

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.

* Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health (UN document: A/63/263, dated 11 August 2008).

- 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.**

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 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.¹

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

¹ Counterfeit drugs (medicines) are defined by the World Health Organisation in *FAQ's on Counterfeit Drugs*, 2008.

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.

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/TDR² 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.**

² UNICEF, UNDP, World Bank, World Health Organisation Special Programme for Research and Training in Tropical 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.³ 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.**

³ Moran. M and others, *The New Landscape of Neglected Disease Drug Development*, The Wellcome Trust, 2005.

- 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;⁴**

⁴ 'Value' as defined in Guideline 11, World Health Organisation Guidelines for Drug Donations.

- 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.

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.
