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**Promotion and protection of human rights: human rights questions, including alternative approaches for improving the effective enjoyment of human rights and fundamental freedoms**

### **The right of everyone to the enjoyment of the highest attainable standard of physical and mental health**

#### **Note by the Secretary-General\*\***

The Secretary-General has the honour to transmit to the members of the General Assembly the report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Paul Hunt, submitted in accordance with Human Rights Council decision 1/102 in which the Council decided to extend, exceptionally for one year, the mandates and the mandate holders of the special procedures of the Commission on Human Rights.

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\* A/61/150.

\*\* The present report is submitted late owing to consultations.



## **Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health**

### *Summary*

The present report, submitted in accordance with Human Rights Council decision 1/102, reflects on the recent activities of, and issues of particular interest to, the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The report examines the relationship between the right to the highest attainable standard of health and two issues at the heart of the Millennium Development Goals: access to medicines and the reduction of maternal mortality.

The first chapter examines the causes of maternal mortality and how they are closely related to a failure to realize the right to the highest attainable standard of health. The chapter highlights the positive contribution of the right to health to reducing maternal mortality. Properly integrated, the right to health can help ensure that the relevant policies are more equitable, sustainable and robust. The right also provides a powerful campaigning tool in the struggle for a reduction in maternal mortality.

The second chapter briefly considers the component of the right to the highest standard of health that relates to medicines, including essential medicines. Using the right to health analytical framework that has been developed in recent years, the first section focuses on the responsibilities of States. The second section provides a brief introduction to the responsibilities of pharmaceutical companies.

The chapter explains that the Special Rapporteur is preparing some draft preliminary guidelines for (a) States and (b) pharmaceutical companies, on access to medicines.

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## I. Introduction

1. By its resolution 60/251 of 15 March 2006, the General Assembly concluded the work of the Commission of Human Rights and created the Human Rights Council. The mandate of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health is set out in Commission resolutions 2002/31 and 2004/27. The Human Rights Council, by its decision 1/102, extended all mandates of the former Commission on Human Rights, including that of the Special Rapporteur. The present report is submitted in accordance with that resolution.
2. From 10 to 18 January 2006, the Special Rapporteur undertook a country mission to Sweden, at the invitation of the Government. A report on his mission will be submitted to the Council at its fourth session.
3. In February 2006, together with four other special procedures mandate holders, the Special Rapporteur submitted a joint report to the Commission on Human Rights, focusing on the human rights situation of detainees at the United States of America naval base at Guantánamo Bay (E/CN.4/2006/120). The report will be considered at the third session of the Human Rights Council.
4. The Special Rapporteur has sent a number of urgent appeals and other communications to various Governments; he has also issued some press releases. He will report on the communications in his annual report to the Council.
5. Over the course of the year 2006, the Special Rapporteur has participated in a number of meetings convened by international organizations, Governments and civil society, including the following. In February and March, he participated in expert consultations on indicators organized by the World Health Organization (WHO) and the Office of the United Nations High Commissioner for Human Rights (OHCHR). Between March and July, he held a series of consultations on the right to medicines with: representatives of international organizations, including WHO; the United Kingdom Department for International Development (DFID); OHCHR; and non-governmental organizations (NGOs) including Realizing Rights: the Ethical Globalization Initiative (EGI), Oxfam and 3D: Trade-Human Rights-Equitable Economy. In April, he spoke at a workshop on sexual rights, development and human rights organized by the Swedish Ministry of Foreign Affairs. At the invitation of a coalition of NGOs, the Special Rapporteur visited Australia in May, where he had various engagements, including participation in a human rights training programme organized by the Diplomacy Training Program, University of New South Wales. In May, he also held meetings with New Zealand's Aid and International Development Agency in Wellington, and attended seminars in Mexico organized by the Graduate School of Public Administration and Public Policy, Monterrey Institute of Technological and Higher Studies, and the Coahuila State University Medicine School. In June, he attended the annual meeting of Human Rights Council special procedures, organized by OHCHR. During the same month, he attended a workshop hosted by the British Medical Association on "Improving health in the developing world: what can national medical associations do?" In July, the Special Rapporteur attended informal consultations with the United Nations Population Fund, WHO, UNICEF, the Pan American Health Organization and OHCHR, focusing on his current and future work on sexual and reproductive health rights.
6. All United Nations documents related to the work of the Special Rapporteur are available on the OHCHR website at <http://www.ohchr.org/english/issues/>

health/right/. For ease of reference, these documents, and selected conference papers, can also be found on the website of the Human Rights Centre, University of Essex, [http://www2.essex.ac.uk/human\\_rights\\_centre/rth.shtm](http://www2.essex.ac.uk/human_rights_centre/rth.shtm).

## **II. Reducing maternal mortality: the contribution of the right to health**

7. In 2000, the estimated number of maternal deaths worldwide was 529,000; 95 per cent of these deaths occurred in Africa and Asia.<sup>1</sup> While women in developed countries have only a 1-in-2,800 chance of dying in childbirth — and a 1-in-8,700 chance in some countries — women in Africa have a 1-in-20 chance. In several countries the lifetime risk is greater than 1 in 10.<sup>2</sup> Women living in poverty and in rural areas, and women belonging to ethnic minorities or indigenous populations, are among those particularly at risk.<sup>3</sup> Complications from pregnancy and childbirth are the leading cause of death for women 15-19 years old in developing countries. Globally, around 80 per cent of maternal deaths are due to obstetric complications, mainly haemorrhage, sepsis, unsafe abortion, pre-eclampsia and eclampsia, and prolonged or obstructed labour.<sup>4</sup> Complications of unsafe abortions account for 13 per cent of maternal deaths worldwide, and 19 per cent of maternal deaths in South America.<sup>5</sup> An estimated 74 per cent of maternal deaths could be averted if all women had access to the interventions for addressing pregnancy and birth complications, in particular emergency obstetric care.<sup>6</sup>

8. For every woman who dies from obstetric complications, approximately 30 more suffer injuries, infection and disabilities.<sup>7</sup> In 1999, WHO estimated that over 2 million women living in developing countries remain untreated for obstetric fistula, a devastating injury of childbirth.

9. There is no single cause of death and disability for men between the ages of 15 and 44 that is close to the magnitude of maternal death and disability.<sup>8</sup>

10. These deeply shocking statistics and facts reveal chronic and entrenched health inequalities. First, the burden of maternal mortality is borne disproportionately by developing countries. Second, in many countries, marginalized women, such as women living in poverty and ethnic minority or indigenous women are more vulnerable to maternal mortality. Third, maternal mortality and morbidity rates reveal sharp discrepancies between men and women in their enjoyment of sexual and reproductive health rights.

11. An increasing number of countries have made progress in reducing maternal mortality. However, progress has stagnated or been reversed in many of the countries with the highest maternal mortality rates.<sup>9</sup> This is despite longstanding international commitment and initiatives to reducing maternal mortality.

12. In recent years, there has been a deepening conceptual understanding of maternal mortality as a human rights issue.<sup>10</sup> In this chapter, the Special Rapporteur explores some of the facets of the relationship between maternal mortality and the right to the highest attainable standard of health.

## A. Right-to-health norms and obligations relevant to maternal mortality

13. The right to the highest attainable standard of health entitles women to services in connection with pregnancy and the post-natal period, and to other services and information on sexual and reproductive health.<sup>11</sup> These entitlements encompass the key technical interventions for the prevention of maternal mortality, including access to a skilled birth attendant, emergency obstetric care, education and information on sexual and reproductive health, safe abortion services where not against the law, and other sexual and reproductive health-care services.<sup>12</sup>

14. While the right to health includes entitlements to specific health-related goods, services and facilities, it should also be understood more broadly as an entitlement to an effective and integrated health system, encompassing health care and the underlying determinants of health, which is responsive to national and local priorities, and accessible to all (see E/CN.4/2006/48, para. 4). This is important in the context of maternal mortality. An equitable, well-resourced, accessible and integrated health system is widely accepted as being a vital context for guaranteeing women's access to the interventions that can prevent or treat the causes of maternal deaths.<sup>13</sup>

15. In recent years, the United Nations Committee on Economic, Social and Cultural Rights, the Special Rapporteur on the right to the highest attainable standard of health, and others, have developed a framework for unpacking the norms and obligations of the right to health. This framework — which is outlined in paragraph 45 — can be applied in the context of particular right-to-health issues such as maternal mortality. The framework provides a useful prism through which to understand the relevance of the right to health in the context of maternal mortality, and can also serve as a useful reference point for integrating the right to health into policymaking (see paras. 16-24). Drawing on this framework, the Special Rapporteur wishes to make some non-comprehensive observations about right-to-health norms and obligations relevant to reducing maternal mortality, including in the context of strengthening health systems.

### Health care

16. The right to health has a particular preoccupation with guaranteeing primary health care. A priority intervention to prevent maternal mortality is ensuring functioning primary health-care systems, “from community-based interventions to the first referral-level facility at which emergency obstetric care is available”.<sup>14</sup>

17. The right to health entitles women to reproductive health-care services, goods and facilities that are:

(a) *Available in adequate numbers.*<sup>15</sup> Among others, this gives rise to an obligation on States to ensure an adequate number of health professionals. Improving human resource strategies, including increasing the number of health professionals and improving terms and conditions, is a vital prerequisite for reducing maternal mortality in many countries;<sup>16</sup>

(b) *Accessible physically and economically.*<sup>17</sup> Physical access to, and the cost of, health services often influence women's decisions about whether or not to seek care.<sup>18</sup> In many countries, reducing maternal mortality will depend on making

relevant services more accessible, including through expansion of relevant services into underserved areas. It will also often depend on ensuring relevant interventions are affordable;

(c) *Accessible without discrimination.* They must be sensitive to gender and to the rights and cultures of minorities and indigenous peoples.<sup>19</sup> Preventing maternal mortality and enhancing access to maternal health care is not simply about scaling up technical interventions or making the interventions affordable. It is also vital to address social, cultural, political and legal factors which influence women's decisions to seek maternal or other reproductive health-care services. This may require addressing discriminatory laws, policies, practices and gender inequalities that prevent women and adolescents from seeking good quality services;

(d) *Of good quality.*<sup>20</sup> The quality of care often influences the outcome of interventions and also influences a woman's decision of whether or not to seek care.

### **Underlying determinants of health**

18. The right to health is not just a right to health care, but an entitlement to other social, economic, cultural and political determinants of health. These include participation in health-related decision-making processes, information on sexual and reproductive health, literacy, nutrition, non-discrimination and gender equality. The majority of these determinants have a direct influence on access to the health services that are essential for preventing maternal mortality. Some, such as nutrition, can be a direct cause of maternal mortality. Several of these issues are given further consideration in paragraph 22 below.

### **Progressive realization, resources and international cooperation**

19. States have a duty to devote maximum available resources, and to take legal and policy measures, to progressively realize the right to health.<sup>21</sup> In many countries, health systems are chronically underfunded and in a state of collapse. Increased expenditure and policies which strengthen health systems and give priority to maternal health are essential for reducing maternal mortality.

20. The right to health gives rise to a responsibility of international assistance and cooperation on developed States to assist developing States realize the right to health.<sup>22</sup> Developed States should support developing States' efforts to reduce maternal mortality. This responsibility is reflected in Millennium Development Goal 8, which is a commitment to develop a global partnership for development. Developed States should ensure that their international development assistance, and other policies, support health systems' strengthening and other relevant policies in developing countries (see also A/59/422 and A/60/348).

### **The right to health and the "three delays" model**

21. It has been suggested that maternal mortality is overwhelmingly due to delays in: deciding to seek appropriate medical help for an obstetric emergency (for reasons of cost, lack of recognition of an emergency, poor education, lack of access to information and gender inequality); reaching an appropriate facility (for reasons of distance, infrastructure and transport); and receiving adequate care when a facility is reached (e.g. because there are shortages in staff, or because electricity, water or medical supplies are not available).<sup>23</sup> The "three delays" are interrelated.<sup>24</sup>

The right to health encompasses norms and obligations which are relevant in each of these contexts.

**B. What can the right to health add to policies and programmes to reduce maternal mortality?**

22. At the United Nations Millennium Summit (2000), States adopted the Millennium Declaration. The Declaration includes a commitment to reduce maternal mortality by three quarters by the year 2015.<sup>25</sup> The Millennium Development Goals (the Goals), which derive from the Millennium Declaration, and which include a commitment to improve maternal health, have become the central platform for international development efforts.

23. Maternal mortality had been an international focus for many years prior to the Goals.<sup>26</sup> However, the Goals represent a renewed and perhaps greater opportunity for reducing maternal mortality. They give relatively greater prominence to this issue, include time-bound targets, are supported by an international apparatus to advise on their implementation, have generated significant support from donors and international organizations, and have increasingly shaped national and international development policies.

24. At the International Conference on Population and Development (ICPD) held in Cairo, from 5 to 13 September 1994, States recognized that sexual and reproductive health is essential to development. In contrast, the Millennium Development Goals are silent on this relationship. However, at the 2005 World Summit, States reaffirmed the ICPD position through committing to: “achieving universal access to reproductive health by 2015, as set out in the ICPD, integrating this goal into strategies to attain the international agreed development goals, including those contained in the Millennium Declaration, aimed at reducing maternal mortality [and] improving maternal health”.<sup>27</sup>

25. While the target for achieving Goal 5 is reducing maternal mortality by three quarters by 2015, its broader goal is improving maternal health. In the last decade, there has been an increasing focus on improving maternal health. In particular, greater attention is rightly being given to obstetric fistula. In 2003 UNFPA and other United Nations agencies launched the global Campaign to End Fistula.

26. The Goals — and a good number of national and international policy frameworks — do not explicitly contain a focus on the right to health or other rights. A related issue is whether the right to health has a contribution to make in the context of policymaking for the reduction of maternal mortality, as well as towards improving maternal health.

27. The Millennium Project Task Force on Child Health and Maternal Health, charged with developing recommendations for Goal 5, is unequivocal in its recognition of the role of human rights, including the right to health, in policymaking to reduce maternal mortality. Other actors have also advocated a rights-based approach to health policymaking, and some have taken steps to integrate human rights into their maternal mortality policies and programmes.

28. There are several reasons why the right to health has a constructive contribution to make in the context of maternal health policymaking:

(a) On account of its grounding in law, widespread acceptance by the international community and detailed framework of relevant norms and obligations, the right to health can help legitimize policies and programmes that prevent maternal mortality;

(b) The right-to-health principles of equality and non-discrimination have three important roles to play in policies to reduce maternal mortality. First, they underpin programmes that promote more equitable distribution of health care, including provision in rural or poor areas, or areas with high indigenous or minority populations. Second, they underpin prioritization of interventions — such as emergency obstetric care — that can guarantee women's enjoyment of the right to health on the basis of non-discrimination and equality. Third, policies which promote non-discrimination and equality — as well as dignity, cultural sensitivity, privacy and confidentiality — in the clinical setting, can improve patient-provider relationships and encourage women to seek health care;

(c) The right to health includes an entitlement to participate in health policymaking at the local, national and international levels. Participation by relevant stakeholders, including women, will help develop more effective and sustainable programmes, reduce exclusion and enhance accountability;

(d) Monitoring and accountability are integral features of the right to health and can help reduce maternal mortality. The right to health demands accountability of various stakeholders, including health-care providers, local health authorities, national Governments, international organizations and civil society.<sup>28</sup> Accessible and effective accountability mechanisms — including courts, tribunals, health ombudsmen, impact assessments and policy review processes — can all help enhance access to health care; and

(e) A right-to-health approach to reducing maternal mortality requires appropriate indicators to monitor progress made, and to highlight where policy adjustments may be needed. The scope of this report does not permit a detailed analysis of which indicators are needed. The Special Rapporteur wishes to refer the General Assembly to his report to the Commission on Human Rights (E/CN.4/2006/48, paras. 22-61 and annex), which sets out a methodology for a rights-based approach to health indicators, including in relation to the reproductive health strategy endorsed by the World Health Assembly in May 2004.

29. In short, a policy that is animated by the right to health is likely to be equitable, inclusive, non-discriminatory, participatory and evidence-based. In the context of maternal mortality policies, these features help to empower women and ensure that policies are likely to be sustainable, robust and effective.

30. Interventions to prevent maternal mortality — including family-planning services, skilled attendants at birth and emergency obstetric care, and other sexual and reproductive health services — are also imperative measures to prevent and treat other causes of sexual and reproductive ill-health, including fistula and other causes of maternal morbidity. A right-to-health approach to reducing maternal mortality is therefore also likely to lead to improvements in sexual and reproductive health, including maternal health.

### **C. The need for a human rights campaign against maternal mortality**

31. In his work, the Special Rapporteur has urged human rights experts and organizations to move beyond their traditional techniques — such as campaigning, naming and shaming, and court-based approaches — to engage with health decision-makers to ensure that the right to health informs policies.

32. Maternal mortality is one of a small number of right-to-health issues where human rights experts and health policymakers have engaged extensively and constructively with each other. These efforts deserve applause and further support; however, there is certainly scope for further interactions at the international, national and local levels.

33. In contrast, the human rights community has given less attention to the traditional human rights techniques for addressing maternal mortality.<sup>29</sup> Naming and shaming, campaigning, and court-based approaches also have an important role to play in strengthening claims, and enhancing accountability for, the reduction of maternal mortality.

34. In the 1990s, domestic violence was identified as a violation of human rights and this helped the global campaign against domestic violence gather momentum. By the same token, the human rights community should be challenged to mount a global human rights campaign against maternal mortality. The human rights community must be urged to remonstrate and demonstrate about maternal mortality just as loudly as it complains about extrajudicial executions, arbitrary detention, unfair trials and prisoners of conscience. Persistently high maternal mortality rates, coupled with the fact that all States are committed to reduce by three quarters the maternal mortality ratio by 2015, suggests that the time is ripe for such an initiative.

35. This is not to underestimate the many challenges that would confront such an undertaking. For example, while violence against women is always a human rights violation, some unavoidable cases of maternal mortality are not. To take another example, the identity of the human rights violator may not always be clear because responsibility for maternal mortality may be attributable to multiple actors, including family members, health professionals and facilities, the relevant State, and the international community. However, that does not stop many maternal deaths from being a human rights violation — and this violation must be investigated precisely to determine where responsibility lies, and so as to better ensure accountability, so that the appropriate policy changes are introduced as a matter of urgency.

36. A human rights campaign against avoidable maternal mortality would inevitably lead to other crucial issues, not least the vital importance of constructing effective health systems that are accessible to all.

### **III. The human right to medicines**

37. Almost 2 billion people lack access to essential medicines.<sup>30</sup> This deprivation causes immense and avoidable suffering: ill health, pain, fear, loss of dignity and life.<sup>31</sup> Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia.<sup>32</sup> Besides deprivation, gross

inequity in access to medicines remains the overriding feature of the world pharmaceutical situation.<sup>33</sup> Average per capita spending on medicines in high-income countries is 100 times higher than in low-income countries: about US\$ 400 compared with US\$ 4. WHO estimates that 15 per cent of the world's population consumes over 90 per cent of the world's production of pharmaceuticals.<sup>30</sup>

38. Existing national and international policies, rules and institutions give rise to these massive deprivations and inequalities. National supply systems for medicines often do not reach those living in poverty. If they do, the medicines are often unaffordable. Historically, research and development has not addressed the priority health needs of those living in poverty. Alternative arrangements are feasible and reforms are urgently required. Indeed, they are demanded by legal and ethical duties, including those arising from international human rights law.

39. Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depend upon improving access to medicines. Indeed, one of the Millennium Development Goal targets is to provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries.<sup>34</sup> Crucially, implementation of the right to the highest attainable standard of health can help to achieve the health-related Goals.

40. Medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right to the highest attainable standard of health.<sup>35</sup> These features depend upon access to medicines. Thus, access to medicines forms an indispensable part of the right to the highest attainable standard of health. Numerous court cases, as well as resolutions of the Commission on Human Rights, confirm that access to essential medicines is a fundamental element of the right to health.<sup>36</sup> Some of the cases also confirm that access to essential medicines issues are closely connected to other human rights, such as the right to life.

41. This chapter briefly examines the medicines component of the right to health. While the chapter focuses upon the responsibilities of States (see sect. A, paras. 47-81 below), it also provides a brief introduction to the responsibilities of pharmaceutical companies (see sect. B, paras. 82-92). The chapter is offered as a preliminary contribution to far-reaching human rights issues of the first importance.

42. Since 2004, the Special Rapporteur has benefited from a number of substantive workshops and other meetings with numerous actors, including representatives of pharmaceutical companies, on the issues introduced in this chapter (see para. 86). With a view to being as practical and constructive as possible, he is preparing some draft guidelines for States and pharmaceutical companies on access to medicines. The draft aims to help States and pharmaceutical companies better understand and discharge their right-to-health responsibilities in relation to access to medicines. Section A addresses the responsibilities of States; section B the responsibilities of pharmaceutical companies. (The preliminary draft can be found at [http://www2.essex.ac.uk/human\\_rights\\_centre/rth/rapporteur.shtm](http://www2.essex.ac.uk/human_rights_centre/rth/rapporteur.shtm).)

43. The Special Rapporteur will work further on this preliminary draft in the coming months with a view to finalizing the guidelines in 2007. He will consult widely on the draft and takes this opportunity to encourage all interested parties to provide him with their comments.<sup>37</sup>

### **The right-to-health analytical framework**

44. The right to the highest attainable standard of health is a large and complex human right. In recent years, the Committee on Economic, Social and Cultural Rights, WHO, civil society organizations, academics and many others, have developed a way of “unpacking” or analysing the right to health with a view to making it easier to understand and apply in practice to health-related policies, programmes and projects (e.g. the Committee’s general comment 14). For his part, the Special Rapporteur has tried to apply and refine this analytical framework in his country and other reports. He strongly recommends that policymakers use this analytical framework because it will deepen their understanding of the right to health, enabling them to strengthen their health-related policies and other interventions. In this way, the analytical framework will become a common language for discussing a wide range of health issues through the lens of the right to health.

45. While the analytical framework is set out in more detail elsewhere, its key elements may be very briefly summarized as follows:

- Identification of the relevant national and international human rights laws, norms and standards;
- Recognition that the right to health is subject to resource constraints and progressive realization, requiring the identification of indicators and benchmarks to measure progress (or the lack of it) over time;
- Nonetheless, recognition that some obligations arising from the right to health are subject to neither resource constraints nor progressive realization, but are of immediate effect, for example, the obligation to avoid *de jure* and *de facto* discrimination;
- Recognition that the right to health includes freedoms (e.g. freedom from non-consensual treatment and non-consensual participation in clinical trials) and entitlements (e.g. to a system of health care and protection). For the most part, freedoms do not have budgetary implications, while entitlements do;
- All health services, goods and facilities shall be available, accessible, acceptable and of good quality. This scheme is briefly applied to medicines in paragraphs 47-51 below;
- States have duties to respect, protect and fulfil the right to the highest attainable standard of health. This, too, is briefly applied to medicines in paragraphs 59-60 below;
- Because of their crucial importance, the analytical framework demands that special attention is given to issues of non-discrimination, equality and vulnerability;
- *Participation*: the right to health requires that there is an opportunity for the active and informed participation of individuals and communities in decision-making that bears upon their health;
- *International assistance and cooperation*: developing countries have a responsibility to seek international assistance and cooperation, while developed States have some responsibilities towards the realization of the right to health in developing countries; and

- *Monitoring and accountability*: the right to health requires that there are effective, transparent and accessible monitoring and accountability mechanisms available at the national and international levels.

46. By way of illustration, this chapter briefly applies elements of this analytical framework to access to medicines.

## A. The responsibilities of States

### **Ensuring medicines are available, accessible, culturally acceptable and of good quality<sup>38</sup>**

47. States have to do all they reasonably can to make sure that existing medicines are available in sufficient quantities in their jurisdictions. For example, they might have to make use of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities by passing and using compulsory licence legislation, thereby ensuring that medicines reach their jurisdictions in adequate quantities. Additionally, the record confirms that research and development has not addressed the priority health needs of developing countries. Thus, within a framework of international assistance and cooperation, States are required to take effective measures to promote the development and availability of new drugs, vaccines and diagnostic tools for those diseases causing a heavy burden in developing countries.<sup>39</sup> States should resort to a variety of economic, financial and commercial incentives in order to influence research and development into specific health needs.

48. In short, States not only have a duty to ensure that existing medicines are available within their borders, they also have a responsibility to take reasonable measures to ensure that much-needed new medicines are developed and thereby become available.

49. In addition to being available, medicines must also be accessible. Accessibility has four dimensions. First, medicines must be accessible in all parts of the country (for example, in remote rural areas as well as in urban centres. This has major implications for the design of medicine supply systems, including outreach programmes. Second, medicines must be economically accessible (i.e. affordable) to all, including those living in poverty. This has major implications for medicine funding and pricing arrangements. It may also mean that a State has to revisit import duties and other taxes on medicines if it is helping to take medicines beyond the reach of the poor. Third, medicines must be accessible without discrimination on any of the prohibited grounds, such as sex, race, ethnicity and socio-economic status. As discussed in the next section, the principle of non-discrimination may require a State to take measures to ensure equality of access for all individuals and groups, such as disadvantaged minorities. Fourth, reliable information about medicines must be accessible to patients and health professionals so they can take well-informed decisions and use medicines safely.

50. As well as being available and accessible, medicines and associated issues must be culturally acceptable and respectful of medical ethics. For example, national measures should support the proper use of traditional medicine and its integration into health-care systems, while clinical trials must ensure the informed consent of research subjects.

51. Medicines must also be of good quality. If rejected in the North because they are beyond their expiry date and unsafe, medicines must not be recycled to the South. Because medicines may be counterfeit or tampered with, States must establish a regulatory system to check medicine safety and quality.

**Combating discrimination, inequality, vulnerability**

52. A national medicines policy must be designed to ensure access for vulnerable individuals and disadvantaged groups, 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.

53. This preoccupation with vulnerability and disadvantage arises from two of the most fundamental principles of international human rights law: non-discrimination and equality. Importantly, these twin principles do not always demand equal treatment; on the contrary, they sometimes require a State to take measures in favour of disadvantaged individuals and communities. Although closely linked to the ethical concept of equity, the principles of non-discrimination and equality have the advantage of being reinforced by law and accountability mechanisms.

54. In relation to access to medicines, non-discrimination and equality have numerous implications. For example, a State is obliged to establish a national medicine supply system that includes programmes specifically tailored to reach the vulnerable and disadvantaged. It is also required to tackle the cultural, social and political factors that inhibit vulnerable groups' access to health care generally and to medicines in particular. So far as possible, data must be disaggregated to identify vulnerable groups and monitor their progress towards equal access (see E/CN.4/2006/48, from para. 62).

**In relation to medicines, how is progressive realization to be measured and monitored? What are the obligations of immediate effect?**

55. The right to the highest attainable standard of health — and thus access to medicines — is subject to progressive realization and resource availability, in accordance with article 2, paragraph 1, of the International Covenant on Economic, Social and Cultural Rights. Put simply, progressive realization means that a State is required to be doing better in five years time than it is doing today, while resource availability means that what is required of a developed State is of a higher standard than what is required of a developing State.

56. This has a number of important implications. For example, States need appropriate indicators and benchmarks so they know whether or not they are progressively realizing the right to health (see human rights-based approach set out in E/CN.4/2006/48). But it also has an important qualification: the right to health includes some core obligations of immediate effect, without which the right would be largely deprived of its *raison d'être*.<sup>40</sup> For example, States have an immediate obligation to avoid discrimination and also to make certain pharmaceuticals — known as “essential medicines” — available and accessible throughout their jurisdictions.<sup>41</sup> These core obligations of immediate effect are not subject to progressive realization.

57. Guided by the WHO Model List of Essential Medicines (2005), a State is required to prepare a national essential medicines list, by way of a participatory inclusive process. If a State declines to prepare its own national essential medicines list, the WHO model list will apply, subject to any obvious contextual revisions. A State has a core obligation of immediate effect — not subject to progressive realization — to make available and accessible throughout its jurisdiction the essential medicines on its national list.<sup>42</sup>

58. In summary, 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. This chapter encompasses non-essential and essential medicines.

#### **Duties to respect, protect and fulfil**

59. States have duties to respect, protect and fulfil the right to the highest attainable standard of health.<sup>43</sup> For example, the *duty to respect* obliges a State to ensure that its medicines policy does not discriminate against women, ethnic minorities, or other disadvantaged groups. The *duty to protect* requires a State to ensure that third parties do not obstruct enjoyment of the right to health, for example, a State must ensure that privatization in the health sector advances, and does not hinder, the realization of the right to health. The *duty to fulfil* requires a State to provide those living in poverty with essential medicines if they would otherwise be unable to access them.

60. In other words, while a State may contract the delivery of health services to a private company, it does not contract out of its right-to-health obligations. A State always retains residual responsibility for the proper regulation of its health and medicines systems, as well as for the well-being of the most disadvantaged in its jurisdiction.

#### **Participation in health policymaking**

61. The active and informed participation of individuals and communities in health policymaking that affects them is an important feature of the right to the highest attainable standard of health. In most cases, a local community will have a keen sense of its health priorities; it is entitled to participate in the identification of priorities and targets that guide the technical deliberations underlying the policy formulation that will affect its members.

62. When formulating its national medicine policy and programmes, a State is required to take steps to ensure the active and informed participation of all those affected, not only professional associations and universities, but also rural communities, non-governmental organizations, patients and consumer associations, and representatives of disadvantaged groups.

#### **International assistance and cooperation in health**

63. The primary obligation for implementing the right to health falls upon the national authorities in the State in question. However, States have the obligation to take steps individually and through international assistance and cooperation towards the full realization of various rights, including the right to health. The Special

Rapporteur has considered the responsibility of those States that are in a position to assist, to engage in international assistance and cooperation, in a number of his other reports (see A/60/348).

64. In the context of medicines, this responsibility means 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.<sup>44</sup> In other words, developed States should not encourage a developing country to accept “TRIPS-plus” standards in any bilateral or multilateral trade agreement. They should help developing countries establish effective, integrated, inclusive health systems that include reliable medicine supply systems delivering quality affordable medicines for all, and support research and development into the priority health needs of developing countries (see also para. 48).

### **Monitoring and accountability**

65. The right to health brings with it the crucial requirement of establishing accessible, transparent and effective mechanisms of monitoring and accountability. Those with right-to-health responsibilities must be held to account in relation to the discharge of their duties, with a view to identifying successes and difficulties; so far as necessary, policy and other adjustments can then be made. There are many different forms of monitoring and accountability mechanisms. While a State will decide which are most appropriate in its particular case, all mechanisms must be effective, accessible and transparent.

66. A national medicines policy must be subject to appropriate monitoring and accountability. This requires that the policy set out: the Government’s right-to-health obligations in relation to medicines; an implementation plan that identifies objectives, timelines, duty holders and their responsibilities, indicators, benchmarks, and reporting procedures. From time to time, a suitable national body (e.g. a health ombudsman) will have to consider the degree to which those responsible for the implementation of the national medicines policy have fulfilled their duties — not with a view to sanction and punishment, but with a view to establishing which policies and institutions are working and which are not, with the aim of improving the realization of the right to medicines for all.

### **A selection of specific, practical issues regarding access to medicines**

67. Ensuring access to medicines for all gives rise to a wide range of specific, practical and important issues. By way of illustration, this section briefly introduces four of these issues, keeping in mind the analytical framework signalled in the preceding paragraphs.

#### *A reliable system for the supply of good-quality affordable medicines*

68. Whether it chooses a supply system that is public, private or mixed, a State has a legal obligation to ensure that there is a reliable, efficient, transparent system for the supply of quality affordable medicines throughout its jurisdiction. The supply system must be attuned to current needs, obtain good value for money, minimize waste and avoid corruption (for more on corruption, see paras. 78-80). Crucially, it must be designed to serve those living in poverty and isolated communities, as well as wealthy urban elites.

69. Of course, this obligation is subject to the resources available in a particular country: Canada is obliged to ensure better access to a wider range of medicines than Chad. However, the obligation of both developed and developing States is subject to progressive realization: all States are required to ensure better access to a wider range of medicines in five years' time than exists today.

70. To measure this progressive realization (or lack of it), States must develop disaggregated indicators and benchmarks for a reliable, efficient medicine supply system.<sup>45</sup> These indicators have to reflect human rights features, for example, the degree to which the system ensures equal access for vulnerable groups (hence the need for disaggregated indicators), and provides effective monitoring and accountability mechanisms.

#### *Quality of medicines*

71. International human rights standards are clear: a State has a legal obligation to ensure that medicines of good quality are available throughout its jurisdiction. Thus, effective medicine regulation is required to ensure the safety, efficacy, and quality of medicines available in both public and private sectors, as well as the accuracy and appropriateness of medicine information available to health professionals and the public.

72. While the safety and quality of medicines is a problem in many developed and developing States, the magnitude of the problem is much greater in developing countries, where poor quality medicines may be the only ones to reach the poor. In recent assessments carried out by WHO, 50-90 per cent of anti-malarial drug samples failed quality control tests, while more than half of antiretrovirals did not meet international standards. The sale of counterfeit and substandard medicines remains a global concern.

73. One third of States have either no medicine regulatory authority or inadequate capacity to regulate the medicines market. The absence of such an authority is clearly inconsistent with the right to the highest attainable standard of health. In line with their human rights responsibility of international assistance and cooperation, developed States should actively help developing countries establish appropriate medicine regulatory authorities.

#### *Financing of medicines*

74. Whether a medicine is affordable depends upon many factors, including financing (i.e. how they are paid for) and pricing. There are different ways of financing medicines, including by way of public or private health insurance, patients' fees, donations, loans, and so on. These are complex issues and here the Special Rapporteur confines himself to one point. Whatever the chosen financing arrangement, a State has a human rights obligation to ensure that medicines are economically accessible (i.e. affordable) to all.

75. In many high-income countries, over 70 per cent of medicines are publicly funded whereas in low- and middle-income countries public expenditure does not cover the basic medicine needs of the majority of the population. In these countries, patients themselves pay for 50 to 90 per cent of medicines. Where the cost of medicines is borne by households, it can further impoverish already disadvantaged populations, and inhibit equitable access to medicines.

76. In developed countries, a course of antibiotics for pneumonia may be bought for the equivalent of two or three hours' wages; in developing countries, a course may cost one month's wages. In developed countries, one year's HIV treatment may consume the equivalent of four to six months' salary and, in most cases, will be covered by health insurance; in many developing countries, one year's HIV paediatric treatment may consume the equivalent of an adult's income for 10 years. Such striking inequalities are deeply repugnant and underscore the importance of developed States' responsibility for international assistance and cooperation.

77. For present purposes, however, the crucial point is that in developed countries most medicines are paid from public funding, whereas in developing countries the majority of households buy their medicines with money from their own pockets. In developing countries, inadequate public funding in the health sector makes medicines less affordable, especially for those living in poverty.

#### *Corruption*

78. In some medicine supply systems, corruption is endemic. Products are diverted; unofficial "fees" are required for customs clearance; counterfeit medicines are permitted to circulate and so on. Corruption can be deadly. As Dora Akunyili, head of Nigeria's Food and Drug Authority, put it: "Drug counterfeiting, facilitated by corruption, kills en masse and anybody can be a victim".<sup>46</sup>

79. Those living in poverty are disproportionately affected by corruption in the health sector because they are less able to afford small bribes for services that are meant to be free, or to pay for private alternatives where corruption has depleted public health services.

80. The right to health includes participation, access to information, transparency, monitoring and accountability. Each of these features helps to establish an environment in which corruption cannot survive. In short, a right-to-health policy is also an anti-corruption policy. Thus, the application of the right to health can help to reduce corruption in health systems in general, as well as medicine supply systems in particular.

#### **Conclusion**

**81. As mentioned in paragraph 42 above, the Special Rapporteur is preparing, by way of a consultative process, guidelines for States and pharmaceutical companies on access to medicines. In the meantime, he wishes to emphasize the crucial importance of all States having an up-to-date national medicines policy and detailed implementation plan. The policy should include a national list of essential medicines. At the turn of the century, almost 100 States did not have a national medicines policy.<sup>47</sup> Two thirds of those with a policy did not have an implementation plan.<sup>48</sup> The Special Rapporteur fails to see how any State can be in conformity with its right-to-health obligations if it does not have an up-to-date and appropriate national medicines policy, implementation plan and essential medicines list, prepared by way of a participatory inclusive process. In this context, he urges States to give close attention to WHO's commendable work on access to medicines, including its *Medicines Strategy, Countries at the Core (2004-2007)*.**

## B. The responsibilities of pharmaceutical companies

82. The previous section emphasized the primary responsibility of States to increase access to medicines. But, of course, this is a shared responsibility. If there is to be an increase in access to medicines, numerous national and international actors have an indispensable role to play. The Millennium Development Goals recognize that pharmaceutical companies are among those who share this responsibility. Goal 8, a global partnership for development, has a number of targets, not least: “*In cooperation with pharmaceutical companies, provide access to affordable, essential drugs in developing countries*” (emphasis added).

83. Last year, a British Government policy paper on access to medicines elaborated on this point: “Responsibility for increasing access to essential medicines rests with the whole international community. Progress depends on everyone working in partnership to build health systems in developing countries, increase financing, make medicines more affordable, and increase the amount of new medicines developed for diseases affecting developing countries”.<sup>49</sup> Significantly, the paper continued: “In this context there is a particular role for pharmaceutical companies. As the producers of existing, and developers of new, medicines they can — and do — make a difference within their sphere of influence”. The paper then sets out a promising “framework for good practice in the pharmaceutical industry”.

84. Since his appointment in 2002, many parties have impressed upon the Special Rapporteur the profound impact of the pharmaceutical sector on the implementation of the right to the highest attainable standard of health. This message has been most clear when on country missions to low-income and middle-income countries. States and others have criticized the pharmaceutical sector for setting prices too high, erratic drug donations, imbalanced research and development, lobbying for TRIPS-plus standards, inappropriate drug promotion, problematic clinical trials, and other practices that are seen to obstruct a State’s ability to discharge its right to health responsibilities.<sup>50</sup> However, States and others have also commended some significant progress in recent years, such as the more widespread use of differential pricing, predictable and sustainable drug donations, and a renewed commitment to research and development into neglected diseases.<sup>51</sup>

85. Under his mandate, the Special Rapporteur is requested, inter alia, to develop a regular dialogue and discuss possible areas of cooperation with all relevant actors; to report on good practices most beneficial to the enjoyment of the right to the highest attainable standard of health, as well as obstacles encountered domestically and internationally to its implementation; and to support States’ efforts by making recommendations.

86. In light of this mandate, over the last three years the Special Rapporteur has engaged in a number of discussions on access to medicines with numerous parties, including pharmaceutical companies. Most of the meetings with the pharmaceutical companies have been organized by Realizing Rights: The Ethical Globalization Initiative, in addition to an international symposium organized by the Novartis Foundation for Sustainable Development.<sup>52</sup> The discussions have been substantive and constructive. They have drawn from the work of the Global Compact, Business Leaders Initiative on Human Rights (BLIHR), OHCHR, States, WHO and other elements of the United Nations system, pharmaceutical companies, civil society organizations and others. The discussions have benefited from the extensive experience and literature on corporate responsibility, which has grown exponentially

in recent years. They have considered good practices, and bad. These discussions have tended to confirm that a growing number of pharmaceutical companies are becoming aware of the contribution they can make to advancing the right to the highest attainable standard of health, as well as the benefits such an approach can bring for their businesses.

87. In these wide-ranging discussions, the Special Rapporteur has introduced the right to the highest attainable standard of health and emphasized the congruity between corporate responsibility, good practices and the right to health. He sought to explain the right-to-health analytical framework (as outlined from para. 45 above). While this framework is primarily designed for States, its application can help to identify policy interventions that a pharmaceutical company can — and should — take to improve access to medicines. The Special Rapporteur tried to dispel some misconceptions about the right to health, for example, by explaining that it can be promoted and protected without recourse to the courts, by shaping good policies. While commending some of the companies' corporate responsibility self-reporting initiatives, he noted that they fell short of the independent accountability mechanisms anticipated by human rights. (Some independent accountability mechanisms are non-judicial, for example a Health Ombudsman.)

88. Although a number of pharmaceutical companies report on their corporate citizenship or corporate responsibility activities, few make specific references in their corporate mission statements to human rights in general or the right to health in particular. Even fewer appear to have carefully examined their policies through the lens of the right to the highest attainable standard of health. This is a missed opportunity because all pharmaceutical companies, whether large or small, research-based or generic, and whether or not their reach is global, would find it beneficial to adopt a rights-sensitive approach to their businesses, as outlined in the excellent joint publication of the Global Compact, BLIHR and OHCHR.<sup>53</sup>

89. In recent years, the general understanding of economic, social and cultural rights has deepened. If this momentum is to be maintained, it is necessary to move from general discussions about economic, social and cultural rights to consideration of specific rights, in relation to specific sectors, actors and issues. This is the point that has now been reached in relation to pharmaceutical companies and the right to health. Today, general statements about pharmaceutical companies and economic, social and cultural rights provide the indispensable foundation for a more detailed examination of specific right-to-health issues arising in the pharmaceutical sector. In short, it is time to explore further the right-to-health responsibilities of pharmaceutical companies that were acknowledged in general terms by the Committee on Economic, Social and Cultural Rights in its general comment 14, paragraph 42.

90. For this reason the Special Rapporteur has embarked on a process of preparing draft guidelines for States and pharmaceutical companies on access to medicines. The draft guidelines for pharmaceutical companies consider specific issues, such as differential pricing, donations, research and development for neglected diseases, public-private partnerships, drug promotion, clinical trials, and corruption. Accompanied by a concept note, they have been prepared keeping in mind the right-to-health analytical framework, as well as a number of studies and reports.<sup>54</sup> As observed by the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises: "It is essential to achieve greater conceptual clarity with regard to the respective responsibilities of States and corporations ... In doing so we should bear in mind

that companies are constrained not only by legal standards but also by social norms and moral considerations” (E/CN.4/2006/97, para. 70).

91. Based on the Special Rapporteur’s understanding of the right to the highest attainable standard of health, the draft guidelines are a modest, constructive, practical, sector-specific contribution to this challenging, long-term process. Once more, the Special Rapporteur warmly invites all parties to provide comments on the draft.<sup>55</sup>

### Conclusion

92. **A consensus is emerging that business enterprises, like all actors in society, have some legal and ethical human rights responsibilities. According to its Preamble, the Universal Declaration of Human Rights gives rise to some human rights responsibilities for “every organ of society”, which must include business enterprises.**<sup>56</sup> The United Nations Global Compact, with more than 2,300 participating companies, affirms that businesses should support and respect the protection of international human rights.<sup>57</sup> The Organization for Economic Cooperation and Development’s Guidelines for Multinational Enterprises require businesses to “respect the human rights of those affected by their activities consistent with the host Government’s obligations and commitments”.<sup>58</sup> While holding that the draft Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights of the Sub-Commission on the Promotion and Protection of Human Rights had no legal standing, the Commission on Human Rights found that the Norms contained “useful elements and ideas”.<sup>59</sup> Some national courts have recognized the impact of pharmaceutical company pricing policies on the human rights of patients.<sup>60</sup> Significantly, some companies have prepared their own guidelines and other statements explicitly affirming their human rights responsibilities.<sup>61</sup>

93. Today, the key issues include, *first*, clarifying the scope and content of these human rights responsibilities and, *second*, identifying which are legal and which are ethical. The Special Rapporteur’s draft guidelines are a modest endeavour focusing on the first of these issues in the specific context of pharmaceutical companies. As for the second, in the opinion of the Special Rapporteur it is inconceivable that some human rights do not place legal responsibilities on business enterprises.<sup>62</sup>

## IV. Conclusions

94. Thanks to the work of innumerable organizations and individuals, the content of the right to the highest attainable standard of health is becoming clearer. In 2000, the Committee on Economic, Social and Cultural Rights developed a general framework that unpacked the right to health in terms of freedoms and entitlements; health care and underlying determinants of health; non-discrimination; participation; and monitoring and accountability.<sup>63</sup> In many of his reports, the Special Rapporteur has applied this *general* framework to a range of *specific* health issues. In so doing, he has sought to develop and refine the framework. In the present report, he begins to apply the framework to maternal mortality and medicines, two health issues encompassed by the Millennium Development Goals.

95. **The right to health makes a number of important contributions to the struggle against maternal mortality and to improve access to medicines. It sharpens analysis of the causes, as well as the responsibilities of various stakeholders. Policies informed by the right to health are likely to be more equitable, sustainable and effective. This contribution is already recognized in the context of some maternal health policies and programmes. In relation to policymaking about medicines, there is also a growing appreciation of the positive contribution that can be made by taking into account the right to the highest attainable standard of health.**

96. **Additionally, experience confirms that traditional human rights techniques, including “naming and shaming” and taking court cases, continue to have an indispensable role to play in the realization of various elements of the right to health, not least access to medicines.**

### Notes

<sup>1</sup> UNFPA website, <http://www.unfpa.org/mothers/statistics.htm>.

<sup>2</sup> *Who's Got the Power? Transforming Health Systems for Women and Children*, Millennium Project, Task Force on Child Health and Maternal Health, 2005.

<sup>3</sup> See, for example, Wirth, M. et al, “Setting the Stage for Equity-sensitive Monitoring of the Maternal and Child Health MDGs”, 84 (7) *WHO Bulletin*, July 2006.

<sup>4</sup> Millennium Project, op. cit. at note 3.

<sup>5</sup> *Unsafe Abortion: Global and Regional Estimates of Incidence of Unsafe Abortion and Associated Mortality in 2000*, WHO, 2004.

<sup>6</sup> Wagstaff, A., and Claeson, M., *The Millennium Development Goals for health: rising to the challenges*, World Bank, 2004.

<sup>7</sup> UNICEF statistics, 2003, reported in Bernstein, S., *Public Choices, Private Decisions: Sexual and Reproductive Health and the MDGs*, Millennium Project, 2006.

<sup>8</sup> See Yamin, A., Maine, D., “Maternal mortality as a human rights issue: measuring compliance with international treaty obligations”, 21 (3) *Human Rights Quarterly*, 1999.

<sup>9</sup> *World health report 2005: making every mother and child count*, WHO, 2005.

<sup>10</sup> E.g., Cook, R., Dickens, B., et al, *Advancing Safe Motherhood Through Human Rights*, WHO, 2001; *International policy on sexual and reproductive health and rights*, Swedish International Development Cooperation Agency, 2006; Freedman, L., “Human rights, constructive accountability and maternal mortality in the Dominican Republic: a commentary”, 82 *International Journal of Gynaecology and Obstetrics*, 2003; Yamin, A., Maine, D., op. cit.

<sup>11</sup> See International Covenant on Economic, Social and Cultural Rights (ICESCR), articles 10 and 12; Convention on the Elimination of All Forms of Discrimination against Women, article 14.

<sup>12</sup> See Committee on Economic, Social and Cultural Rights (CESCR), general comment 14, paras. 14, 21, Committee on the Elimination of All Forms of Discrimination against Women, general recommendation 24, para. 27; ICPD, para. 8.25.

<sup>13</sup> Freedman, L., “Achieving the MDGs: health systems as core social institutions”, *Development*, 2005; *World Health Report 2005*, WHO.

<sup>14</sup> Millennium Project, op. cit., note 3.

<sup>15</sup> CESCR, general comment 14, para. 12.

<sup>16</sup> Millennium Project, op. cit., note 3.

- <sup>17</sup> CESCR, general comment 14, para. 12.
- <sup>18</sup> Millennium Project, op. cit., note 3.
- <sup>19</sup> CESCR, general comment 14, para. 12.
- <sup>20</sup> *ibid.*
- <sup>21</sup> ICESCR, article 2.
- <sup>22</sup> *Ibid.*
- <sup>23</sup> Maine, D., *Safe Motherhood Programs: Options and Issues*. Columbia University, 1991.
- <sup>24</sup> See Millennium Project, op. cit., note 3.
- <sup>25</sup> General Assembly resolution 55/2; para. 19 of United Nations Millennium Declaration.
- <sup>26</sup> See, for example, International Conference on Population and Development (1994) and the Fourth World Conference on Women (1995); Safe Motherhood Initiative, established in 1987, and the Partnership for Safe Motherhood and Newborn Health, established in 2004.
- <sup>27</sup> World Summit Outcome Document, 2005 (A/60/L.1, para. 57). For a full discussion on sexual and reproductive health and the Millennium Development Goals, see Bernstein, S., op. cit., note 8.
- <sup>28</sup> Freedman, L., "Human rights, constructive accountability and maternal mortality in the Dominican Republic: a commentary", 82 *International Journal of Gynaecology and Obstetrics*, 2003.
- <sup>29</sup> Some human rights organizations are starting to focus more on maternal mortality, e.g. *Maternal mortality in Herat province, Afghanistan: the need to protect women's rights*, Physicians for Human Rights, 2002; *Perú: Mujeres pobres y excluidas: la negación del derecho a la salud materno-infantil*, Amnesty International, 2006.
- <sup>30</sup> *WHO Medicines Strategy: Countries at the Core, 2004-2007*, WHO, 2004. Fewer than one quarter of all AIDS patients in Africa, and less than one tenth of children with AIDS, receive the life-saving antiretroviral medicines they need, according to WHO statistics presented at the XVI International AIDS Conference, Toronto, 2006.
- <sup>31</sup> Some of this chapter draws upon the Montreal Statement on the Human Right to Essential Medicines (2005), see Marks, S. (ed.), *Health and Human Rights: Basic International Documents*, 2006.
- <sup>32</sup> *Increasing access to essential medicines in the developing world*, DFID, 2004.
- <sup>33</sup> *The World Medicines Situation*, WHO, 2004.
- <sup>34</sup> Millennium Development Goals, Target 17 of Goal 8.
- <sup>35</sup> See article 12 (2) (c) and (d), ICESCR.
- <sup>36</sup> For an excellent summary of relevant national jurisprudence, see Hogerzeil, H. et al., "Is access to essential medicines as part of the fulfilment of the right to health enforceable through the courts?", *Lancet*, 2006. See also Commission resolutions 2005/23, 2004/26 and 2003/29.
- <sup>37</sup> The comments can be sent to the Right to Health Unit, Human Rights Centre, University of Essex, at [rthu@essex.ac.uk](mailto:rthu@essex.ac.uk).
- <sup>38</sup> See CESCR, general comment 14, para. 12.
- <sup>39</sup> For this right-to-health problem in the context of Uganda's neglected diseases, see the Special Rapporteur's report E/CN.4/2006/48/Add.2, especially from para. 62.
- <sup>40</sup> CESCR, general comment 3, para. 10.
- <sup>41</sup> CESCR, general comment 14, paras. 43-44.

- <sup>42</sup> CESCR, general comment 14, paras. 12 (1) and 43 (4).
- <sup>43</sup> CESCR, general comment 14, paras. 34-37.
- <sup>44</sup> For example, see the Special Rapporteur's reports on the World Trade Organization (E/CN.4/2004/49/Add.1, from para. 66), and Peru (E/CN.4/2005/51/Add.3, from para. 47).
- <sup>45</sup> *WHO Medicines Strategy, 2004-2007*, chapter 4.
- <sup>46</sup> *Global Corruption Report*, Transparency International, 2006.
- <sup>47</sup> Hogerzeil, H., "Essential medicines and human rights", *WHO Bulletin*, 2006.
- <sup>48</sup> *The World Medicines Situation*, WHO, 2004.
- <sup>49</sup> *Increasing people's access to essential medicines in developing countries*, DFID, 2005.
- <sup>50</sup> Some of this information has been provided while on mission and confirmed in, for example, Interim Report of Task Force 5 Working Group on Access to Essential Medicines, Millennium Project, 2004, and Cullet, P., "Patents and medicines: the relationship between TRIPS and the human right to health", *International Affairs*, 2003.
- <sup>51</sup> On the latter, see Moran, M. and others, "The new landscape of neglected disease drug development", The Wellcome Trust, 2005.
- <sup>52</sup> The right to health: a duty for whom?: International symposium report, Novartis Foundation for Sustainable Development, 2004.
- <sup>53</sup> See "A guide for integrating human rights into business management" available at <http://www.blihr.org/>.
- <sup>54</sup> E.g. *Public Health, Innovation and Intellectual Property Rights*, CIPIH, 2006; *Increasing people's access to essential medicines in developing countries*, DFID, 2005; Leisinger, K., "On Corporate Responsibility and Human Rights", 2006; *Branding the Cure*, Consumers International, 2006.
- <sup>55</sup> The draft is available at [http://www2.essex.ac.uk/human\\_rights\\_centre/rth/rapporteur.shtml](http://www2.essex.ac.uk/human_rights_centre/rth/rapporteur.shtml) and comments may be sent to [rthu@essex.ac.uk](mailto:rthu@essex.ac.uk).
- <sup>56</sup> Robinson, M., "The business case for human rights" in *Visions of Ethical Business*, *Financial Times Management* (London, Financial Times Professional, 1998); de Mello, S.V., "Human rights: what role for business?" 2(1) *New Academy Review* (2003).
- <sup>57</sup> For more information on Global Compact, see <http://www.unglobalcompact.org/>.
- <sup>58</sup> The OECD Guidelines for Multinational Enterprises, 2000.
- <sup>59</sup> Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights (E/CN.4/Sub.2/2003/12/Rev.2) (2003).
- <sup>60</sup> *AIDS Access Foundation and others v. Bristol-Myers Squibb and others*, 2002 (10) BC Tor Por 34/2544.
- <sup>61</sup> "Novartis Corporate Citizenship Guideline 4 (Human Rights)", available at [www.novartisfoundation.com](http://www.novartisfoundation.com).
- <sup>62</sup> A view consistent with the interim report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations, see, for example, E/CN.4/2006/97, para. 61, last sentence. Generally, see Clapham, A., *Human Rights Obligations of Non-State Actors*, 2006.
- <sup>63</sup> CESCR, general comment 14.