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Draft for Consultation

Comments by 31 December 2007 to rkhosl@essex.ac.uk

Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines[*]

Prepared by the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health

Introductory Note

A. Almost 2 billion people lack access to essential medicines. Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South-East Asia. Access to medicines is characterised by profound global inequity. 15% of the world's population consumes over 90% of the world's pharmaceuticals.

B. The 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. One of the Millennium Development Goal targets is to provide, in cooperation with pharmaceutical companies, access to affordable essential drugs in developing countries.

C. The Constitution of the World Health Organisation (WHO) affirms that the highest attainable standard of health is a fundamental right of every human being. The Universal Declaration of Human Rights lays the foundations for the international framework for the right to the highest attainable standard of health. This human right is now codified in numerous national constitutions, as well as legally binding international human rights treaties, such as the International Covenant on Economic, Social and Cultural Rights and the Convention on the Rights of the Child.

D. Medical care and access to medicines are vital features of the right to the highest attainable standard of health.

E. States have primary responsibility for enhancing access to medicines. While on country mission, the Special Rapportour routinely questions Governments about their national medicines policies, research and development for neglected diseases, anti-counterfeiting measures, and so on. Most of his report to the United Nations General Assembly, on the human right to medicines, is devoted to the

[*] Medicines include active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other healthcare technologies.

responsibilities of States.[1] However, since his appointment in 2002, many States have emphasised the profound impact - positive and negative - of pharmaceutical companies on the ability of governments to realise the right to the highest attainable standard of health for individuals within their jurisdictions.

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

G. Accordingly, the Special Rapporteur has engaged in many substantive discussions on access to medicines with numerous parties, including pharmaceutical companies. These discussions have been informed by the work of States, pharmaceutical companies, United Nations Global Compact, Office of the High Commissioner for Human Rights, WHO, Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, Business Leaders Initiative on Human Rights, civil society organisations and others. These discussions – and this work - have shaped these draft Guidelines. The Special Rapporteur is especially grateful to Realizing Rights: Ethical Globalization Initiative and the Access to Medicine Foundation.

H. In 2000, the United Nations Committee on Economic, Social and Cultural Rights confirmed that the private business sector has responsibilities regarding the realisation of the right to the highest attainable standard of health.[2] While this general statement of principle is important, it provides no practical guidance to pharmaceutical companies and others. The present draft draws upon the growing jurisprudence on the right to the highest attainable standard of health and sets out human rights Guidelines for pharmaceutical companies in relation to access to medicines. In this way, the Guidelines aim to help pharmaceutical companies enhance their contribution to these vital human rights issues. Additionally, the Guidelines will assist those who wish to monitor the human rights performance of the pharmaceutical sector in relation to access to medicines.

I. The right to the highest attainable standard of health is complex and extensive. In recent years, it has been analysed by courts, the United Nations Committee on Economic, Social and Cultural Rights as well as other international human rights treaty-bodies, WHO, civil society organisations, academics and others, with a view to making it easier for States, and others, to apply in practice. The key elements of this right-to-health analysis may be briefly summarised as follows:[3]

[1] 13 September 2006, A/61/338.
[2] General Comment No.14, paragraph 42.
[3] The various reports of the Special Rapporteur on the right to the highest attainable standard of health set out, and apply, this right-to-health analysis in considerable detail e.g. in relation to mental disability E/CN.4/2005/51, 11 February 2005.

i. Identification of the relevant national and international human rights laws, norms and standards.
ii. Recognition that the right to health is subject to resource constraints and progressive realisation, requiring the identification of indicators and benchmarks to measure progress (or the lack of it) over time.
iii. Nonetheless, recognition that some obligations arising from the right to health are subject to neither resource constraints nor progressive realisation, but are of immediate effect e.g. the obligation to avoid de jure and de facto discrimination.
iv. Recognition that the right to health includes freedoms (e.g. freedom from non-consensual treatment and non-consensual participation in clinical trials) and entitlements (e.g. to a system of health care and protection). For the most part, freedoms do not have budgetary implications, while entitlements do.
v. All health services, goods and facilities shall be available, accessible, acceptable, of good quality and safe. Accessible has a number of dimensions, such as affordable (i.e. financially accessible) and transparent (i.e. accessible health-related information).
vi. States have duties to respect, protect and fulfil the right to the highest attainable standard of health.
vii. Because of their crucial importance, the analytical framework demands that special attention is given to issues of non-discrimination, equality and vulnerability.
viii. The right to health requires that there is an opportunity for the active and informed participation of individuals and communities in decision-making that bears upon their health.
ix. Developing countries have a responsibility to seek international assistance and cooperation, while developed States have some responsibilities towards the realisation of the right to health in developing countries.
x. The right to health requires that there are effective, transparent and accessible monitoring and accountability mechanisms available at the national and international levels.

J. While this analysis has been developed keeping in mind the responsibilities of States, many of its elements are also instructive in relation to the responsibilities of non-State actors, including pharmaceutical companies. For example, the element requiring that health services shall be accessible bears upon the policies of both States and non-State actors, as does the requirement that there should be effective monitoring and accountability mechanisms. The following draft Guidelines are grouped into overlapping categories; at the beginning of each group, there is a brief italicised commentary signalling some of the elements of the right-to-health analysis that are especially relevant to that category.

K. Importantly, the present Guidelines remain a draft. Comments on this draft are invited and should be sent as soon as possible - and before 31 December 2007 – to Rajat Khosla at rkhosl@essex.ac.uk.

General

Formal recognition of human rights, and the right to the highest attainable standard of health, resonates with I.i (see above) and provides an important foundation upon which the company's activities can be constructed (Guideline 1). Formal recognition, however, is not enough: operationalisation is the challenge (Guideline 2). Many of the following Guidelines suggest ways in which human rights considerations can be operationalised or integrated into the company's activities. Despite its limitations, the Global Compact remains the leading United Nations human rights initiative for the private sector and companies should participate in it (Guideline 3). The right to the highest attainable standard of health has a particular pre-occupation with disadvantaged individuals and communities, women, children and those living in poverty (Guideline 6(i)-(iv)). It also demands access to information, transparency and as much participation as possible (Guideline 6(v)-(vi)).

1. The company's corporate mission statement should expressly recognise 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 join the United Nations Global Compact.

4. 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.

5. 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.

6. Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should:

    (i) give particular attention to disadvantaged individuals and communities, such as those living in poverty;

    (ii) give particular attention to gender-related issues;

    (iii) give particular attention to the needs of children;

    (iv) give particular attention to the very poorest in all markets;

(v) be transparent;

(vi) encourage and facilitate the participation of all stakeholders, including disadvantaged individuals and communities.

Management

Human rights, including the right to the highest attainable standard of health, require effective, transparent and accessible monitoring and accountability mechanisms, otherwise they can become little more than window-dressing (see I.x above). The mechanisms come in various forms. Usually, a mix of mechanisms will be required. While some mechanisms are internal, others are external and independent. Both types of mechanisms are needed. Guidelines 7-11 address the issue of internal corporate monitoring and accountability. They should be read with Guidelines 47-48 which addresses the issue of an external, independent monitoring and accountability mechanism. Guideline 10 reflects the importance that human rights attach to participation.

7. The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines strategy.

8. The company should have a public global policy on access to medicines that sets out general and specific objectives, time frames, who is responsible for what, and reporting procedures.

9. The company should have clear management systems, including quantitative targets, to implement and monitor its access to medicines strategy.

10. The company should have mechanisms that encourage and facilitate stakeholder engagement and participation in the formulation, implementation and management of its medicines strategy.

11. The company should produce a comprehensive, public, annual report, including qualitative and quantitative information, enabling an assessment of the company's strategies, policies, programmes, projects and other activities that bear upon access to medicines.

Public policy influence, advocacy and lobbying

Transparency is a cardinal human rights principle upon which several other human rights considerations depend, such as participation, monitoring and accountability. In the right-to-health analysis, this principle is reflected in the requirement that as much health-related information as possible should be made accessible (see I.v above). The Guidelines in this category reflect these right-to-health issues in the context of pharmaceutical company advocacy and lobbying.

12. The company and its subsidiaries should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact on access to medicines.

13. 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.

14. The company board should give prior approval to all lobbying positions (guideline 12) and financial support (guideline 13). The board should also receive reports on such lobbying positions and financial support. The requirement of prior approval by, and reporting to, the board is subject to the nature and scale of the activity. Where the relationship between the activity and access to medicines is significant, or likely to be significant, there should be prior approval by, and reporting to, the board.

Research and development for neglected diseases

The record confirms that research and development has not addressed the priority health needs of low-income and middle-income countries. More specifically, health research and development has given insufficient attention to neglected diseases that mainly afflict the poorest people in the poorest countries, although there is evidence that some pharmaceutical companies are taking active measures to reverse this trend.[4] The right to the highest attainable standard of health not only requires that existing medicines are accessible without discrimination, but also that much-needed new medicines are developed and thereby become available to those who need them (see I.v above). From the perspective of the right to the highest attainable standard of health, neglected diseases demand special attention because they tend to afflict the most disadvantaged and vulnerable (see I.vii above).

15. The company should make a public commitment to contribute to research and development for neglected diseases.

16. The company should consult widely with WHO, WHO/TDR,[5] Drugs for Neglected Diseases Initiative and other relevant organisations with a view to enhancing its contribution to research and development for neglected diseases.

17. The company should either provide in-house research and development for neglected diseases; or support external research and development for neglected

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

[5] UNICEF, UNDP, World Bank, WHO Special Programme for Research and Training in Tropical Diseases.

diseases; or both. In any event, it should disclose how much it invests in research and development for neglected diseases.

18. The company's contribution to research and development for neglected diseases should focus on formulations for low-income and middle-income country use and for all key affected patient groups, including especially disadvantaged individuals and communities.

Patents and licensing

The right to the highest attainable standard of health requires that medicines are available and accessible (see I.v above). Intellectual property rights impact upon the availability and accessibility of medicines; they attempt to strike a balance between the interests of various stakeholders, for example by establishing various 'flexibilities' within the TRIPS regime. Guidelines 19-26 aim to ensure that the features of intellectual property rights that protect the right to health of patients, the public and the most disadvantaged are recognised, respected and applied.

19. 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), 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 a public commitment not to lobby for more demanding protection of intellectual property interests than is required by TRIPS, such as additional limitations on compulsory licensing ('TRIPS-plus' standards). Also, the company should not, in practice, lobby for 'TRIPS-plus' standards.

20. The company should always respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health that recognises a State's right to protect public health and promote access to medicines for all.

21. The company should support States that wish to implement the WTO Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), and issue compulsory licenses for exports to developing countries without manufacturing capacity.

22. Given that some least-developed countries are exempt from granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.

23. The company should develop arrangements with other manufacturers for licenses and technology transfers to enhance access to medicines for HIV/AIDS, tuberculosis and malaria, as well as an increasing number of other treatments.

24. The company should have non-exclusive voluntary license agreements to increase access to medicines in low-income and middle-income countries; the terms of such agreements should be disclosed.

25. In low-income and middle-income countries, the company should consent to National Drug Regulatory Authorities using test data/override test data exclusivity for registration purposes.

26. The company should not extend patent duration, or file patents for new indications for existing medicines, in low-income and middle-income countries.

Quality and technology transfer

Guideline 27 (and Guideline 44) reflects the requirement arising from the right to the highest attainable standard of health that medicines are of good quality and safe (see I.v above). Guideline 28 reflects that those in a position to assist have a responsibility to take reasonable measures towards the realisation of the right to the highest attainable standard of health in developing countries (see I.ix above). This includes north-south and south-south assistance.

27. The company should manufacture medicines of the highest quality.

28. The company should enter into technology transfer agreements with local companies in low-income and middle-income countries.

Pricing, discounting and donations

These Guidelines mainly derive from the right to health requirement that medicines should be accessible, including financially accessible or affordable (see I.v above). Access extends to disadvantaged individuals and communities, including those living in poverty. Guideline 29(ii) reflects that the right to health takes into account resource availability within a country (see I.ii above). Regarding Guidelines 30-33, while unsustainable in the long-term, carefully targeted donations have a role to play in ensuring access, especially to those living in poverty and other disadvantaged individuals and communities in low-income countries (see I.v and vii above).

29. The company should ensure that its pricing and discount schemes:

    (i) conform to guidelines 6(i)-(vi);

    (ii) take into account a country's stage of economic development; prima facie, the price of a medicine in a low-income country should be less than the price of the same or equivalent medicine in a middle-income country, which should be less than the price of the same or equivalent medicine in a high-income country;

    (iii) progressively extend its differential pricing and discount schemes to all medicines; such arrangements must not be limited to the company's flagship products; they should

encompass non-communicable diseases, such as heart disease and diabetes.

30. The company should have a board-approved policy that fully conforms to the WHO's Guidelines for Drug Donations.

31. The company should disclose the absolute quantity and value of its drug donations.[6]

32. The company should disclose the amount of any tax benefit arising from its donations.

33. 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 restrictive delivery channels that, in practice, exclude disadvantaged individuals and communities.

Ethical promotion and marketing

As already observed, transparency is a cardinal human rights principle upon which several other human rights considerations depend, including monitoring and accountability (see commentary to Guidelines 12-14). In the right-to-health analysis, this principle is reflected in the requirement that as much health-related information as possible should be made accessible (see I.v above). Guidelines 34-35 reflect these right-to-health issues.

34. The company should take effective measures to ensure that all information bearing upon the safety, and possible side effects, of a medicine are easily accessible to individuals so they can take informed decisions about its possible use.

35. The company should have a board-approved code of conduct and policy that fully conforms to WHO's Ethical 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.

Clinical trials

The right to the highest attainable standard of health includes certain freedoms, such as freedom from non-consensual participation in clinical trials (see I.iv above).

[6] 'Value' as defined in Guideline 11 of WHO's Guidelines for Drug Donations.

Treatment must also be acceptable to the individuals and communities involved i.e. respectful of medical ethics, such as the requirements of informed consent (see I.v above).

36. A company's clinical trials should observe the highest ethical and human rights standards. This is especially vital in those States with weak regulatory frameworks.

37. The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects and the WHO Guidelines for Good Clinical Practice.

38. Additionally, when undertaking clinical trials, the company must respect the inherent dignity of the individual and all human rights principles, such as non-discrimination and equality.

Public Private Partnerships

While Public Private Partnerships make an important contribution to enhancing access to medicines, they are subject to human rights 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 and access to information (see I.v above).

39. When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.

40. If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.

41. 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.

42. A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these guidelines. If, despite warnings, a Partnership fails to conform to these guidelines, a participating company should withdraw from the Partnership.

Corruption

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 are disproportionately affected by corruption in the health sector because they are less able to pay for private alternatives where corruption has depleted public health services. Features of the right to health, such as participation, transparency, access to information, monitoring and accountability, help to establish an environment in

which corruption cannot survive. A right-to-health policy is also an anti-corruption policy.

43. A company should adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.

44. In collaboration with States, the company should take all reasonable measures to address counterfeiting.

Associations of pharmaceutical companies

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

45. 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 those associations. For example, the Guidelines on lobbying (Guidelines 12 and 19) and financial support (Guideline 13) shall apply equally to all associations of pharmaceutical companies.

46. 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. If, despite warnings, an association fails to conform to these guidelines, a member company should resign from the association.

Monitoring and accountability

Effective, transparent, accessible and independent monitoring and accountability mechanisms are an integral feature of human rights, including the right to the highest attainable standard of health (see I.x above). See the commentary accompanying Guidelines 7-11. Implementation of Guideline 11 will contribute to Guidelines 47-48.

47. 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. There should be 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 and communities;

    (ii) monitors, and holds the company to account in relation to, these Guidelines.

48. Where such a monitoring and accountability mechanism already exists, the company should fully cooperate with it. If it does not yet exist, the company should establish such a mechanism.

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