Robert Wiessman

17 September 2007

Confidential Draft

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 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 and regional human rights treaties.

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 and implementation plans. Most of his report to the United Nations General Assembly, on the human right to medicines, is devoted to the responsibilities of States (A/61/338). 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, United Nations Global Compact, Business Leaders Initiative on Human Rights, Office of the High Commissioner for Human Rights, WHO and other elements of the United Nations system, pharmaceutical companies, Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, civil society organisations and others. These discussions – and this work - have informed these draft Guidelines.

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 (General Comment No.14, paragraph 42). 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 assist pharmaceutical companies, as well as those monitoring their activities.

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:[1]

   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.

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[1] 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.

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 has 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 fourteen 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.

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 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 never take any steps that will or may encourage a State to act in a way that is inconsistent with its legal obligations, including those arising from national and international human rights law.

5. 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, including 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 as transparent as possible;

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

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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 monitoring and accountability 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 Guideline 46 which addresses the issue of an external, independent

monitoring and accountability mechanism. Guideline 10 reflects the importance that human rights attach to participation.

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

7. 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.

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

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

10. 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.

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

12. The company should annually disclose its financial support to key opinion leaders, patient associations, political parties, political candidates, issue campaigns (including but not limited to political referenda), trade associations, academic departments, research centres, and advocacy groups, or any other third parties by which the company seeks to influence, directly or indirectly, 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. Similar disclosures should be provided for direct company spending, or expenditures through contractors, to influence, directly or indirectly, public policy and national, regional, and international law and practice.

13. 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

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Deleted: *Human rights do not object to advocacy and lobbying by pharmaceutical companies, provided such activities are accompanied by full, contemporary (not historic) disclosure.*

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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 reflecting the global disease burden and 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 (also known as poverty-related or tropical 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. 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). In short, a balanced research and development programme that reflects the global disease burden and neglected diseases is a requirement arising from the right to the highest attainable standard of health. Guidelines 15-18 address both the global disease burden and neglected diseases, while Guidelines 19-20 give particular attention to neglected diseases. 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.

14. The company should make a public commitment to contribute to research and development that reflects both the global disease burden and neglected diseases.

15. In house, the company should invest in research and development for new treatments that reflect the global disease burden and neglected diseases.

16. The company should support external research initiatives that contribute to research and development for new treatments that reflect the global disease burden and neglected diseases.

17. The company should consult widely with WHO, WHO/TDR, DNDI and other relevant organisations with a view to enhancing its contribution to research and development for neglected diseases.

18. The company's investment in research and development for neglected diseases should be focussed on formulations for low-income and middle-income country use and for all key affected patient groups, including disadvantaged individuals and communities.

19. The company should undertake other activities (not covered by other guidelines) to support research and development for neglected diseases, including research into new treatments and improvement of formulations of existing medicines for low-income and middle-income countries.

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20. The company should study, develop and make available commercially marketable pediatric formulations of the medicines it markets that are used or needed by children.

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 21-28 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.

21. The company should respect the right of countries to use, to the full, the provisions in the TRIPS Agreement 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 or advocate for patent and related intellectual property standards more stringent than those required under the TRIPS Agreement ('TRIPS-plus' standards). Also, the company should not, in practice, urge countries to adopt 'TRIPS-plus' standards, or ask governments to encourage or pressure countries to adopt TRIPS-plus standards, including but not only via trade or investment agreements.

22. 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.

23. The company should support States that wish to exercise the flexibilities in the TRIPS Agreement and reiterated in the Doha Declaration on the TRIPS Agreement and Public Health (30 August 2003), including the issuance of compulsory licenses on grounds of their choosing.

24. Given that the WTO does not obligate member states that are least-developed countries to grant or enforce patents until 2016, the company should not lobby for such countries to grant or enforce patents, and the company should announce and implement a policy of not applying for or enforcing patents in least-developed countries.

Where the company holds a patent or patents on an important medicine, and the price of the medicine is a significant barrier preventing people in a country who need the medicine from accessing it, then the company should issue non-exclusive licenses on the patent(s). The licenses should contain a reasonable royalty, and be made available to any person or firm that seeks to manufacture, import, export, or sell the medicine. The terms of such agreements should be publicly disclosed.

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25. In developing countries, the company should authorize National Drug Regulatory Authorities and/or generic firms to use or rely on test data for registration purposes. If exclusivity provisions are in place, a company may seek reasonable compensation, based on its demonstrated testing costs, and pro-rated for a generic firm's market share for the medicine in question.

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

27. The company should rapidly register important medicines in every country.

28. The company should publicly disclose all patents it claims on medicines, listed by country, and the date on which the patent will expire. The company should also disclose all countries in which each of its products is registered, and the dates on which they were registered.

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Quality and technology transfer

Guidelines 29 and 30 reflect 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 31 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).

29. The company should manufacture drugs of the highest quality.

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

31. If domiciled in a high-income State, the company should enter into technology transfer agreements with local companies in developing countries.

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Pricing and discount schemes

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 32(ii) reflects that the right to health takes into account resource availability within a country (see I.ii above). Guideline 34 is important because product diversion can undermine pricing and discount schemes that are designed to ensure that those living in poverty have access to medicines.*

32. 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 extends its differential pricing and discount schemes to all important medicinessuch arrangements must not be limited to communicable diseases or other narrow disease categories; they should encompass non-communicable diseases, such as heart disease and diabetes;

33. The company should ensure that its discount 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.

Donations

While donations are not sustainable in the long-term, they 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).

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

35. The company should disclose the absolute volume and value of its drug donations, as well as the tax benefits obtained from those donations. Where possible, the company should also disclose the number of beneficiary patients treated per year.

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 37-38 reflect these right-to-health issues.

36. 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.

37. 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.

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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). 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).

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

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

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40. 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.

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Public Private Partnerships

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). 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.

41. If a company joins a Public Private Partnership:

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(i) the company should disclose any interest it has in the Partnership's decisions and activities;

(ii) the Partnership should be monitored for conformity with the relevant national and international human rights law and practice.

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.

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

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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.

43. 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 14 and 21) and financial support (guideline 15) shall apply equally to all associations of pharmaceutical companies.

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44. 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.

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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). Also, see the commentary accompanying Guidelines 7-11. Implementation of Guideline 11 will contribute to Guideline 46.

45. 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. Accordingly, the company should establish an effective, transparent, accessible and independent monitoring and accountability mechanism that:

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(i) assesses the impact of its 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.

Paul Hunt
UN Special Rapporteur on the right to the highest attainable standard of health

17 September 2007

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Page 7: [1] Comment **Rob Weissman** **09/07/1908 5:08 AM**

I don't recall if I commented on this point, or exactly how the discussion evolved. But the Paragraph 6 "solution" a) deals with a very particular circumstance only; b) was drafted so as to be very difficult to use; and c) is not necessary and can be avoided altogether through use of compulsory licenses issued to remedy anti-competitive practices. So, it is something of a distraction; and in any case, the much bigger political pressure is on importing countries, rather than exporters. I think a more important point, worth asserting on its own, is that countries should be free to issue CLs without interference. This would in any case include CLs issued under the paragraph six approach. As edited, this point is slightly redundant with the original number 21, but I think important distinct enough to merit its own assertion.

Page 7: [2] Comment **Rob Weissman** **09/07/1908 5:28 AM**

At the meeting, I raised a concern about not limiting this point to HIV, and perhaps about the use of "essential medicines." I'm now suggesting that it be deleted, because it is redundant with the following point.

Page 7: [3] Deleted **Rob Weissman** **20/09/2007 1:22 PM**

The company should develop arrangements with other manufacturers for licenses and technology transfers to make HIV medications and diagnostics, and an increasing number of other essential medicines, more affordable and accessible.

Page 7: [4] Deleted **Rob Weissman** **20/09/2007 1:31 PM**

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.