pledge for the international realisation of human rights and access to medicines in soft law. Finally, with regard to *enforcement*, states are entitled to prosecute foreign states for the transnational effects of actions detrimental to their peoples’ access to medicines. Furthermore, they can act for violations of the human right to medicines taking place abroad claiming breaches of obligations *erga omnes*.

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<sup>671</sup> For instance, within the ICESCR regime, interim measures are not provided in the Covenant but have been included in the (not yet operational) Optional Protocol (*see* above Section 4.2.1).

<sup>672</sup> *See* Chapter 6 section 6.4.3.

With regard to *non-state actors*, several *treaties* declare that individuals, groups, international organisations should respect human rights and attribute to them responsibilities relating to the realisation of these rights. However, these duties are imposed on non-state actors indirectly: it is states that are ultimately liable internationally for the protection of human rights from third-party violations. Furthermore, the wording of the obligations concerning non-state actors is overall vague. The identification of duties from customary international law has proved to be extremely tentative. Indeed, I could not overcome the paradox of whose practice and whose *opinio juris* should be searched when seeking the inter-national custom binding *non-state* actors. It was proposed that, holding international legal personality, non-state actors can be liable for the respect of the human right to health sanctioned in international customary law. However such prescription is extremely vague. Short of customary law, the investigation in this area identified several instances of soft law, self-regulation and other quasi-law attributing responsibilities for human rights and access to medicines to the non-state actors which have considerable influence on access to medicines in sub-Saharan Africa, that is, international organisations, NGOs and pharmaceutical companies.

Thus, Chapters 3 and 4 demonstrated that, from the perspective of Luhmann's social systems theory, the human right to medicines is in some instances positivised in the legal subsystem. Sub-Saharan African countries are bound by international law to recognise and realise access to medicines as fundamental part of the human right to health. This is meant to produce legal effects in the domestic legal systems, as international and domestic law intertwine, and all the more with regard to human rights.<sup>673</sup> It is therefore recalled that at the domestic level the human right to health or the human right to health care are recognized in the constitutions of at least 31 sub-Saharan African countries and 115 countries around the world [Kinney and Clark 2004; UNOHCHR and WHO 2008: 10].<sup>674</sup> Foreign states also have duties with regard to access to medicines in sub-Saharan Africa under international human rights law. The duties of non-state actors with regard to the human right to medicines can instead be framed, generally, as communications of the meta-positive 'human rights subsystem': these duties are non-binding, and derive from treaties as well as soft law and self-regulation. The meta-positive 'human rights subsystem' is in effect prompter to prescribe obligations

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<sup>673</sup> See Chapter 3 section 3.1.

<sup>674</sup> See Chapter 1 section 1.3.

relating to the human right to medicines onto all actors (home states, foreign states and non-state actors).

It was also showed in the thesis, furthermore, that the positive human right to medicines is affected by what I would call ‘*systemic contingencies*’ in the legal subsystem, that is, uncertainties, contradictions and paradoxes within the law (substantive and procedural), *de jure*. To begin with the law often does not prescribe clear and precise actions onto the duty-bearers. Uncertainty is also generated when the human right to medicines complements its indeterminacy by referring to non-binding sources, framed in other social subsystems (for example the meta-positive ‘human rights subsystem’, the political subsystem) through structural coupling. For treaties, the pronouncements of treaty bodies can be used to interpret – and develop – the law. However, the binding power of those sources is questionable. The treaty-bodies, in turn, have often referred to non-binding norms such as WHO’s recommendations on the identification of ‘essential medicines’. The assessment of customary law can be found to rest on the ‘paper practice’ of states, *e.g.* the adherence to international declarations or pledges that are not in fact legally binding. To note, an open-ended approach to interpretation of the law introduces uncertainty in the law. Next, a paradox was found in that not all actions reducing access to medicines violate the respect of the human right to medicines. Not all shortcomings in protection and fulfilment of access to medicines violate this right. Human rights law often allows for some flexibility, a margin of toleration – but it is not clear generally where this margin is situated. In addition, the law can also be contradictory. Certain formulations by the ICESCR, the CESCR and the African Commission for example operationalised the human right to health and medicines as concerned with the collective dimension – populations and groups. This indication clashes with the principle that everyone has equal importance and dignity.<sup>675</sup> More specifically, the focus on collectivities conflicts with the formulation of the human right to health according to which everyone is entitled to the maximum attainable standard of health [ICESCR art. 12(1); ACHPR art. 16]. Indeed, a subjective human right to medicines (or health care, health) faces the paradox of referring to objective rights,

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<sup>675</sup> See, *e.g.*, ICESCR preambular paragraphs 1 and 3 [ICESCR preambular paras. 1, 3] and ACHPR article 2: “[e]very individual shall be entitled to the enjoyment of the rights and freedoms recognized and guaranteed in the present Charter without distinction of any kind such as race, ethnic group, color, sex, language, religion, political or any other opinion, national and social origin, fortune, birth or other status” [ACHPR art. 2].

pertaining to categories.<sup>676</sup> Finally, with regard to enforcement, the right is sanctioned by different sources of law, domestic and international, which present different procedures for redress. Therefore the obligations that – universal – human rights instruments prescribe have different legal consequences according to the legal systems utilised. Chapters 5 and 6 have consequently attempted to establish how the human right to medicines, with its *de jure* contingencies, can be put into *practice*.

### **7.3 The human right to medicines and access to medicines in sub-Saharan Africa *de facto***

Chapters 5 and 6 critically enquired the operationalisation, implementation and enforcement of the human right to medicines in sub-Saharan Africa. In order to do so, the chapters studied the obligations of home states, foreign states and non-state actors to respect, protect, fulfil and enforce the human right to medicines. Where the legal subsystem refers by structural coupling to the ‘human rights subsystem’, some meta-positive communications have also been considered. The operationalisation and implementation of the human right to medicines were consequently examined normatively through interdisciplinary and empirical research of access to medicines in sub-Saharan Africa, including a two-month field-work in Tanzania. Such multidimensional analysis pointed out the limitations of the human right to medicines to guide and redress access to medicines in sub-Saharan Africa.

In particular, **Chapter 5** analysed the operationalisation, implementation and enforcement of the duties borne by *home states*, at the national level. It demonstrated that, with regard to the duty to *respect*, questions are posed for example regarding the selection by states of the ‘essential’ medicines they make accessible in the public health facilities, as the medicines excluded can be nonetheless necessary for certain patients (*see infra*). The regulation of intellectual property is also delicate: the protection of intellectual property rights, and in particular patents on pharmaceutical medicines, can reduce the affordability of new medicines but can also promote pharmaceutical research and development. Furthermore, intellectual property rights can be morally warranted as they can reward the inventor’s efforts, and/or foster the economy at large. The prohibition of non-discrimination is problematic as formal non-discrimination does not

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<sup>676</sup> *See* Chapter 1 section 1.4.

solve the problem of inequality, while substantive non-discrimination is difficult to operationalise and implement. The principle of substantive non-discrimination attempts to dedicate different treatment to different situations. In fact, in order not to be discriminatory, it establishes 'objective' categories which fit with difficulty to the subjectivities of individuals. The implementation of the duty to *protect* with regard to the control of quality and safety presents practical and cognitive problems, as the safety and efficacy of medicines are not certain. Decisions need to be taken by the regulatory authorities on the threshold of risk that can be tolerated: certain medicines bring health benefits but can also cause dangerous side effects. Next, an adequate design of competition policies is uncertain. Doubts concern the identification of excessive prices or the 'abuse' of intellectual property. The implementation of the state duty to protect can clash with the private initiative for example by regulating the private health insurance policies or imposing price controls on medicines. Such clashes can also have adverse ('self-defeating') effects for access to medicines. Price controls for instance can discourage enterprise and reduce the availability of medicines.

Finally, difficulties have been found in the operationalisation of the human right to medicines with regard to the *fulfilment* of the right in sub-Saharan Africa. The prescriptions of human rights law regarding these decisions are often indeterminate and paradoxical with respect to whose needs to respond, for instance referring to the individuals as well as populations and groups. In effect, as mentioned above, the identification of 'essential' medicines imposes sensitive ethical questions regarding the rationing of health assistance. These questions have been illustrated by analysing the three main competing principles which inform health-care prioritisation (at the macro level): aggregate health status of a population, individual health needs and equity. The justifications underpinning – and the arguments challenging – each principle were complex, based on practical, economic, moral, subjective reasons. These theoretical dilemmas also inform the design of alternative systems for the financing and distribution of medicines. As also seen in Chapter 2, none of these systems is perfect. For example, out-of-pocket expenditures are not affordable for the worse-off, free delivery by the public health system is affordable for the patient but is not affordable for the limited budgets of African states, cost-sharing is more affordable for the health facility, responsabilises the patient, but is less affordable for the patient than the free delivery of treatment. A main question is, ultimately, how much funds can the state request from the population in order to finance collectively access to medicines. Beside the theoretical

dilemmas, moreover, limited resources and bureaucratic inefficiencies affect the realisation of access to medicines by the state. Finally, with regard to *enforcement*, much uncertainty was revealed over the use of legal remedies, especially to redress the lack of fulfilment of the human right to medicines. Domestic courts are hesitant worldwide about recognising individual entitlements to medicines, even as part of minimum core state duties, considering the resource constraints. Whenever courts have decided that states violated the human right to health with regard to medicines, furthermore, the judicial remedies have not necessarily been effective for the claimants' health needs (for example, the awards were too limited, and the sentences have not been enforced by the executive). In sub-Saharan Africa the only case I found where a home state has been declared guilty in a national court for not providing medicines, and thereby breaching the human right to health, has been *TAC v. Ministry of Health* [South Africa, Constitutional Court, *Ministry of Health v. TAC*, 2002].

**Chapter 6** subsequently undertook an analysis of the operationalisation, implementation and enforcement of the duties that *extra-governmental actors* bear with regard to the international human right to medicines. In particular, it searched possible relief from the limitations that were shown in the capacity of sub-Saharan African states to fulfil the human right to medicines at home. Indeed the human right to medicines, primarily binding on states, nurtures 'expectations' with regard to the roles and responsibilities of foreign states and non-state actors towards the realisation of the right. The legal subsystem, therefore, structurally couples to the 'human rights subsystem', which in effect communicates that foreign states and non-state actors bear human rights duties for access to medicines. Those non-binding duties are named in soft-law (including UN-sanctioned declarations and resolutions) and self-regulation of several international organisations, NGOs and pharmaceutical companies. Both positive and meta-positive obligations have been analysed in this chapter.

The analysis of the duties to respect, protect and fulfil the human right to medicines has revealed that, to begin with, it is not clear which intellectual property international agreements and actions by foreign states violate the *respect* of the human right to medicines in sub-Saharan Africa. For example, the WTO/TRIPS will certainly impair the access to certain new medicines for sub-Saharan African countries. These countries indeed import extensively from countries such as China and India which have recently started to protect intellectual property, inter alia as a consequence of TRIPS.

TRIPS flexibilities for importation/exportation (*e.g.* compulsory licenses and parallel importation), often presented as a solution to this problem, are in fact cumbersome to implement. However, the protection of the intellectual property worldwide can be justified as rewarding and stimulating innovation. Furthermore, other factors influence access to medicines in sub-Saharan Africa, besides the availability of generic medicines. A univocal condemnation could not be expressed about the international financial institutions' structural adjustments programmes demanding restraint to the social welfare policies of African states (for example, through the imposition of cost sharing for health care and medicines). The implementation of the prohibition of discrimination is particularly problematic for extra-governmental actors if it is operationalised as demanding *de facto* and substantive non-discrimination. The contributions of these actors are by nature selective. Moreover, provision of quality health services is generally at odds with the possibility of the provision of these services to all. In relation to *protection*, the international standardisation and control of the safety of medicines was found to be difficult given medical, contextual and practical contingencies. Major problems subsist in the operationalisation of the role of extra-governmental actors for the *fulfilment* of the human right to medicines. Extra-governmental actors contribute to access to medicines in sub-Saharan African countries but are not capable of realising the human right to medicines in the region. Their resources are limited, therefore they select whose health-care needs they will attend. The interdisciplinary analysis showed that prioritisation imposes contingent and morally sensitive biopolitical choices, as also seen in Chapter 5. In effect extra-governmental actors, taking these decisions, wield power and biopower to foster or disallow life.<sup>677</sup> Such powers are exacerbated by the fact that extra-governmental actors are generally poorly accountable to the subjects of their influence in sub-Saharan Africa.

With regard to the *enforcement*, Chapter 6 investigated: 1) the enforcement of the duties held by foreign states 2) the enforcement by foreign states of the duties of (sub-Saharan African) home states 3) the enforcement of the duties held by non-state actors. Little practice could be found for any of those categories of enforcement. I analysed with particular attention the enforcement by foreign states of the duties of home (sub-Saharan African) states to fulfil the human right to medicines in their jurisdictions.<sup>678</sup> Such

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<sup>677</sup> Foucault defined biopower as the 'power to *foster* life or *disallow* it to the point of death' ('*faire vivre ou rejeter dans la mort*') [Foucault 1976: 138].

<sup>678</sup> Enforcement is meant to span prosecution, adjudication and remedy.

enforcement, in principle, could provide legal remedy, internationally, to the lack of medicines affecting the African people. However at a closer look contingencies were found that discourage a reliance on this type of redress. A preliminary substantive problem is that the identification of ‘violations’ of the right may not be straightforward, considering that the implementation of the right is supposed to be progressive and conditioned on the availability of resources (which are particularly limited in sub-Saharan Africa). The conduct and results in fulfilling the human right to medicines, it is sometimes proposed, can be measured through targets and indicators. However, they have to be designed taking into account the contingent trade-off between, on the one hand, standardisation, comparability, simplicity and, on the other hand, accuracy, depth and contextualisation to the economic, social, political and cultural circumstances. Furthermore, these gauges are generally aggregative, not relating about the situations of individuals. From a procedural point of view, moreover, it was showed that the international procedures most frequently utilised to defend the human right to medicines, *ie* treaty-bodies complaint procedures, do not produce legally binding decisions. Decisions are in fact seldom complied with. Moreover, the individual right-holder does not generally benefit directly from international procedures available to sub-Saharan Africa (also including international courts, state action against violations of *erga omnes* obligations etc.), which generally concern the aggregate dimension, *ie* group (or ‘gross’ and ‘large-scale’) violations. Some institutions and procedures have been recently created to address such shortcoming but, until now, they have not been very productive with regard to the human right to health and medicines. Furthermore, with regard to the monitoring of the implementation of human rights treaties, it was demonstrated that even though the reporting guidelines of the CESCR and the African Commission would warrant an attention to access to medicines, in practice, the monitoring has not been systematic.

Thus, the legal, meta-positive, interdisciplinary and empirical study of the utilisation of the human right to medicines found no ‘indisputable’ path for the implementation of access to medicines in sub-Saharan Africa. In fact, the ‘good’ of the actions for access to medicines depended on the *environmental contingencies* of the human right to medicines relating to, inter alia: the circumstances of local African health systems (*e.g.*, type of burden of disease, type of health care financing, available resources); the limits of steering of the legal and political subsystems; the uncertainties of planning access to medicines policies (*e.g.* uncertainties about: the effects of

regulatory interventions such as intellectual property protection; the causality and impact of economic phenomena such as development); the uncertainties about the science in medicine and pharmacy (*e.g.* uncertainties about: medicine; the safety and efficacy of a pharmaceutical product); the roles and behaviours of the different actors influencing access to medicines in a health systems; bioethical predicaments concerning which and whose health condition to treat; and ethical predicaments concerning the impact on other rights, needs, interests and liberties in society. The contingencies, problems and paradoxes identified through socio-legal analysis in Chapters 3-6 are further elaborated in the next session, which provides my answer to the research question.

#### **7.4 Can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa?**

So can a human right to medicines be utilised to solve the problem of access to medicines in sub-Saharan Africa? As specified in Chapter 1 section 1.3 this question is two-fold asking if – descriptively – the right has the legal weight and if – normatively – it ought to be utilised to solve the problem of access to medicines in sub-Saharan Africa. The answer to both facets of the question is that the human right to medicines has strong limitations.

From a *descriptive* point of view, the human right to medicines, *de jure*, can be claimed in sub-Saharan Africa. The human right to medicines can be utilised, more precisely, by claiming the human right to health. Most African countries are internationally bound to recognise and realise the human right to health sanctioned in the ICESCR (which binds 43 African countries) and the ACHPR (which binds all African states) [ICESCR art. 12; ACHPR art. 16]. The obligations to respect, protect and fulfil the human right to health enshrined in these treaties also apply to access to medicines.<sup>679</sup> Such international obligations are meant to produce legal effects in the domestic legal systems: as discussed in Chapter 3 section 3.1 international and domestic law intertwine, and all the more with regard to human rights.<sup>680</sup> Foreign states and non-state actors also

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<sup>679</sup> See Chapter 3 sections 3.2.1.1 and 3.2.1.2.

<sup>680</sup> It is also recalled that the right to health or the right to health care are recognized in the constitutions of 31 countries in sub-Saharan Africa [Kinney and Clark 2004]. See *generally* Chapter 3 and section 7.2 above.

have international legal obligations with respect to the human right to medicines.<sup>681</sup> However, the law demonstrated *systemic contingencies* (uncertainties, contradictions and paradoxes) which make its application to access to medicines in sub-Saharan Africa, *de facto*, difficult. Importantly, with regard to an entitlement to medicines, the ICESCR and the ACHPR regimes include an obligation of home states to immediately provide essential medicines. However, apart from the fact that this obligation only relates to the medicines identified to be ‘essential’ by each state, the law is contradictory with regard to the provision of a subjective entitlement to medicines. While everyone has a right to health according to the CESCR, for example, the states’ minimum core obligation to satisfy access to essential medicines entails that “a State party *in which any significant number of individuals*” is deprived of essential medicines is, *prima facie*, failing to discharge its obligations under the Covenant [CESCR 1990(b): para. 10, *emph. add.*].<sup>682</sup> In effect, courts in sub-Saharan Africa have not accepted claims of a subjective (individual) entitlement to medicines *or* other medical treatment.<sup>683</sup> The South African Constitutional Court has instead awarded a claim relating to access to medicines founded on the right to health in the judicial review of a government health-care policy (the provision of nevirapine) which was judged to be ‘unreasonable’ [South Africa, Constitutional Court, *Ministry of Health v. TAC*, 2002].<sup>684</sup> Moreover, a case aiming at access to medicines and referring *inter alia* to the right to health has been successfully presented at the Competition Commission in South Africa [Tau et al 2002; Competition Commission 2003(a)].<sup>685</sup> Worldwide, several cases have been awarded which granted access to medicines based on the human right to health and other human rights. The recognition of an individual entitlement to medicines has however been sporadic.<sup>686</sup> International treaty-bodies have decided in a few cases that the failure to respect access to medicines by African states was a violation of the right to health and other human rights.<sup>687</sup> However, overall, there is no correspondence between the lack of medicines and the adjudication of access to medicines as a human right in courts. The adjudication of extra-governmental actors on issues relating to the human right to medicines was also found to be very rare.

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<sup>681</sup> See Chapter 4 and section 7.2 above.

<sup>682</sup> See Chapters 3 and 4 and section 7.2 above.

<sup>683</sup> See Chapters 5 and 6.

<sup>684</sup> See Chapter 5 section 5.4.3.

<sup>685</sup> See Chapter 5 section 5.3.2.

<sup>686</sup> See Chapter 5 section 5.4.3.

<sup>687</sup> See Chapters 5 and 6.

From a *normative* point of view, a human right to medicines presents, in principle, two interesting features for access to medicines in sub-Saharan Africa. First, the recognition of access to medicines as a human right could give access to medicines the supremacy to overrule ordinary law and government policies. Secondly, the international human right to medicines could provide a regulatory and policy framework for a comprehensive approach to access to medicines, at the national and international level. As it was showed, indeed, access to medicines involves a variety of interwoven factors and actors. In fact, a critical and ethical analysis of the human right to medicines demonstrated that these normative arguments have limitations. With regard to the first idea the thesis has abundantly demonstrated the repercussions that medicine policies can have on other rights, interests, needs and liberties in society. Access to medicines is certainly imperative in sub-Saharan Africa, but at any cost? From a legal perspective it can be objected that there are other norms which have supremacy in the legal subsystem – and the resolution of conflicts between those norms is to great extent contingent. From an ethical perspective, indeed, Luhmann called ‘human rights fundamentalism’ the idea that human rights are natural, indispensable, based on principles, and are supposed to have unlimited validity [Luhmann 1997: 1022].<sup>688</sup> Instead, there is nothing ‘fully independent of consequences’ in human rights.<sup>689</sup> With regard to the second argument, it has not been possible to identify a convincing regulatory framework for access to medicines that should overrule the present laws, policies and behaviours. No ideal system for access to medicines was found, given the contingencies and complexities of access to medicines and health systems in sub-Saharan Africa.<sup>690</sup>

Thus, normatively, the thesis identifies important limitations with regard to the utilisation of human rights to guide and redress access to medicines, as well as other ‘fundamental’ measures of health care and health. In fact it is argued that human rights are a ‘second-best’, both as moral principles and legal instruments. The utilisation of human rights as moral principles, overall, suffers from the shortcoming that human rights communications tend to simplify contingencies and de-problematise ethical predicaments,

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<sup>688</sup> Cited and translated in Moeller [2008: 139]. *See also* Luhmann [2008] on ‘indispensable’ norms. As Luhmann observed, with regard to values, in effect, “values are *necessary* in order to give decisions indisputability. Decisions however bring the *necessity* into the form of *contingency*” [Luhmann 2008: 29]. On values *see also* Paterson [2008].

<sup>689</sup> Luhmann defines indispensable norms as those norms ‘fully independent of consequences’ [Luhmann 2008: 19].

<sup>690</sup> *See* section 7.3 above.

as the empirical and ethical enquiry in the thesis demonstrated. This is not a point about relativism vis-à-vis human rights universalism – or sub-Saharan Africa vis-à-vis the rest of the world. Indeed the thesis criticised those approaches which, especially founded in the discourse of development, see developing countries as *exceptions*, therefore calling for exceptional measures such as ‘normalising’ their ‘populations’. The point maintained here is precisely what Philippopoulos-Mihalopoulos noted reading Luhmann on human rights: “... this is not a preference for the particular over the universal, but a consideration... of the impossibility of capturing the particular through the universal and therefore a necessity of shifting focus... from the distinction particular/universal to that of social system/human consciousness” [Philippopoulos-Mihalopoulos 2010: 158]. Philippopoulos-Mihalopoulos further remarked that a related aporia has been identified by Brown, in her feminist research, with regard to the possibility of utilising human rights for the emancipation of women: “[i]f too ‘universal’, generic and neutral, human rights simply reinstate the status quo; if too specific and particularised, they maintain the fence around identity and discrete components of suffering, with which women identify and in which they remain immured”.<sup>691</sup> Thus, I resent the reduction of moral reasoning, *including* reasoning for policies, regulations and court decisions to arguments founded on human rights.<sup>692</sup> Human rights, after all, are part of the autopoiesis of the political and legal subsystems, as recalled below. Next, as legal instruments, it was noted, the human right to health care is too ‘weak’ to guide and redress the need for medicines in sub-Saharan Africa. My conclusion does not suggest, however, reinforcing the utilisation of economic and social rights, for example by demanding courts to be more ‘activist’.<sup>693</sup> Too much, it was showed, *cannot* be decided in terms of the human right to medicines/health care/health. For example, it is hard to overcome the paradox of a human right to health care which is not possible to award comprehensively and is in effect exclusive. Why do people suffering from rare, expensive conditions not deserve to have their human right to health care realised in contexts of limited resources? Human rights, consequently, are also inadequate to redress the use of power in relation to health care

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<sup>691</sup> Philippopoulos-Mihalopoulos [2010: 156] referring to Brown [2002].

<sup>692</sup> *See also* the studies in the philosophy of law and ethics. For example some works enquire on which normative principles are best suited to inform morality – whether rights, duties or goals [Mackie 1984; O’Neill 1996; Raz 1984]. *See also* the works researching the moral foundation of rights [Steiner 1994; Sumner 1987].

<sup>693</sup> *See contra* Bilchitz favouring an expanded role of the courts seeing human rights protection as the justification of judicial review and suggesting that courts should look, for economic and social rights, at overall budgets focussing on a minimum core approach [Bilchitz 2007]. *See also* Chapter 4 section 5.4.3.

and access to medicines. Indeed as Luhmann noted, “[a] subjective right offers a guarantee of freedom in a double sense: for the holder and for those against whom those rights are ineffective” [*id.*: 418].<sup>694</sup>

In fact, the function of human rights in social systems fosters the very duty-holders’ power and biopower. With regard to the role of states, in particular, human rights do not overcome their structural coupling to politics, which takes place through law. The ‘human rights subsystem’ structurally couples to law – human rights are often seen as the ‘foundation’ of the rule of law [Luhmann 2004: 414]. Human rights gain ascendancy through the (human rights) law. In effect, however, it is politics which establishes/‘recognises’ human rights in law. Human rights indeed do not hold a higher metaphysical legitimacy as they are in fact ‘product of society’ [Luhmann 1997(b): 35]. Human rights consequently act as gate-keepers of the subsystems’ autopoiesis. As Luhmann sharply noted, human rights limit the scope of politics, keeping it functionally differentiated from the other social subsystems (*e.g.*, the legal, moral, economic subsystems) [Luhmann 2002/1965: 60-61]. Human (constitutional, fundamental) rights are indeed meant to be the ultimate guarantee against the assault of the state. At the same time, still, such differentiation is condition of existence (and autopoiesis) of politics. Without human rights the other social subsystems would collapse into the absolute power of politics [*id.*] – and politics itself would no longer be ‘politics’. The theory of social systems also suggests that the differentiation entrenched by human rights is – as well as communication produced within other subsystems – a communication produced within the autopoietic political subsystem. In effect the political subsystem through human rights designs its competence and legitimacy. States are communications/programmes of the human rights utopia (which incidentally includes also non-state actors), but the human rights utopia, is a communication/programme of the states.<sup>695</sup> As Philippopoulos-Mihalopoulos aptly put it: “[human] rights are part of the *representation* aspect of the political system towards its environment, a pivotal part of the arsenal of values in the nature of which the political system legitimises itself” [Philippopoulos 2010: 154, *emph. orig.*].<sup>696</sup> Therefore, states are the recipients of duties as well as legitimate powers for the realisation of human rights.

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<sup>694</sup> See also Luhmann [2004: 151, 165].

<sup>695</sup> See Luhmann [1997(b): 992-3].

<sup>696</sup> See also Luhmann [2004: 417].

The ‘politicisation’ of human rights is also evident as human rights, according to many human rights instruments, can in fact be limited for the ‘public’ – as it will be defined by politics – interest.<sup>697</sup> Moreover, human rights often sanction a ‘margin of discretion’.<sup>698</sup> Economic and social rights, in particular, are to be realised progressively, that which virtually concedes perpetual legitimacy to the shortcomings of state action. Also, with specific regard to health, it is recalled that the human right to health envisages the protection of public health, and this can constitute legitimate grounds for limiting human rights [Tomasevski 1995: 125].<sup>699</sup> Indeed, Agamben notes that the state obtains legitimate biopower for intervening in public health and the health of the ‘bare lives’ from the inscription of the bare life (bios) in the juridico-political order which take place in human rights declarations:

Declarations of rights represent the originary figure of the inscription of natural life in the juridico-political order of the nation-state. The same bare life that in the ancien régime was politically neutral and belonged to God as creaturely life and in the classical world was (at least apparently) clearly distinguished as *zoē* from political life (bios) now fully enters into the structure of the state and even becomes the earthly foundation of the state’s legitimacy and sovereignty. [Agamben 1998: 127]

Furthermore non-state actors, too, are attributed power and biopower whenever they are attributed a ‘public’ role, *inter alia*, by human rights norms. This power is not political/state ‘binding’ power, but can be influential and unfettered all the more as such actors are not politically accountable.

It is recalled that the exercise of power is morally problematic for two main reasons:<sup>700</sup> power is generally a reduction of liberty for the individuals subject to it and can impose morally undesirable policies and actions. The thesis has illustrated that the spectrum where power can be exercised in relation to the human right to medicines is

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<sup>697</sup> See for example ICESCR article 4 [ICESCR art. 4]. On limitations to the international human right to health, for example in relation to ‘general welfare’ see also Toebes [1999: Chapter VI, text to notes 34-48]. With regard to national constitutional documents for example Bilchitz reports of the limitations contained in the South African Constitution [Bilchitz 2007: 175]. See also the *TAC v. Ministry of Health* judgment wherein the South African Constitutional Court read the human rights provisions in the South African Constitution as attributing powers to the state [South Africa, Constitutional Court, *TAC v. Ministry of Health*, para. 28].

<sup>698</sup> See also CESCR [2000: para. 53].

<sup>699</sup> Public health often demands to limit human rights such as the right to privacy, autonomy, or even the right to health of the individual, in favour of the collective interest [Beaglehole and Bonita 2004: 264-266; D’Oronzio 2001; O’Neill 2002: 36].

<sup>700</sup> On the concept of power see also Chapter 1 section 1.4.

ample. States have to respect, protect, fulfil the human right to medicines – therefore they have to regulate and implement, inter alia, intellectual property rights, the safety of medicines, the modality of medicines financing (*e.g.* cost sharing, national insurance, general taxation), the selection of the medicines provided and the price of the medicines distributed. All those policies are consequential for health, but they are not precisely regulated by the human right to health. Thus, for example, the initiatives for access to medicines of states, international organisations, NGOs and pharmaceutical companies, while claiming to be non-discriminatory and objective (*e.g.* by pursuing aggregate DALYs of a population), may neglect individual medical needs or impose unwarranted public health policies.<sup>701</sup> To note, states have a vested interest in the health of the ‘population’ at the *aggregate* level, which is instrumental to ‘security’, and thence more power, as argued by Foucault [Foucault 2007].<sup>702</sup> Human rights law, however, does not necessarily challenge such aggregative focus; in fact in some instances it sanctions a public health approach. Furthermore, the ethical problems of regulation and policies for access to medicines are not confined to health. Importantly, the implementation of the human right to medicines (as well as the human right to health care and other human rights) is costly, in terms of financial resources that have to be collected from the subjects and in terms of other legitimate interests, rights, needs and liberties that have to be forgone.

Therefore, I argue that the differentiation of politics should be addressed critically with another sort of ‘de-differentiation’. Indeed, through the differentiation also enacted by human rights, politics remains autopoietic; human rights collaborate to distance politics from people, while coding people into politics according to the political communication – just as the legal subsystem re-constructs people in law as juridical subjects [Luhmann 2004: 417]). As Luhmann underlined, in effect: “autopoiesis precludes humanism, the reason being that there is no unity of all the autopoietic systems which make up the human being” [Luhmann 1986: 86]. Thus, while human rights can be seen as the fallback option against the assault of political power (although they are a paradoxical option, especially in those legal and political systems where they struggle to be recognised and enforced), the ‘first best’ is the questioning of politics (and law, and

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<sup>701</sup> *See also* Porter on the use of quantification in order to justify public policies as objective [Porter 1995].

<sup>702</sup> Accordingly, the best deal for a state is to focus on the least expensive interventions which deliver the most healthy population overall.

their structural couplings) *without* its autopoietic distinction – and defence – from society. The ‘binding decisions’ of the *public administration* should therefore be critically analysed through active democracy, participation, accountability and, when necessary, opposed through positive and ordinary law (tort law, criminal law, administrative law etc.).<sup>703</sup> The problematisation of access to medicines (or health care and other social problems) has to be multidimensional, ‘interdisciplinary’, and take into account the ethical problems, operational contingencies and the limits of steering of politics and law. The human right to medicines instead de-problematizes the complexities of action for the achievement of public goods. Too many issues in effect are not conclusively solved through the application of human rights: discussions relating to human rights risk being restricted to disciplined, inclusive yet exclusive channels.<sup>704</sup> Furthermore, the thesis demonstrated that, with regard to extra-governmental actors, human rights law as well as non-binding commitments to human rights are particularly vague, presenting serious challenges to the operationalisation, implementation and enforcement of such prescriptions. Other parameters and procedures of accountability are instead needed.

In sum, I point out a fundamental limitation in that human rights can enhance the autopoietic distinction of politics and, by including the person in the juridico-political order, exclude her. Indeed, as observed by Philippopoulos-Mihalopoulos, system theory suggests that:

... human rights are a tangible representation, not of a full-on humanism, but precisely of the need to relocate the question from the human to the boundary between system and environment. In this respect rights constitute the *actualisation of exclusion*... human rights are predicated precisely on the exclusion of the human flesh and blood from society – otherwise the discourse would revert to a situation of total inclusion. [Philippopoulos-Mihalopoulos 2010: 155, 157]

Thus, the human right to medicines – or, the “fundamental component of the human right to health regarding access to medicines” – is ultimately affected by the paradox that *it is not sufficiently human*. Social systems theory has helped identifying the limits of rationalising the world and the individual according to autopoietic systems, as well as the constructed meanings that communications transmit in the different social systems. As Paterson remarked, in effect, “it is undoubtedly true that individuals *are*

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<sup>703</sup> Recalling from Chapter 1 section 1.4, politics is the subsystem differentiated through communications power/non power, whose function is taking binding decisions [Luhmann 2002/1965: 55, 58].

<sup>704</sup> *See also* Luhmann [2004: 135-6].

constructs of social systems but it is *also* true that social systems exist as constructs for individuals” [Paterson 1996: 89, *emph. orig.*]. I hope, therefore, that this thesis contributed to the identification and problematisation of the paradoxes, contingencies and limitations of human rights and access to medicines, in the sight of the ‘human flesh and blood’ in sub-Saharan Africa.<sup>705</sup> Paradoxes in effect, as Luhmann suggested in his study on the paradoxes of human rights, are not ‘scandalous’, but rather the rule for social construction.<sup>706</sup>

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<sup>705</sup> See Paterson defending social systems theory against Bankowski’s critique of the alleged demise of the person in the sight of autopoiesis [Bankowski 1996; Paterson 1996: 82]. In fact Paterson uncovers ‘the importance of autopoiesis in the sight of the person’ [Paterson 1996: 89]. For the uncovering of the ‘flesh and blood’, and the ‘absences manifesting in the theory’, see Philippopoulos-Mihalopoulos [2010: 8, 77-8, 157].

<sup>706</sup> See Luhmann [1995(b)] in Moeller [2008: 131].

## ANNEXE A: LIST OF INTERVIEWEES

List of the people I interviewed during my field work in Tanzania and Kenya, July-August 2009. Only the interviewees who agreed to be named are listed.

### Central government

Name	Role, Institution	Place	Date
Dr Fred Lwilla	Senior Programme Officer, National Tuberculosis and Leprosy Programme (NTLP)	National Tuberculosis and Leprosy Programme, Ministry of Health and Social Welfare, Dar es Salaam, Tanzania	20/07/09
Dr Fabrizio Molteni	Malaria Technical Advisor, National Malaria Control Programme (NMCP)	National Malaria Control Programme, Ministry of Health and Social Welfare; Molteni's home, Dar es Salaam, Tanzania	15/07/09; 19/07/09
Joseph Salinga Muhume	Assistant Director (Chief Pharmacist), Ministry of Health and Social Welfare	Diamond Jubilee, Maliki Road, Dar es Salaam, Tanzania	12/08/09

### Local government

Beatrice Koni	Municipal Health Secretary, Sumbawanga, Rukwa region	Bomani, Sumbawanga, Rukwa region, Tanzania	30/07/09
Mbonja Kasembwa	Health Officer, Kilombero District	Ifakara Bomani, Kilombero, Morogoro region, Tanzania	04/08/09
Dr George M. Kassiga	Acting District Medical Officer, Kilombero	Ifakara Bomani, Kilombero, Morogoro region, Tanzania	04/08/09
Dr Akilimali Mpozemenya	Municipal Medical Officer, Sumbawanga, Rukwa region	Bomani, Sumbawanga, Rukwa region, Tanzania	29/07/09
Hamidi Njouvu	Acting Municipal Director, Sumbawanga, Rukwa Region	Sumbawanga City Hall, Rukwa region, Tanzania	29/07/09

Procurement of medicines in the public and private sector

Dr Eunice Gathitu	Pharmacist, Provincial Hospital of Mombasa	Provincial Hospital of Mombasa, Kenya	20/08/09
Hajiri Haruni	Shopkeeper of 'Mwikola' Duka la Dawa Muhimu (ADDO)	Michenga village, Kilombero district, Morogoro region, Tanzania	06/08/09
Cosmas Mwaifwani	Director of Customer Services & Sales, Medical Stores Department (MSD)	Medical Stores Department, Marajani, Dar es Salaam, Tanzania	20/07/09
Miriam Mzirany	Clinical Officer, Michenga Dispensary	Michenga Dispensary, Kilombero, Morogoro region, Tanzania	06/08/09
Adrian Siwalima	Regional Pharmacist of the Rukwa region	Regional Hospital, Sumbawanga, Rukwa region, Tanzania	30/07/09
Cecilia Wanalwa	Pharmacist, Kilifi District Hospital	Kilifi District Hospital, Kilifi, Kenya	19/09/09

Tanzania civil society, consumer groups

Bernard E. Kihyo	Executive Director, Tanzania Consumer Advocacy Society	Tanzania Consumer Advocacy Society, Kariakoo, Dar es Salaam, Tanzania	14/07/09
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International organisations

Rose Shija	Director, WHO Essential Drugs Programme Tanzania	WHO, Luthuli Road, Dar es Salaam, Tanzania	20/07/09
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Foreign cooperation, foreign aid

Charles Llewelyn	Health and Population Officer, USAID	United States Embassy, Dar es Salaam, Tanzania	13/08/09
Elise Jensen	Head of USAID's HIV/AIDS Office; Chair, USAID/ Development Partners Group (DPG) AIDS, Country Coordinating Mechanism of the Global Fund for AIDS, Tuberculosis and	United States Embassy, Dar es Salaam, Tanzania	12/08/09

	Malaria		
Gregory Smith	Consultant, Irish Aid	Movempick Hotel, Dar es Salaam, Tanzania	23/07/09

#### Non-profit, NGOs

Abdinasir Abass Amin	Senior Researcher/Malaria Principal Investigator, Population Services International (PSI)	Population Services International, Regional Innovations Office, Whitefield Place, School Lane, Westlands, Nairobi, Kenya	18/08/09
Donata Dalla Riva	Doctors with Africa Cuamm	Doctors with Africa Cuamm, Dar es Salaam, Tanzania	14/07/09
Dr Yahya Abdallah Ipuge	Country Director, Clinton Foundation	Clinton Foundation, Dar es Salaam, Tanzania	13/08/09
Jafari Liana	Management Science for Health (MSH), Tanzania	Management Science for Health (MSH), Dar es Salaam, Tanzania	21/07/09
Romuald Mbwasi	Management Science for Health (MSH), Tanzania	Management Science for Health (MSH), Tanzania, Dar es Salaam	21/07/09
Ssanyu Nyinondi	JSI/SCMS Tanzania	JSI/SCMS Tanzania, Zambia Street, Plot no. 32 in Oyster bay, Tanzania	15/07/09
Tim Rosche	USAID   DELIVER PROJECT – John Snow, Inc. (JSI)	USAID   DELIVER PROJECT - John Snow, Inc. (JSI), Dar es Salaam, Tanzania	17/07/09
Dr Hellmuth Rossler	Branch manager/ Pharmacist, Action Medeor TZ	Action Medeor TZ, Dar es Salaam, Tanzania	16/07/09
Rosemary Silaa	Clinton Foundation	Clinton Foundation, Dar es Salaam, Tanzania	13/08/09

#### Medical personnel

Dr Janet Bulemela	Acting Head of St. Francis Hospital	St. Francis Hospital, Ifakara, Morogoro region, Tanzania	08/08/09
Dr Mussa Makori	General Practitioner, Dr Atiman Memorial	Dr Atiman Memorial Council Designated	17/08/09

	Council Designated Hospital	Hospital, Sumbawanga, Tanzania	
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Research institutions

Dr Catherine Goodman	KEMRI/Wellcome Trust Research Programme and Lecturer, Health Economics & Policy Health Policy Unit London School of Hygiene & Tropical Medicine	KEMRI/Wellcome Trust Research Programme, Kenyatta National Hospital, Nairobi, Kenya	24/08/09
Dr Flora Kessy	Ifakara Health Institute	Ifakara Health Institute, Dar es Salaam, Tanzania	10/08/09
Felix Lubuga	Ifakara Health Institute	Ifakara Health Institute, Mikocheni Office, Dar es Salaam, Tanzania	22/07/09
Dr Vicki Marsh	Kilifi Research Unit	Kenya Medical Research Institute/Wellcome Trust Centre for Geographic Medicine Research-Coast, Kilifi, Kenya	18/08/09
Dr Dominick Mboya	Ifakara Health Institute	Ifakara Health Institute, Dar es Salaam, Tanzania	05/08/09
Christopher Mshana	Ifakara Health Institute	Ifakara Health Institute, Ifakara, Tanzania	04/08/09
Dr Cornelia Staehelin	Medical Researcher	Ifakara Health Institute, Dar es Salaam, Tanzania	05/08/09
Leka Tingitana	Tanzania Training Centre for International Health (TTCIH), Ifakara Health Institute	Ifakara Health Institute, Ifakara, Kilombero, Morogoro, Tanzania	04/09/09
Frank Wafula	Health Systems Research Group, KEMRI/ Wellcome Trust/ Oxford University Collaboration	KEMRI/ Wellcome Trust Programme, Nairobi, Kenya	24/08/09

Pharmaceutical sector

Ashok Gupta	Head – Formulation Development & DRA Department, Shelys Pharmaceuticals Ltd,	Shelys Pharmaceuticals Ltd, Dar es Salaam, Tanzania	14/08/09
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Professor Dr Klaus M. Leisinger	President and Managing Director of the Novartis Foundation for Sustainable Development	Ifakara Health Institute, Ifakara, Kilombero, Morogoro, Tanzania	08/08/09; 09/08/09
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Pharmaceutical products regulating authorities

Emmanuel Alphonse	Inspection and Enforcement Manager, Tanzania Food and Drugs Authority (TFDA)	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	
Bryccesson Kibassa	Acting Manager ADDO Programme, Tanzania Food and Drugs Authority (TFDA)	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	14/08/09
Akida M. Khea	Tanzania Food and Drugs Authority (TFDA), Manager Medical Devices Assessment and Enforcement	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	17/08/09
Legu R. Mhangwa	Tanzania Food and Drugs Authority (TFDA), Pharmacy Adviser	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	17/08/09
John E. Mponela	Head of the Anti-Counterfeits Department, Fair Competition Commission	Fair Competition Commission, Dar es Salaam, Tanzania	07/08/09
Moses Nandonde	Pharmacist Analyst, Tanzania Food and Drugs Authority (TFDA)	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	24/07/09
Margareth Ndomondo-Sigonda	Director General, Tanzania Food and Drugs Authority (TFDA)	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	24/07/09
Hiiti B. Sillo	Director Medicines and Cosmetics, Tanzania Food and Drugs Authority (TFDA)	Tanzania Food and Drugs Authority (TFDA), Dar es Salaam, Tanzania	14/08/09

## ANNEXE B: CAUSES OF DEATH IN SUB-SAHARAN AFRICA

Cause of death in all persons (10,778,044)	Total deaths (%)
1 HIV/AIDS	20.4
2 Malaria	10.1
3 Lower respiratory infections	9.8
4 Diarrheal diseases	6.5
5 Perinatal conditions	5.1
6 Measles	4.1
7 Cerebrovascular disease	3.3
8 Ischemic heart disease	3.1
9 Tuberculosis	2.8
10 Road traffic accidents	1.8
11 Pertussis	1.6
12 Violence	1.2
13 COPD	1.1
14 Tetanus	1.0
15 Nephritis and nephrosis	0.9
16 Malnutrition	0.9
17 War	0.8
18 Syphilis	0.8
19 Diabetes mellitus	0.7
20 Drownings	0.6
21 All other specific causes	23.2

Estimates of leading causes of death in sub-Saharan African, 2000. Source: Rao et al [2006: 53]

**ANNEXE C: DALYS LOST TO DIFFERENT CONDITIONS IN SUB-SAHARAN AFRICA**

Cause	Total	Cause	Total
<i>Population (millions)</i>	668	<b>II. Noncommunicable diseases</b>	<b>73,069</b>
<b>All causes</b>	<b>344,754</b>	<b>A. Malignant neoplasms</b>	<b>6,281</b>
<b>I. Communicable, maternal, perinatal, and nutritional conditions</b>	<b>242,837</b>	1. Mouth and oropharynx cancers	284
<b>A. Infectious and parasitic diseases</b>	<b>173,484</b>	2. Esophageal cancer	343
1. <b>Tuberculosis</b>	<b>8,084</b>	3. Stomach cancer	487
2. <b>Sexually transmitted diseases excluding HIV/AIDS</b>	<b>3,842</b>	4. Colon and rectal cancers	291
a. Syphilis	2,347	5. Liver cancer	762
b. Chlamydia	559	6. Pancreas cancer	117
c. Gonorrhea	894	7. Trachea, bronchus, and lung cancers	225
d. Other sexually transmitted diseases	41	8. Melanoma and other skin cancers	118
3. <b>HIV/AIDS</b>	<b>56,820</b>	9. Breast cancer	574
4. <b>Diarrheal diseases</b>	<b>22,046</b>	10. Cervix uteri cancer	627
5. <b>Childhood-cluster diseases</b>	<b>23,198</b>	11. Corpus uteri cancer	41
a. Pertussis	6,116	12. Ovarian cancer	152
b. Poliomyelitis	17	13. Prostate cancer	416
c. Diphtheria	45	14. Bladder cancer	133
d. Measles	13,539	15. Lymphomas and multiple myeloma	622
e. Tetanus	3,481	16. Leukemia	245
6. <b>Meningitis</b>	<b>941</b>	Other malignant neoplasms	844
7. <b>Hepatitis B<sup>a</sup></b>	<b>536</b>	<b>B. Other neoplasms</b>	<b>188</b>
<b>Hepatitis C<sup>a</sup></b>	<b>217</b>	<b>C. Diabetes mellitus</b>	<b>1,448</b>
8. <b>Malaria</b>	<b>35,447</b>	<b>D. Endocrine disorders</b>	<b>2,706</b>
9. <b>Tropical-cluster diseases</b>	<b>4,897</b>	<b>E. Neuropsychiatric conditions</b>	<b>15,151</b>
a. Trypanosomiasis	1,310	1. Unipolar depressive disorders	3,275
b. Chagas' disease	—	2. Bipolar affective disorder	1,204
c. Schistosomiasis	1,184	3. Schizophrenia	1,146
d. Leishmaniasis	312	4. Epilepsy	1,373
e. Lymphatic filariasis	1,656	5. Alcohol use disorders	685
f. Onchocerciasis	436	6. Alzheimer's and other dementias	450
10. <b>Leprosy</b>	<b>24</b>	7. Parkinson's disease	100
11. <b>Dengue</b>	<b>4</b>	8. Multiple sclerosis	77
12. <b>Japanese encephalitis</b>	<b>—</b>	9. Drug use disorders	929
13. <b>Trachoma</b>	<b>1,455</b>	10. Post-traumatic stress disorder	224
14. <b>Intestinal nematode infections</b>	<b>905</b>	11. Obsessive-compulsive disorder	619
a. Ascariasis	476	12. Panic disorder	519
b. Trichuriasis	119	13. Insomnia (primary)	234
c. Hookworm disease	309	14. Migraine	329
Other intestinal infections	1	15. Mental retardation, lead-caused	1,505
Other infectious diseases	15,068	Other neuropsychiatric disorders	2,481
<b>B. Respiratory infections</b>	<b>31,107</b>	<b>F. Sense organ diseases</b>	<b>8,939</b>
1. Lower respiratory infections	30,455	1. Glaucoma	937
2. Upper respiratory infections	371	2. Cataracts	5,169
3. Otitis media	281	3. Vision disorders, age-related	920
<b>C. Maternal conditions</b>	<b>9,743</b>	4. Hearing loss, adult onset	1,912
1. Maternal hemorrhage	1,643	Other sense organ disorders	2
2. Maternal sepsis	1,843	<b>G. Cardiovascular diseases</b>	<b>15,069</b>
3. Hypertensive disorders of pregnancy	842	1. Rheumatic heart disease	479
4. Obstructed labor	919	2. Hypertensive heart disease	937
5. Abortion	1,557	3. Ischemic heart disease	4,579
Other maternal conditions	2,940	4. Cerebrovascular disease	5,125
<b>D. Perinatal conditions<sup>b</sup></b>	<b>20,047</b>	5. Inflammatory heart diseases	945
1. Low birthweight	7,891	Other cardiovascular diseases	3,004
2. Birth asphyxia and birth trauma	9,256	<b>H. Respiratory diseases</b>	<b>6,150</b>
Other perinatal conditions	2,899	1. Chronic obstructive pulmonary disease	1,631
<b>E. Nutritional deficiencies</b>	<b>8,455</b>	2. Asthma	1,925
1. Protein-energy malnutrition	5,220	Other respiratory diseases	2,595
2. Iodine deficiency	951		
3. Vitamin A deficiency	548		
4. Iron-deficiency anemia	1,688		
Other nutritional disorders	49		

<b>Cause</b>	<b>Total</b>
<b>I. Digestive diseases</b>	<b>7,226</b>
1. Peptic ulcer disease	345
2. Cirrhosis of the liver	1,212
3. Appendicitis	44
Other digestive diseases	5,626
<b>J. Genitourinary diseases</b>	<b>2,623</b>
1. Nephritis and nephrosis	1,633
2. Benign prostatic hypertrophy	292
Other genitourinary system diseases	697
<b>K. Skin diseases</b>	<b>956</b>
<b>L. Musculoskeletal diseases</b>	<b>2,171</b>
1. Rheumatoid arthritis	252
2. Osteoarthritis	1,278
3. Gout	94
4. Low back pain	214
Other musculoskeletal disorders	333
<b>M. Congenital anomalies</b>	<b>3,441</b>
1. Abdominal wall defect	36
2. Anencephaly	47
3. Anorectal atresia	14
4. Cleft lip	12
5. Cleft palate	28
6. Esophageal atresia	2
7. Renal agenesis	2
8. Down syndrome	419
9. Congenital heart anomalies	1,651
10. Spina bifida	293
Other congenital anomalies	938
<b>N. Oral conditions</b>	<b>720</b>
1. Dental caries	496
2. Periodontal disease	23
3. Edentulism	181
Other oral diseases	21
<b>III. Injuries</b>	<b>28,848</b>
<b>A. Unintentional injuries</b>	<b>18,876</b>
1. Road traffic accidents	6,374
2. Poisonings	954
3. Falls	976
4. Fires	1,739
5. Drownings	1,720
6. Other unintentional injuries	7,112
<b>B. Intentional injuries</b>	<b>9,972</b>
1. Self-inflicted injuries	882
2. Violence	4,996
3. War	4,090
Other intentional injuries	3

Estimates of Disability-Adjusted Life Years (DALYs) lost to different conditions in sub-Saharan Africa in 2001. Source: Mathers et al [2006: 216-221].

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