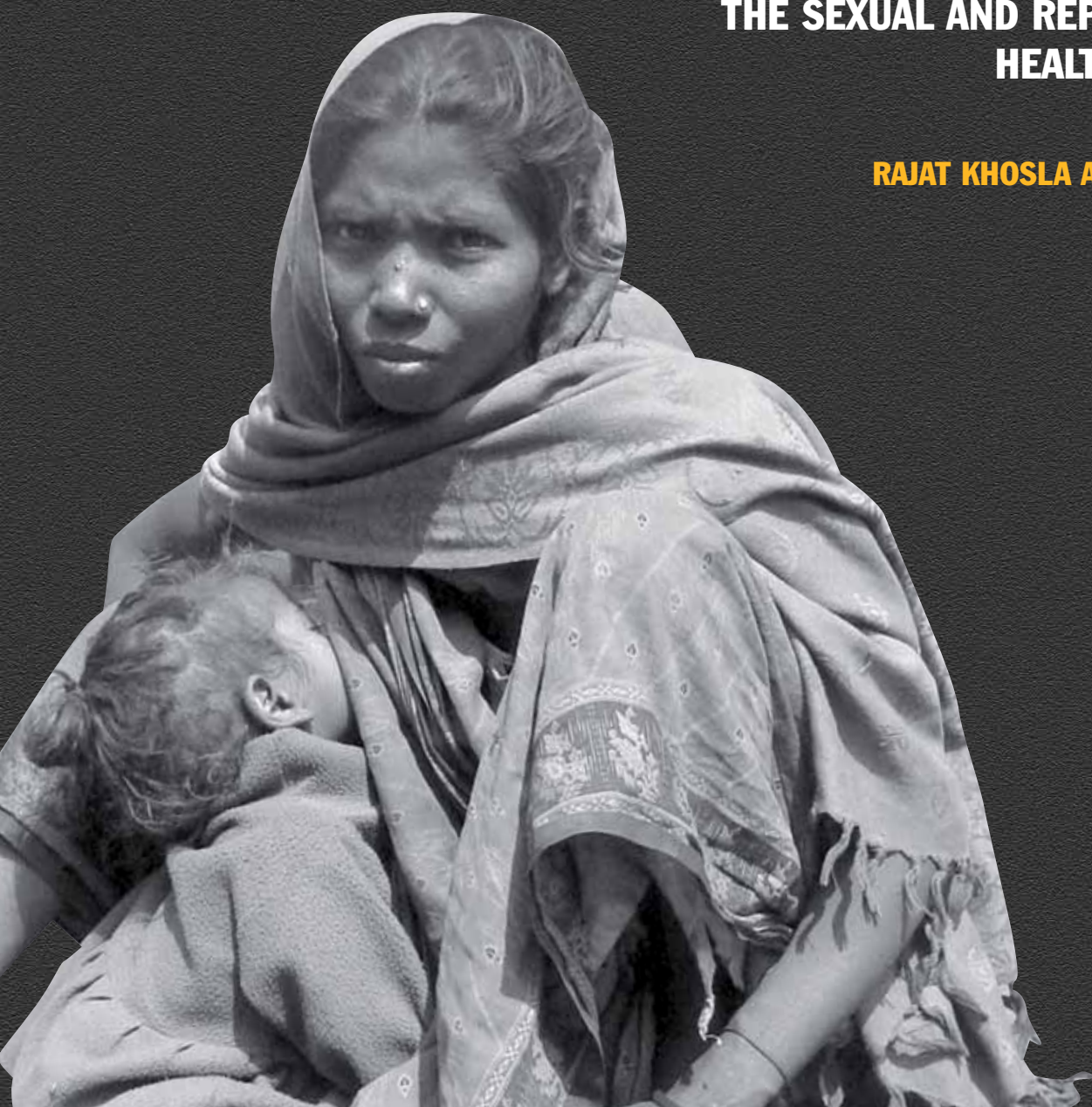


HUMAN RIGHTS CENTRE

**HUMAN RIGHTS GUIDELINES
FOR PHARMACEUTICAL
COMPANIES IN RELATION
TO ACCESS TO MEDICINES**

**THE SEXUAL AND REPRODUCTIVE
HEALTH CONTEXT**

RAJAT KHOSLA AND PAUL HUNT



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Cover photograph © 2008 Gautam Pandey, Courtesy of Photoshare. A mother and her child wait outside a vaccination center at a primary health center on the outskirts of Delhi, India.

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INTRODUCTION

Almost 2 billion people lack access to essential medicines.¹ This deprivation causes immense and avoidable suffering: ill health, pain, fear, loss of dignity and life.² Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia.³ Besides deprivation, gross inequity in access to medicines remains the overriding feature of the world pharmaceutical situation.⁴ 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. The World Health Organisation (WHO) estimates that 15 per cent of the world's population consumes over 90 per cent of the world's production of pharmaceuticals.⁵

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.

Millennium Development Goals (MDGs), including those connected to sexual and reproductive health 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 MDG targets is to provide, "in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries."⁶ Crucially, implementation of the right to the highest attainable standard of health can help to achieve the sexual and reproductive health-related Goals.

Medical care in the event of sickness, as well as the prevention, treatment and control of diseases, are central features of the right of everyone to the enjoyment of the highest attainable standard of physical and health (in short, the "right to the highest attainable standard of health" or "right to health").⁷

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 United Nations (UN) Commission

on Human Rights, confirm that access to essential medicines is a fundamental element of the right to health.⁸ 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.

In 2002, the Commission on Human Rights, which was at that time the principal political body dealing specifically with human rights in the UN system, decided to appoint a Special Rapporteur to focus on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. A Special Rapporteur is an independent expert appointed to monitor, examine and report on either a particular human rights issue or the human rights situation in a particular country or territory.

In 2002, the Commission on Human Rights appointed Paul Hunt, a New Zealand national, as Special Rapporteur for a period of three years. In 2005, the Special Rapporteur's mandate was extended by a further three years. The mandate of the Special Rapporteur is set out in Commission on Human Rights resolutions on the right to health, in particular resolution 2002/31 establishing the mandate. The Special Rapporteur is required to submit annually a report to the Human Rights Council and an interim report to the General Assembly, detailing the activities performed under his mandate.

During his tenure as the Special Rapporteur on the right to the highest attainable standard of health (2002-2008), Paul Hunt regularly analysed the issue of access to medicines as a component of the right to the highest attainable standard of health. One focus of this work was the responsibilities of pharmaceutical companies in relation to the right to health. This briefing is closely based on the report on this subject that the Special Rapporteur submitted to the UN General Assembly in 2008. The report observes that a consensus is starting to emerge that business enterprises, like all actors in society, have



Photograph © 2005 Nilayan Dutta/Drik India, Courtesy of Photoshare. A patient waits at the medication counter to receive her free medicine at a makeshift clinic in Gosaba, Sundarban, India. The doctor visits the clinic once a week with a mobile boat dispensary and provides treatment, x-rays, and other pathological tests at a very low price that poor rural residents can afford.

“Trying to run sexual and reproductive health programmes without contraceptives... and other reproductive health commodities is like trying to eradicate smallpox without vaccines. It simply cannot be done.” Steven Sinding, Director-General International Planned Parenthood Federation, 2003

some legal and ethical human rights responsibilities.⁹ The *application* of human rights may vary from one type of actor to another. For example, a State may be required to implement a human right in one way (e.g. enact laws) and a non-State actor in another way (e.g. reduce prices for those living in poverty). But, the logic of human rights will inevitably lead to their application, in one form or another, to non-State actors.

This briefing examines the issue of access to medicines in the context of sexual and reproductive health. Sexual and reproductive health are key elements of the right to the highest attainable standard of health. The briefing considers the responsibilities of pharmaceutical companies for enhancing access to medicines. The briefing also introduces the background and content of the *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines* (“the Guidelines”). Based on the right to health responsibilities of pharmaceutical companies, the Guidelines provide a framework for enhancing access to medicines.

I. MEDICINES AND SEXUAL AND REPRODUCTIVE HEALTH

Ensuring the rights to sexual and reproductive health is central to achieving the MDGs.¹⁰ Sexual and reproductive ill-health constitutes a significant proportion of the disease burden in developing countries. However a majority of the population in these countries often does not have access to essential sexual and reproductive health medicines.¹¹ According to WHO, it is estimated that 201 million couples are at risk of unintended pregnancy. These are couples who would like to space or limit their births, but are not using modern methods of contraception to do so.¹² A lack of access to medicines needed to maintain sexual and reproductive health threatens the well-being of individuals, families, and communities.

According to WHO, unsafe sex is the second most important risk factor leading to disability, disease or death in developing countries and the ninth most important in

developed countries.¹³ Many of these problems can be significantly reduced if sexual and reproductive health medicines are available, accessible, of good quality, and properly used. However, access to contraceptives, medicines for preventing and treating sexually transmitted infections (STIs), and drugs to support a healthy pregnancy and safe delivery, requires an integrated approach, involving governments and the corporate sector.

In this briefing paper we will examine the role of the pharmaceutical industry in ensuring access to medicines generally and in particular for sexual and reproductive health. Before examining the responsibilities of the pharmaceutical industry, the briefing examines the relationship between two specific sexual and reproductive health problems, HIV/AIDS and the human papillomavirus, and access to medicines.

Box 1: The rights to sexual and reproductive health

Sexual and reproductive health are vital elements of the right to the highest attainable standard of health. Sexual health is a state of physical, emotional, mental and social well-being related to sexuality, not merely the absence of disease, dysfunction or infirmity (E/CN.4/2004/49). Reproductive health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes (Program of Action of the International Conference on Population and Development, Cairo, 1994). Many elements of sexuality are non-reproductive: while

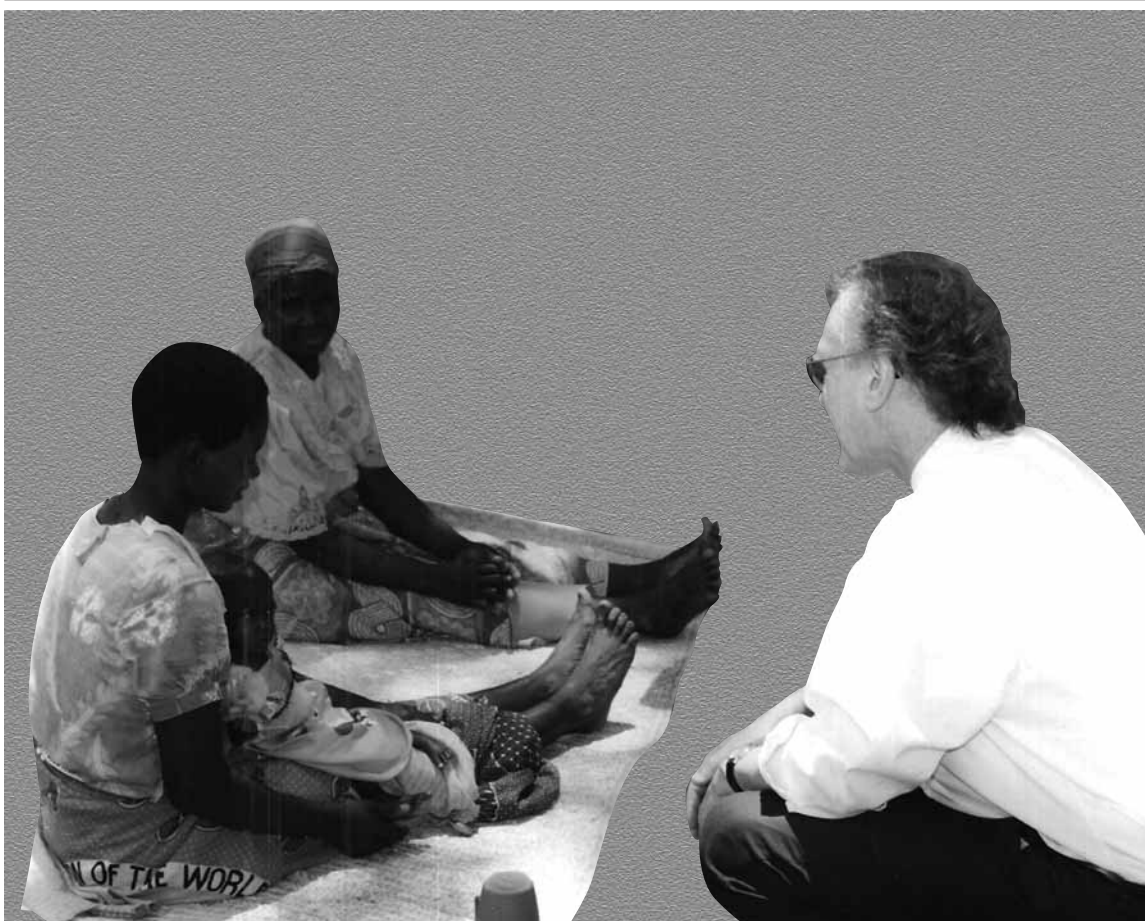
sexual and reproductive health are closely linked, they are therefore also distinct. At the International Conference on Population and Development the international community recognised the importance of human rights, including the right to health, for guaranteeing sexual and reproductive health, both as a goal in its own right and as a strategy for poverty reduction. Not only have the rights to sexual and reproductive health, and other related human rights, often guided relevant policies and programmes, but also legal protections in international and domestic laws have been used to protect against, and provide redress for, violations of these human rights.

A: HIV/AIDS AND MEDICINES

There is a strong link between HIV/AIDS and sexual and reproductive health.¹⁴ The large majority of HIV infections are transmitted through unprotected sex or associated with pregnancy, childbirth and breastfeeding. In addition, sexual and reproductive ill-health and HIV/AIDS share root causes, including poverty, gender inequality and social marginalization of the most vulnerable populations.¹⁵ The international community agrees that the MDGs will not be achieved without ensuring access to sexual and reproductive health services and an effective

global response to HIV/AIDS.

The availability of antiretroviral therapy (ART) has significantly reduced AIDS morbidity and mortality in developed countries. Yet in developing countries, where 95% of HIV positive people live, the overwhelming majority still does not have access to life-sustaining medication.¹⁶ According to recent estimates, ART coverage still remains low: only 31% of people estimated to be in need of treatment in low-income and middle-income countries were receiving it in 2007.¹⁷ It is also reported that only 11



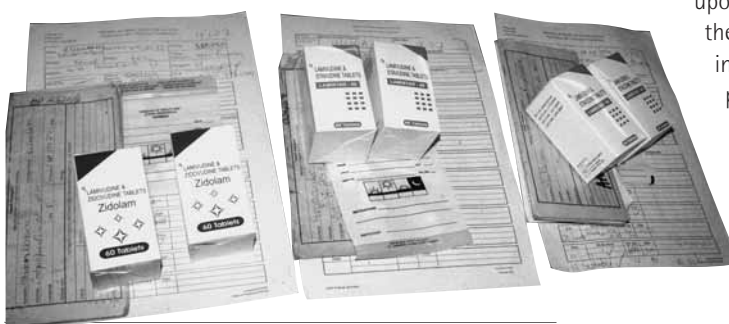
Photograph © 2004 Samuel Makaka, Courtesy of Photoshare. HIV-positive babies are visited by United Nations representatives at a rural clinic in Malawi, as part of a UN envoy on HIV/AIDS. Many people in Malawi are persuaded by the fact that when you go for voluntary testing and you are found HIV positive, you are automatically put on free ARVs. Only 9,000 people at the time of this visit were on free ARVs.

percent of HIV pregnant women have access to interventions designed to prevent mother-to-child transmission (MTCT).¹⁸ MTCT is almost entirely preventable, provided services are available and accessible. However in many low-income and middle-income countries the coverage levels are very low.¹⁹ Long and short courses of single, dual or triple antiretroviral prophylaxis have been shown to reduce HIV transmission to infants. Short courses of antiretroviral drugs, started in late pregnancy or during labour, reduce the risk of in utero and peripartum HIV transmission two- to three-fold and are used in many countries.²⁰

The UN Committee on Economic, Social and Cultural Rights, International Guidelines on HIV/AIDS and Human Rights, as well as other international human rights bodies

and instruments, recognise the right to medical treatment, including access to medicines.²¹ However, the enforcement of these rights is not evident in the current global situation, where often entire populations, particularly the poor and underprivileged, have little or no access to even essential medicines.²²

The establishment of the Global Fund to Fight AIDS, Tuberculosis, and Malaria, as well as the World Bank Multi-Country HIV/AIDS Program, have provided developing countries with valuable resources and incentives to improve their procurement of, and management systems for, medicines. However, despite widespread global attention, scaling up effective medical care for people living with HIV/AIDS (PLWHA) continues to pose a massive challenge. Enhancing access to HIV/AIDS treatment can only be done by addressing the underlying issues that impact upon access in the first place. Addressing these issues require an integrated approach involving a number of sectors, including the pharmaceutical industry. The social contract demands pharmaceutical companies take creative, wide-ranging steps to increase access to medicines.²³ The Guidelines in section III highlight some of the measures that, 'if systematically implemented', would enhance access to medicines.



Photograph © 2005 Alfredo L. Fort, Courtesy of Photoshare. Packages of antiretroviral drugs sit on a table, waiting to be dispensed to AIDS patients in Katutura Hospital, Windhoek, Namibia.

Box 2: Accelerating Access Initiative (AAI)

In May 2000, a partnership of five international organisations (UNAIDS Secretariat, WHO, UNICEF, UNFPA and the World Bank) and seven research and development-based pharmaceutical companies (Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, F. Hoffmann-La Roche and Merck & Co., Inc.) was launched to accelerate access to care and treatment for HIV/AIDS. AAI is designed to improve access to more affordable HIV medicines and diagnostics for least-developed countries and others hardest hit by

the pandemic in the context of a broader framework of care, treatment and support.

AAI aims to increase sustained access to appropriate, good quality interventions (including antiretrovirals therapy) through new alliances involving committed governments, industry, the UN agencies, development organisations, NGOs and people living with HIV/AIDS.

More information on AAI can be found at www.gsk.com/responsibility/cr_report_2004/la_aids.htm

B: HUMAN PAPILLOMAVIRUS AND MEDICINES

Human papillomavirus (HPV) is responsible for 99.7% of cervical cancers. HPV is primarily spread through sexual contact²⁴ and is associated with a wide-range of diseases, including genital warts and many forms of cancer in addition to cervical cancer. HPV is one of the most common sexually transmitted diseases.

Cervical cancer and precancerous cervical lesions constitute a major problem for women's health. Every year 470,000 cases of cervical cancer are diagnosed worldwide, and about half the women afflicted will die from the disease.²⁵ The incidence of cervical cancer differs between regions, particularly between high-income and low-income countries.²⁶ Almost 80 percent of cases occur in low-income countries, where cervical cancer is the most common. In Western Europe, some 30,000 new cases per year are diagnosed and about 15,000 deaths are recorded.²⁷ In sub-Saharan Africa and Latin America

types 16 and 18, which are two high-risk types of HPV, account for 65 percent of invasive cancers.²⁸

HIV-infected individuals are at higher risk of HPV infection and are infected by a broader range of HPV types.²⁹ According to a recent study nearly 40% of HIV-infected women had an HPV infection.³⁰ Simultaneous infection with multiple HPV genotypes is more common in HIV-infected women than in non-HIV infected women. HIV-infected men and women are also at increased risk of HPV associated anal cancer.³¹

Cervical cancer is a gender-specific disease that disproportionately affects women in the lowest socioeconomic groups throughout the world. Widespread vaccination has the potential to reduce cervical cancer deaths around the world by as much as two-thirds.³²

In 2006, the U.S. Food and Drug Administration (FDA)

Pharmaceutical companies manufacturing the vaccines... should develop culturally appropriate information packages to avoid a negative reaction against the vaccination

Box 3: Essential sexual and reproductive health medicines and supplies

UNFPA and WHO have agreed a list of drugs and commodities to be procured for key needs in the area of sexual and reproductive health. This includes:

- A full range of contraceptives (such as hormonal methods, intrauterine devices, barrier methods, and subdermal implants).
- Maternal and neonatal healthcare commodities (anesthetics, analgesics, antibacterials, anticonvulsants, antiseptics/disinfectants, oxytocics, vaccines, and vitamins, among others, including equipment for emergency obstetric care).
- Reproductive tract infection commodities

(diagnostic tests and first-line drugs).

- HIV prevention commodities (male and female condoms and drugs to prevent mother-to-child transmission).
- General equipment and supplies for providing primary and secondary healthcare (sterilizing equipment, lighting, anesthetics and their equipment and supplies, oxygen, postoperative medication, operating theater equipment, ward equipment, drugs for gastric acidosis, muscle relaxation, and anaphylaxis, and cholinesterase inhibitors).

Source: UNFPA and WHO 2003.

approved Gardasil, a vaccine that prevents persistent infection with HPV types 16 and 18, which cause most (70 percent) cervical cancers worldwide, and types 6 and 11, which cause virtually all (90 percent) genital warts.³³ Another vaccine that recently received FDA approval is Cervarix which is produced by GlaxoSmithKline (GSK). Cervarix also protects against persistent infection with HPV types 16 and 18.

Currently, the vaccinations are very costly and thus unaffordable to many millions in low-income and middle-income countries. In order to prevent widening the access gap, strong public-private partnerships need to be forged. States, the United Nations Population Fund (UNFPA), WHO, global alliances such as the Global Alliance for Vaccines and Immunisations (GAVI) and pharmaceutical companies can play an important role in ensuring access to vaccination to all those in need.

Further, there are severe misconceptions about HPV and the vaccinations. Misconceptions are grounded in moral, religious, political, economic, and socio-cultural arguments. For instance it is argued that the vaccine increases sexual risk-taking, sends mixed messages about abstaining from sexual intercourse and usurps parental authority.³⁴ Pharmaceutical companies manufacturing the vaccines, such as Merck (Gardasil) and GSK (Cervarix), should develop culturally appropriate information packages to avoid a negative reaction against the vaccination. Critically, if access it to be enhanced, prices must come down.

The Guidelines in section III of this briefing provide guidance for ensuring the availability and accessibility of vaccinations for immunisation against serious sexual and reproductive health problems, such as HPV.



II. HUMAN RIGHTS GUIDELINES FOR PHARMACEUTICAL COMPANIES IN RELATION TO ACCESS TO MEDICINES: BACKGROUND AND CONTEXT

States have primary responsibility for enhancing access to medicines. Between 2002-2008, the Special Rapporteur regularly scrutinised States' duties in relation to access to medicines. For example, these duties are the main focus of a chapter on the human right to medicines in one of his reports to the General Assembly (see *Box 4*) and are a key theme during several of his country missions, including to Uganda and Peru and reports on

these missions.³⁵ Another report looks at States' duties in relation to access to medicines and the World Trade Organisation.³⁶ Some of his press statements have focussed on States' duties in relation to access to medicines.³⁷ Also, some of his other publications have examined States' duties in relation to access to medicines, such as *Neglected diseases: A human rights analysis*.³⁸

Box 4: The responsibilities of States to ensure that medicines are available, accessible, culturally acceptable and of good quality

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. Historically, research and development has not addressed the priority health needs of low-income and middle-income 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. States therefore are required to resort to a variety of economic, financial and commercial incentives in order to influence research and development into specific health needs.

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.

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 they are 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. 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.

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.

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.

Source: Report of the UN Special Rapporteur on the right to the highest attainable standard of health (A/61/338)

On numerous occasions over the last six years, Ministers, senior public officials and others have informed the Special Rapporteur that, when endeavouring to implement the right to the highest attainable standard of health, States encounter many obstacles. Among the obstacles they have mentioned, two stand out. First, the policies and practices of donor countries; for this reason, the Special Rapporteur has looked, on numerous occasions in several reports, at the role of donors, most recently in his report on Sweden as a donor.³⁹

Second, Ministers, senior public officials and others have argued that the policies and practices of some pharmaceutical companies constitute obstacles to States' implementation of the right to the highest attainable standard of health and, in particular, their endeavours to enhance access to medicines. They have mentioned, for example, excessively high prices, inadequate attention to research and development concerning diseases that disproportionately impact people in developing countries, inappropriate drug promotion, and problematic clinical trials. Ministers and senior public officials have also acknowledged, however, that the pharmaceutical sector has an indispensable role to play in relation to the right

to health and access to medicines. Moreover, they have recognised the constructive contribution of specific pharmaceutical companies.

The Special Rapporteur's mandate expressly requires him to identify, *inter alia*, obstacles to the implementation of the right to the highest attainable standard of health. He is also expressly mandated to report on good practices, and to make recommendations, that will help to promote and protect the right to the highest attainable standard of health.

Although States have primary responsibility for ensuring both the right to the highest attainable standard of health and enhancing access to medicines, this is a shared responsibility. If access to medicines is to be enhanced, numerous national and international actors have an indispensable role to play. The Millennium Development Goals recognise that pharmaceutical companies are among those sharing 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).

A: BACKGROUND AND DRAFTING HISTORY

Between 2003–2006, the Special Rapporteur engaged in many discussions on access to medicines with numerous parties, including pharmaceutical companies. These substantive discussions took place at symposia and workshops, as well as informal visits to pharmaceutical companies. They were informed by the work of States, pharmaceutical companies (and their associations, such as the International Federation of Pharmaceutical Manufacturers and Associations), United Nations Global Compact, Office of the High Commissioner for Human Rights (OHCHR), WHO and other elements of the United Nations system, Business Leaders Initiative on Human Rights, numerous civil society organisations, and others. More recently, the Special Rapporteur has benefited from the reports of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises.

During these numerous discussions, the human rights duties of States in relation to access to medicines were reasonably clear, and these duties are now explored, in considerable detail, in the Special Rapporteur's various reports.⁴⁰ However, it became apparent during these discussions that the nature and scope of pharmaceutical companies' human rights responsibilities in relation to access to medicines were not clear. The United Nations Committee on Economic, Social and Cultural Rights, for example, confirms that the private business sector has responsibilities regarding the realisation of the right to the highest attainable standard of health, but it has not taken further steps to specify these responsibilities.⁴¹ While the Committee's general statement of principle is

very important, it provides no practical guidance about the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

It became imperative, therefore, to address this situation. How can pharmaceutical companies sensibly be asked to respect their human rights responsibilities in relation to access to medicines without much more specific guidance, as well as the identification of good practices? How can they be monitored, and held to account, if their human rights responsibilities in relation to access to medicines are unclear?

In an effort to shape a collaborative approach aimed at addressing these questions, a series of substantive meetings with a number of major pharmaceutical companies, and civil society groups, was organised by the Special Rapporteur and Mary Robinson, President of Realizing Rights: Ethical Globalization Initiative and former UN High Commissioner for Human Rights. The result of these discussions was a two-phase proposal suggesting a way forward. This proposal was discussed at length with the companies involved and revised to accommodate a number of their concerns.

First, it was suggested that a small group of human rights experts, and representatives from pharmaceutical companies, work together to identify as much common ground as possible, as well as good faith disagreements, in relation to pharmaceutical companies' human rights responsibilities and access to medicines. It was proposed that this process would take two years and would generate an important, useful report that clarified what can

properly be asked of pharmaceutical companies in relation to access to medicines and human rights.

The second part of the proposal outlined a process through which a small group of experts would then be appointed, by consensus among those participating in the initiative, to use this report to evaluate the policies and practices of certain pharmaceutical companies. These evaluations would be made public. This second phase would last for an initial period of three years.

The hallmark of this two-phase, five-year proposal was constructive cooperation and collaboration with a number of major pharmaceutical companies.

To their credit, two companies, Novartis and NovoNordisk, were willing to proceed with the proposal. Unfortunately, however, the majority of companies involved in the initiative were unwilling to go-ahead. Reluctantly, the Special Rapporteur and Mrs Robinson decided that buy-in from only two companies was insufficient for what was designed to be a collaborative initiative engaging a range of major pharmaceutical companies. It was agreed that there was no choice, unfortunately, other than to put the proposal aside.

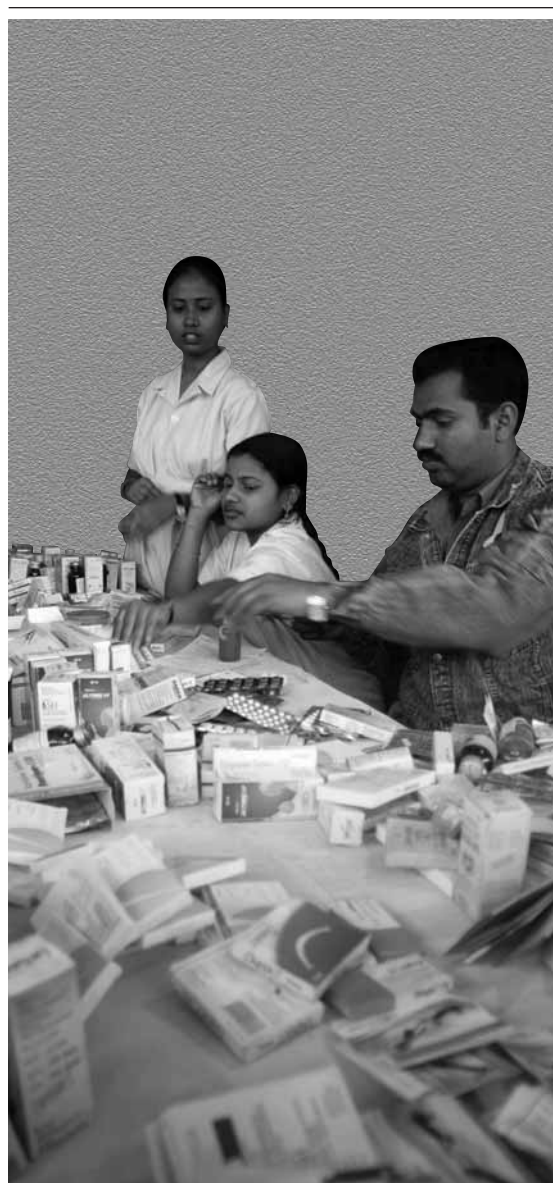
The regrettable refusal of some pharmaceutical companies to engage in this collaborative project did not diminish the need to pursue the central objective. Given that some States allege that the practices of some pharmaceutical companies are obstacles to access to medicines, the urgent need remained for greater clarity regarding the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

Of course, the long-term goal is the development of internationally recognised human rights guidelines for both States and pharmaceutical companies in relation to access to medicines. However, there is greater clarity about the human rights responsibilities of States than there is about the responsibilities of pharmaceutical companies regarding access to medicines. As already observed, several reports of the Special Rapporteur explore the access to medicines responsibilities of States. Indeed, one report applies the right-to-health analytical framework and sets out in detail the numerous human rights responsibilities of States in relation to access to medicines.⁴² There is no comparable human rights guidance for pharmaceutical companies in relation to access to medicines. In these circumstances, the Special Rapporteur's priority focus was on human rights guidelines for pharmaceutical companies in relation to access to medicines.

Thus, as signalled in his 2006 report to the General Assembly,⁴³ the Special Rapporteur embarked on a process of preparing, for consultation, draft human rights guidelines for pharmaceutical companies in relation to access to medicines. This process drew heavily upon the extensive discussions with pharmaceutical companies and others that had taken place between 2003–2006. There were additional consultations, too. In 2007, for example, the University of Toronto organised a multi-stakeholder workshop, attended by pharmaceutical companies.

This process led to the publication of draft *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* in September 2007. The draft was available for public comment until 31 December 2007; to allow as much consultation as possible, this deadline was postponed until 31 March and again until 15 May 2008. To facilitate consultation, the draft was placed on the websites of the Office of the High Commissioner for Human Rights, as well as the Human Rights Centre, University of Essex. The draft was also posted on numerous other websites, too.

Since September 2007, the Special Rapporteur actively sought comments on the draft. In October, the Government of Brazil held an open consultation, attended by States, in the main UN building in New York. There were two consultations with a number of major institutional investors; one consultation took place in New York, the other in London. The draft was discussed with WHO and, on two occasions, with the International Federation



Photograph © 2007 Gopal Bhattacharjee, Courtesy of Photoshare. Health workers distribute free medicine to the pilgrims of "Gangasagar" (where the Ganges River meets the Bay of Bengal) in a temporary camp at Kolkata, India. Every year millions of pilgrims from all over India take shelter here on the way to the "Gangasagar holy bath".

of Pharmaceutical Manufacturers and Associations. Other non-governmental organisations were also consulted.

Unfortunately, when the Special Rapporteur approached some pharmaceutical companies to meet and discuss the draft all declined, with the honourable exception of NovoNordisk. A few companies sent helpful written comments on the draft. Some forty stakeholders sent written comments, all of which were placed on the web, with a small handful of exceptions where confidentiality was requested.

B: THE GUIDELINES

The draft Guidelines of September 2007 were extensively revised in light of the very numerous written and oral comments. The final version of the Guidelines is in the next section of this briefing. Beginning with a Preamble, the Guidelines are grouped by themes, such as transparency, management, monitoring and accountability, pricing and ethical marketing. Each theme is followed by a brief Commentary.

The Guidelines should be read with the Special Rapporteur's report to the General Assembly on access to medicines.⁴⁴ This report includes a section on the responsibilities of States and another on the responsibilities of pharmaceutical companies. This discussion and analysis will not be repeated here. Instead, some inter-related points are briefly emphasised.

Health systems

At the heart of the right to the highest attainable standard of health lies an effective and integrated health system, encompassing medical care and the underlying determinants of health, which is responsive to national and local priorities, and accessible to all. Medical care and access to medicines are vital elements of an effective, integrated, responsive and accessible health system. Crucially, their full realisation depends upon such a

In summary, extensive written and oral comments on the draft were received from a very wide range of stakeholders encompassing States, institutional investors, pharmaceutical companies, specialised agencies, national human rights institutions, non-governmental organisations, academics and others.

When the Special Rapporteur informed the General Assembly in October 2006 that he intended to prepare draft guidelines, he was encouraged to proceed with this challenging project.

system being in place. In many countries, however, health systems are failing and collapsing (see the Special Rapporteur's report A/HRC/7/11). There are, in many countries, extremely grave systemic obstacles to enhancing access to medicines, such as clinics without health workers and the most basic facilities. While immediate steps can be taken by a range of actors to enhance access to medicines, it is imperative that systemic obstacles are recognised and tackled as a matter of priority and urgency.

Enhancing shareholder value

Pharmaceutical companies operate in complex market and social settings that give rise to a range of responsibilities to various stakeholders. Of course, companies have a responsibility to enhance shareholder value. This responsibility has to be seen in the context of other social, developmental and human rights responsibilities, especially the pharmaceutical sector's central societal mission to develop high quality medicines that are accessible to those in need. Moreover, all pharmaceutical companies would find it beneficial to adopt a rights-sensitive approach to their businesses, as outlined in the excellent joint publication of the United Nations Global Compact, Business Leaders Initiative on Human Rights, and OHCHR.⁴⁵

Box 5: A business case for human rights

The 2004 Pharmaceutical Shareowners Group (PSG) recognised that there was a high level of consensus about the potential significance of the issue and the business case for a proactive response. The following drivers were recognised by the PSG:

- Defending the 'social contract' between governments and pharmaceutical companies, upon which intellectual property law and future innovation depends;
- Limiting the potential for emerging markets to opt out of international patent treaties;

- Protecting company reputation and license to operate with potential impacts on pricing power in the USA and other lucrative markets;
- Building political goodwill to help secure future markets;
- Improving stakeholders relations;
- Enhancing employee morale and recruitment prospects.

Source: PSG, *The Public Health Crisis in Emerging Markets*, September 2004.

Practical, constructive guidance

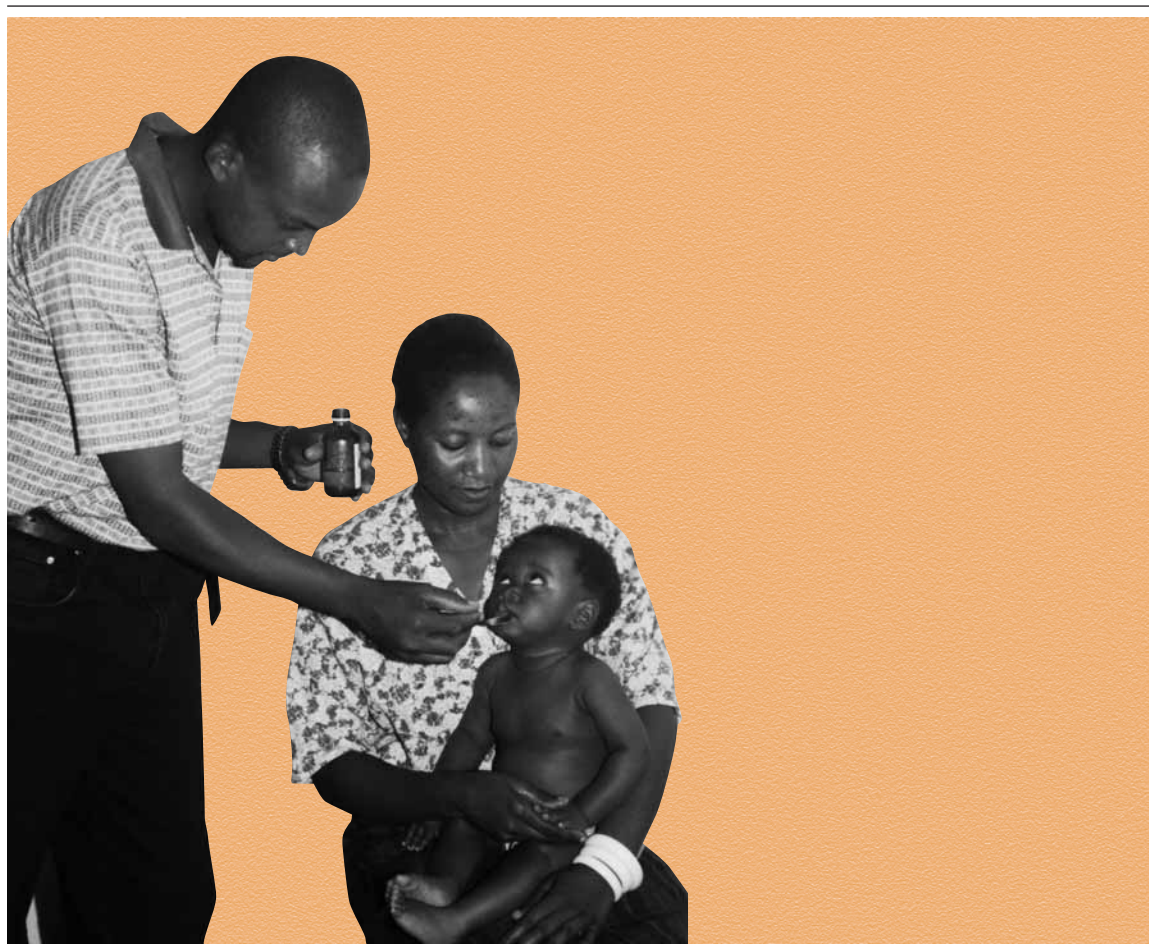
The Guidelines do not use the peremptory word “must”, but the more modest language “should”. In other words, they deliberately avoid some of the most controversial doctrinal questions (such as, “are businesses legally bound by international human rights law?”) that have dominated debates about business and human rights for many years. These discussions are important, and the Special Rapporteur has contributed to them elsewhere, but the

central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other interested parties, including those who wish to monitor companies and hold them to account.⁴⁶ The Guidelines are consistent with and complementary to the helpful analysis recently provided by the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises.

Box 6: Key human rights standards upon which the Guidelines are based

The Guidelines are based on human rights principles that are enshrined in the Universal Declaration of Human Rights (UDHR), including non-discrimination, equality, transparency, monitoring and accountability. The Guidelines are also informed by human rights, such as some features of the right to the highest attainable standard of health. As the Constitution of the World Health Organisation affirms, “enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being”. UDHR

lays the foundations for the international framework for this fundamental human right, now codified in numerous national constitutions, as well as international human rights treaties, including the Convention on the Rights of the Child and International Covenant on Economic, Social and Cultural Rights. The Guidelines also draw from other widely accepted standards, such as instruments on medicines adopted by the World Health Organisation in recent years.



Photograph © 1999 Luke Mwanza/CCP, Courtesy of Photoshare. A couple feeds their infant chloroquine syrup, an antimalarial drug used to treat and to prevent malaria.

III. HUMAN RIGHTS GUIDELINES FOR PHARMACEUTICAL COMPANIES IN RELATION TO ACCESS TO MEDICINES

PREAMBLE

- a. Almost two billion people lack access to essential medicines; improving access to existing medicines could save ten million lives each year, four million of them in Africa and South-East Asia.
- b. 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.
- c. One of the Millennium Development Goal targets is, "in cooperation with pharmaceutical companies, (to) provide access to affordable essential drugs in developing countries."
- d. Medical care and access to medicines are vital features of the right to the highest attainable standard of health.
- e. Access to medicines depends upon effective, integrated, responsive and accessible health systems. In many countries, health systems are failing and collapsing, constituting a grave obstacle to increasing access to medicines. While a range of actors can take immediate steps to increase access to medicines, health systems must be strengthened as a matter of priority and urgency.
- f. States have the primary responsibility for realising the right to the highest attainable standard of health and increasing access to medicines.
- g. In addition to States, numerous national and international actors share a responsibility to increase access to medicines.
- h. As confirmed by the United Nations Global Compact, the Special Representative of the Secretary General on Human Rights and Transnational Corporations and Other Business Enterprises, the Committee on Economic, Social and Cultural Rights, the Business Leaders Initiative on Human Rights, and many others, the private business sector has human rights responsibilities.
- i. Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines.
- j. Pharmaceutical companies also have other responsibilities, for example, a responsibility to enhance shareholder value.
- k. Pharmaceutical companies are subject to several forms of internal and external monitoring and accountability; however, these mechanisms do not usually monitor, and hold a company to account, in relation to its human rights responsibilities to enhance access to medicines.
- l. Pharmaceutical companies contribute in various ways to the realisation of the right to the highest attainable standard of health, such as providing individuals and communities with important information about public health issues. Enhancing access to medicines, however, has the central place in the societal mission of pharmaceutical companies. For this reason, these non-exhaustive, inter-related Guidelines focus on the human rights responsibilities of pharmaceutical companies in relation to access to medicines.
- m. Pharmaceutical companies' human rights responsibilities are not confined to the right to the highest attainable standard of health. They have human rights responsibilities, for example, regarding freedom of association and conditions of work. These human rights responsibilities, however, are not addressed in these Guidelines.
- n. While most of the Guidelines address issues that are highly relevant to all pharmaceutical companies, including innovator, generic and biotechnology companies, a few of the Guidelines address issues of particular relevance to some companies within the pharmaceutical sector.
- o. These Guidelines apply to pharmaceutical companies and their subsidiaries.

- p. These Guidelines are based on human rights principles enshrined in the Universal Declaration of Human Rights, including non-discrimination, equality, transparency, monitoring and accountability. The Constitution of the World Health Organisation affirms that the "enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". This fundamental human right is codified in numerous national constitutions, as well as international human rights treaties, including the Convention on the Rights of the Child and International Covenant on Economic, Social and Cultural Rights. Accordingly, these Guidelines are informed by some features of the right to the highest attainable standard of health, such as the requirement that medicines are of good quality, safe and efficacious. The Guidelines also draw from other widely accepted standards, such as instruments on medicines adopted by the World Health Organisation.
- q. For the purposes of these Guidelines, medicines include active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other related healthcare technologies.
- r. For the purposes of these Guidelines, neglected diseases are defined as those diseases primarily affecting those living in poverty, especially in rural areas, in low-income countries. Sometimes called tropical or poverty-related diseases, they include, for example, leishmaniasis (kala-azar), onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis (bilharzias), lymphatic filariasis, African trypanosomiasis (sleeping sickness) and dengue. Although in recent years HIV/AIDS, tuberculosis and malaria have attracted increasing attention and resources, they may also be regarded as neglected diseases.
- s. These Guidelines adopt the World Bank definition of low-income, middle-income and high-income countries.

GENERAL

- 1 The company should adopt a human rights policy statement which expressly recognises the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company.
- 2 The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company.
- 3 The company should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled.
- 4 The company should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.

Commentary

Formal, express recognition of the importance of human rights, and the right to the highest attainable standard of health, helps to establish a firm foundation for the company's policies and activities on access to medicines (Guideline 1). Such recognition, however, is not enough: operationalisation is the challenge (Guideline 2). Many of the Guidelines signal ways in which right-to-health considerations can be operationalised and integrated into the company's activities. There are numerous national and international (including regional) legal provisions that safeguard aspects of the right to the highest attainable standard of health. It is axiomatic that they must be respected, at all times, by all pharmaceutical companies, in accordance with elementary principles of corporate good governance (Guidelines 3-4).

DISADVANTAGED INDIVIDUALS, COMMUNITIES AND POPULATIONS

- 5 Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should give particular attention to the needs of disadvantaged individuals, communities and populations, such as children, the elderly and those living in poverty. The company should also give particular attention to the very poorest in all markets, as well as gender-related issues.



Photograph © 2007 Requel Legaspino/AHP/ACS, Courtesy of Photoshare. Children smile after receiving vitamins and other medications from their doctors during a medical mission conducted by the Adventist Health Professionals in Buruun, Iligan City, Philippines.

Commentary

Equality and non-discrimination are among the most fundamental features of international human rights, including the right to the highest attainable standards of health. They are akin to the crucial health concept of equity. Equality, non-discrimination and equity have a social justice component. Accordingly, the right to the highest attainable standard of health has a particular pre-occupation with disadvantaged individuals, communities and populations, including children, the elderly and those living in poverty. Like equity, the right-to-health also requires that particular attention be given to gender. All the other Guidelines must be interpreted and applied in the light of Guideline 5, which has fundamental importance.

TRANSPARENCY

- 6 In relation to access to medicines, the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines. This presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data collected during clinical trials.
- 7 In conjunction with other pharmaceutical companies, the company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time.
- 8 Either alone or in conjunction with others, the company should establish an independent body to consider disputes that may arise regarding the disclosure or otherwise of information relating to access to medicines. This body may be the monitoring and accountability mechanism referred to in Guideline 14.

Commentary

Transparency is another cardinal principle of international human rights, including the right to the highest attainable standard of health. It is not possible to properly understand and meaningfully evaluate access to medicines policies and practices without the disclosure of key information. There is a presumption in favour of disclosure, which may be rebutted on limited grounds (Guideline 6). Commonsense confirms that the principle of transparency not only requires that information be made publicly available, it also requires the information be made publicly available in a form that is accessible, manageable and useful (Guideline 7). An independent, trusted and informal body should be established to consider any disputes that may arise about whether or not a particular piece of information relating to access to medicines should be disclosed (Guideline 8). This body should also provide guidance on the legitimate grounds of non-disclosure. While Guidelines 6-8 have general application to access to medicines, other Guidelines apply the cardinal principle of transparency in specific contexts, such as public policy influence, advocacy and lobbying (Guidelines 17-19).

MANAGEMENT, MONITORING AND ACCOUNTABILITY

- 9 The company should encourage and facilitate multi-stakeholder engagement in the formulation of its policies, programmes, projects and other activities that bear upon access to medicines. In keeping with Guideline 5, this engagement should include the active and informed participation of disadvantaged individuals, communities and populations.
- 10 The company should have a publicly available policy on access to medicines setting out general and specific objectives, time frames, reporting procedures, and lines of accountability.
- 11 The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines policy.
- 12 The company should have clear management systems, including quantitative targets, to implement and monitor its access to medicines policy.
- 13 The company should publish a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the company's policies, programmes, projects and other activities that bear upon access to medicines.
- 14 In the context of access to medicines, internal monitoring and accountability mechanisms have a vital role to play, but they should also be supplemented by a mechanism that is independent of the company. Until such a mechanism is established by others, the company should establish an effective, transparent, accessible and independent monitoring and accountability mechanism that:
 - i. assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations;
 - ii. monitors, and holds the company to account in relation to, these Guidelines.

Commentary

All human rights, including the right to the highest attainable standard of health, require effective, transparent and accessible monitoring and accountability mechanisms. The mechanisms have a variety of forms; usually a mix of mechanisms is required. While some mechanisms are internal, others are external and independent; both types are needed. Guidelines 9-13 address the issue of internal corporate monitoring and accountability regarding access to medicines. Guideline 14 addresses the issue of an external, independent monitoring and accountability mechanism regarding access to medicines.

CORRUPTION

- 15 A company should publicly adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.
- 16 In collaboration with States, the company should take all reasonable measures to address counterfeiting.

Commentary

Corruption is a major obstacle to the enjoyment of the right to the highest attainable standard of health, including access to medicines. Those living in poverty, for example, are disproportionately harmed by corruption because they

Corruption is a major obstacle to the enjoyment of the right to the highest attainable standard of health, including access to medicines



are less able to pay for private alternatives where corruption has depleted public health services. Numerous features of the right to the highest attainable standard of health, such as transparency, monitoring and accountability, help to establish an environment in which corruption can neither thrive nor survive. In short, a right-to-health policy is also an anti-corruption policy. As emphasised in the Preamble, improving access to medicines is a responsibility shared by numerous national and international actors; Guideline 16 provides one specific example of this shared responsibility in relation to counterfeiting.⁴⁷

PUBLIC POLICY INFLUENCE, ADVOCACY AND LOBBYING

- 17** The company should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact upon access to medicines.
- 18** The company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional and international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.
- 19** When providing any financial or other support, the company should require all recipients to publicly disclose such support on all appropriate occasions.

Commentary

Like many other businesses, pharmaceutical companies devote considerable resources to advocacy, lobbying and related activities. While some of these activities may impact positively on access to medicines, for example, lobbying to lower taxes on medicines, other activities may impact negatively. Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8). Guidelines 17-19 apply this general principle of transparency to the specific context of public policy influence, advocacy and lobbying.

QUALITY

- 20** The company should manufacture medicines that comply with current World Health Organisation Good Manufacturing Practice Guidelines, as well as other appropriate international regulatory requirements for quality, safety and efficacy.

Commentary

Guideline 20 reflects the elementary right-to-health requirement that all medicines must be of good quality, safe and efficacious.

CLINICAL TRIALS

- 21** A company's clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent. This is especially vital in those States with weak regulatory frameworks.
- 22** The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, as well as the World Health Organisation Guidelines for Good Clinical Practice.

Commentary

The right to the highest standard of health encompasses medical ethics. Guidelines 21-22 emphasise the right-to-health responsibility of pharmaceutical companies to observe the leading international standards on ethics and clinical trials. Guidelines 9-14 emphasise the importance of effective, transparent and accessible monitoring and accountability mechanisms; these mechanisms should monitor, and hold to account, pharmaceutical companies in relation to their policies and practices on clinical trials.

Photograph © 2005
Emily J. Phillips,
Courtesy of Photoshare.

A young Afghan mother of 15 receives a vaccination with her child in Ghor Province, Afghanistan. Immunizations are vital for preventing the spread of disease among the millions of Afghans that live in rural areas where the health facilities are basic mud and brick buildings with few medical staff.



NEGLECTED DISEASES

- 23 The company should make a public commitment to contribute to research and development for neglected diseases. Also, it should either provide in-house research and development for neglected diseases, or support external research and development for neglected diseases, or both. In any event, it should publicly disclose how much it contributes to and invests in research and development for neglected diseases.
- 24 The company should consult widely with the World Health Organisation, WHO/TDR⁴⁸ and other relevant organisations, including leading civil society groups, with a view to enhancing its contribution to research and development for neglected diseases.
- 25 The company should engage constructively with key international and other initiatives that are searching for new, sustainable and effective approaches to accelerate and enhance research and development for neglected diseases.

Commentary

By providing an incentive for pharmaceutical companies to invest in research and development, the intellectual property regime makes a major contribution to the discovery of new medicines that save lives and reduce suffering. Where there is no economically viable market, however, the incentive is inadequate and the regime fails to generate significant innovation. For this reason, a different approach is needed to address the vitally important right-to-health challenge of neglected or poverty-related diseases. Defined in the Preamble, neglected diseases mainly afflict the poorest people in the poorest countries. The record shows that research and development has not addressed key priority health needs of low-income and middle-income countries. More specifically, research and development has given insufficient attention to neglected diseases. There is evidence, however, that some pharmaceutical companies are taking active measures to reverse this trend.⁴⁹ The right to the highest attainable standard of health not only requires that existing medicines are accessible, but also that much-needed new medicines are developed as soon as possible. Neglected diseases demand special attention because they tend to afflict the most disadvantaged (Guideline 5). Guideline 23 does not make the unreasonable demand that all companies provide in-house research and development for neglected diseases. Rather, all companies should make some contribution towards research and development for neglected diseases. Guidelines 23-25 signal other steps that companies should take to address the historic neglect of poverty-related diseases.

PATENTS AND LICENSING

- 26 The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing.
- 27 The company should respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) that recognises a State's right to protect public health and promote access to medicines for all.
- 28 The company should not impede those States that wish to implement the World Trade Organisation Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003) by issuing compulsory licences for exports to those countries, without manufacturing capacity, encompassed by the Decision.
- 29 Given that some least-developed countries are exempt from World Trade Organization rules requiring the granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.
- 30 As part of its access to medicines policy, the company should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines. The licences, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy set out in Guideline 20. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.
- 31 As a minimum, the company should consent to National Drug Regulatory Authorities using test data (i.e. the company should waive test data exclusivity) in least-developed countries and also when a compulsory licence is issued in a middle-income country.
- 32 In low-income and middle-income countries, the company should not apply for patents for insignificant or trivial modifications of existing medicines.

Commentary

The preceding Commentary recognises the major contribution made by the intellectual property regime to the discovery of life-saving medicines. Crucially, this regime contains various 'flexibilities' and other features that are designed to protect and promote access to existing medicines. Carefully constructed, they were agreed, after protracted negotiations, by the world community of States. Because they protect and promote access to existing medicines, which is a key component of the right to the highest attainable standard of health, these 'flexibilities' and other features should not be limited, diminished or compromised. Some of the key 'flexibilities' and other features are addressed in Guidelines 26-29. In brief, pharmaceutical companies should not seek to limit, diminish or compromise the 'flexibilities' and other features of the intellectual property regime that are designed to protect and promote access to existing medicines. Voluntary licences have a vital role to play in extending access to medicines (Guideline 30). Consistent with a company's responsibility to enhance shareholder value, commercial voluntary licences are designed to generate revenue for the patent holder. The terms of the licences should include appropriate safeguards, for example, relating to the quality, safety and efficacy of the product. Non-exclusive licences are more likely to extend access than exclusive licences. Voluntary licences respect, and depend upon, the intellectual property regime. Because data exclusivity has the potential to hinder access to medicines, companies should waive such exclusivity in all appropriate cases; while Guideline 31 identifies two occasions when the company should waive data exclusivity, there will be other occasions when a waiver is appropriate as a way of enhancing access to medicines for disadvantaged individuals, communities and populations. Access to medicines may be hindered when a company applies for a patent for improvements to an existing medicine; Guideline 32 is designed to mitigate this problem in low-income and middle-income countries.

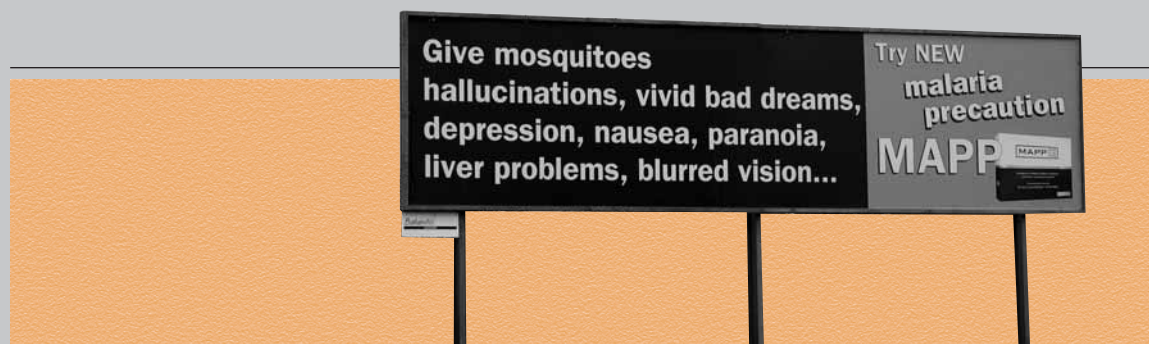
PRICING, DISCOUNTING AND DONATIONS

- 33 When formulating and implementing its access to medicines policy, the company should consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible. In keeping with Guideline 5, the company should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and the very poorest in all markets. The arrangements should include, for example, differential pricing between countries, differential pricing within countries, commercial voluntary licences, not-for-profit voluntary licences, donation programmes, and Public Private Partnerships.
- 34 The arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country. The same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country.
- 35 The arrangements should extend to all medicines manufactured by the company, including those for non-communicable conditions, such as heart disease and diabetes.
- 36 The company should have a board-approved policy that fully conforms to the current World Health Organisation Guidelines for Drug Donations.
- 37 The company should ensure that its discount and donation schemes and their delivery channels are:
- i. as simple as possible e.g. the schemes should place the minimum administrative burden on the beneficiary health system;
 - ii. as inclusive as possible e.g. the schemes should not be confined to delivery channels that, in practice, exclude disadvantaged individuals and communities.
- 38 The company should disclose:
- i. as much information as possible about its pricing and discounting arrangements;
 - ii. the absolute quantity and value of its drug donations; 50
 - iii. where possible, the number of beneficiary patients treated each year;
 - iv. the amount of any tax benefit arising from its donations.

Commentary

While recognising they have a responsibility to enhance shareholder value, companies also have a human rights responsibility to extend access to medicines for all, including disadvantaged individuals, communities and populations (Guideline 5). In this context, pricing has a critical role to play. Lower prices do not necessarily mean lower profits. Sometimes the goal of enhancing access to medicines coincides with commercial interests. There are numerous arrangements that may reduce prices and increase sales, some of which are mentioned in Guidelines 33 and 34. Because the lives and health of millions are at stake, companies must approach such arrangements with urgency, creativity and boldness. They cannot act alone: here is another example of the shared responsibility emphasised in the Preamble. Inventive arrangements should neither be confined to a company's 'flagship' products nor a narrow range of communicable diseases (Guideline 35). Although unsustainable in the long-term, a carefully constructed donation programme may extend access (Guidelines 36–37). Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6–8); Guideline 38 applies this general principle of transparency to the specific context of pricing, discounting and donations.

Photograph © 2007 Lee Mantini, Courtesy of Photoshare. A billboard in Botswana uses humor to advertise a new anti-malaria medication.



ETHICAL PROMOTION AND MARKETING

- 39 The company should take effective measures to ensure that all information bearing upon the safety, efficacy, and possible side effects of a medicine are easily accessible to individuals so they can take informed decisions about its possible use.
- 40 The company should have a board-approved code of conduct and policy that fully conforms to the current World Health Organisation Criteria for Medicinal Drug Promotion. In the context of this code and policy, the board should receive regular reports on its promotion and marketing activities.
- 41 The company should publicly disclose its promotional and marketing policies and activities, including costs.

Commentary

Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6–8); Guidelines 39–41 apply this general principle of transparency to the specific context of ethical promotion and marketing. Promotion and marketing give rise to a wide-range of access to medicines issues, such as advertising to health professionals and the general public, packaging and labelling, and information for patients. Based on ethical considerations, the World Health Organisation Criteria for Medicinal Drug Promotion provides authoritative guidance on these important matters (Guideline 40).

PUBLIC PRIVATE PARTNERSHIPS

- 42 When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.
- 43 If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.
- 44 So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of Public Private Partnerships, they shall apply equally to such Partnerships.
- 45 A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these Guidelines.

Commentary

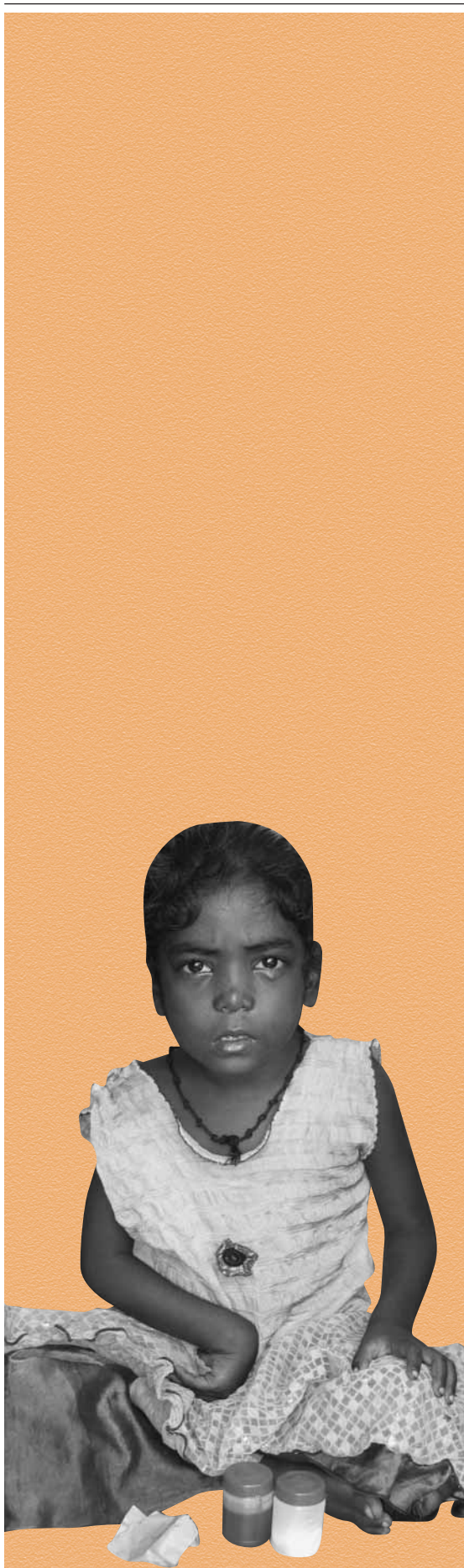
Public Private Partnerships can make an important contribution to enhancing access to medicines. They are subject to right-to-health considerations corresponding to those set out in these Guidelines. Where conflicts of interest may arise, disclosure is important, consistent with the human rights requirements of transparency.

ASSOCIATIONS OF PHARMACEUTICAL COMPANIES

- 46 So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of associations of pharmaceutical companies, they shall apply equally to all such associations. The Guidelines on lobbying (Guidelines 17 and 26) and financial support (Guideline 18), for example, shall apply equally to all associations of pharmaceutical companies.
- 47 A company that is a member of an association of pharmaceutical companies should take all reasonable steps to ensure the association fully conforms to these Guidelines.

Commentary

A company has a responsibility to ensure that its professional associations are respectful of the right-to-health considerations set out in these Guidelines, otherwise a company could use an association as a way of avoiding its human rights responsibilities.



Photograph © 2005 Galia Barkai, Courtesy of Photoshare. An Indian child, affected by the Tsunami in a fishermen's village near Madras, India receives medication from an Indian-Israeli medical volunteer team.

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- 44 Ibid.
- 45 "A Guide for Integrating Human Rights into Business Management" available at <http://www.blihr.org/>.
- 46 "(I)t is inconceivable that some human rights do not place legal obligations on business enterprises", A/61/338, paragraph 93.
- 47 Counterfeit drugs (medicines) are defined by the World Health Organisation in *FAQ's on Counterfeit Drugs*, 2008.
- 48 UNICEF, UNDP, World Bank, World Health Organisation Special Programme for Research and Training in Tropical Diseases.
- 49 Moran, M., et al., *The New Landscape of Neglected Disease Drug Development*, The Wellcome Trust, 2005.
- 50 'Value' as defined in Guideline 11, World Health Organisation Guidelines for Drug Donations.

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