Specific comments from F&C Management Ltd. are included throughout the text and offset by bold, italics and underlining (10 March 2008).

19 September 2007

Draft for Consultation

Comments by 1 March 2008 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. ***This could also reference the growing inequity in developed countries.***

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 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.

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

[1] 13 September 2006, A/61/338.

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. ***[It is our understanding that a substantive dialogue with pharmaceutical companies was not realized. As this is a key component of building legitimacy for the Guidelines, we would recommend some more specific information about the depth of the consultation and interchange with the companies to whom this applies directly. One particular idea is to release a separate document that reflects the final changes that were made to these standards in order to demonstrate that the process was indeed responsive to outside critique. Such a document would help combat critical voices that allege that company views were not sufficiently included. We also note that in our experience consultation with industry bodies should be seen as an addition to – and not a substitute for – discussion with individual 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. ***[This is a key section, but it is rather buried within the introduction. We would recommend leading with this more readily.]*** In this way, the Guidelines aim to help pharmaceutical companies enhance their contribution to these vital human rights issues [***suggest adding the phrase: "without compromising their responsibilities to shareholders and within the context that it is primarily the responsibility of governments to set the framework within which companies operate"' [In our view, this assertion needs to be expanded and supported. It is a very important, fundamental argument the Guidelines make, yet it appears to be one that the pharmaceutical companies do not agree with. Additional explanation would be very helpful.]*** 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]

[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)).

[It should be clear whether the UN believes that an access to medicines strategy is obligatory at all companies. The shareholder perspective would be that it is necessary where it adds value to shareholders, but for some companies it will not be necessary and may destroy value. Civil society could, on the other hand, argue that all companies should give away as much as possible. Somehow the Guidelines need to reconcile these potentially contradictory positions, both of which are legitimate.]

1. The company's ***[This is an example of where defining what kinds of companies fall under the purview of the Guidelines would be very useful]***. corporate mission statement [add wording "or its equivalent"] 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 ***[suggested addition: "within a shareholder value framewor," as this is an important constraint for 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 ***["where appropriate". For example, if the project is building an office building in New York, is not likely to be appropriate].***

3. The company should join the United Nations Global Compact. ***[While this is a clear directive for action, it is unclear how the UNGC dovetails with the Guidelines or why pharmaceutical companies in particular should take this step?]***

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. ***[Suggest deleting this as it sounds like" a) setting the bar very low; and b) patronising. Alternatively, it could be expanded to encompass the principle of extra-territoriality (i.e. do abroad what you do at home), or specifically reference the framework of IP laws and the company's approach to them. In addition, such laws certainly include a duty to shareholders, which is absent from the Guidelines, but a powerful commercial reality***.]

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 ***[Suggest adding "and the intellectual property framework of the World Trade Organisation" (e.g. a local generics company lobbying its home government to break international patent law. In general, we found this particular action item to be somewhat accusatory and its evaluation would be so entirely subjective as to make it impractical. We recommend removing it or reconsidering its presentation.]***

6. Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines ***[This assertion is so broad that it makes implementation difficult. If the Guidelines apply to all kinds of disease management (e.g. heart disease, diabetes, cancer, etc), then we are unsure of what company actions aren't related to access to medicine?]*** 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, ***[We would suggest "lines of accountability"]*** 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. ***[The Guidelines should also recommend that companies strive to provide data that is comparable with peers so that stakeholders may judge relative performance against one another. This would likely require some cooperation among companies or with a trade association, but it is an important goal to move away from anecdotal and situational reporting to more systematic provision of data which is deeply needed.]***

[In general, this is a strong section with which F&C agrees.]

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 ***[F&C's policy is that all formal lobbying positions should be disclosed, irrespective of subject]*.**

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). ***[We do not believe that prior board level approval for all lobbying positions and all financial support or donations is reasonable or practical. We agree that the board should be involved in setting the overall political donations budget, and, ideally, that shareholders should vote to approve the total budget; and that companies should report retrospectively on how the budget was spent. However, recommendation for shareholder voting on a donations budget is more appropriate for a listing standard or corporate governance policy than for a UN policy on human right. We have attached F&C's governance policy statement on these matters for your consideration (attached). We support enhanced disclosure of lobbying positions, but we do not believe that the board should spend such time debating the relative merits of each lobbying positions related to every aspect of running the business, which would include positions related to financial regulation, employee management laws, accounting rules, etc***.]. 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.

[While we agree generally with points #12 and #13 of this section, we have concerns with the final point as described above. Moreover, the relative positioning of this section, so early in the document, comes across as hostile and mistrustful of the sector. This section would be better positioned toward the end of the Guidelines and connected with the section on Trade Associations.]

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* **[Does this mean that *all* drugs should be accessible, despite purchasing power? Is there an agreed-upon classification for life-saving drugs versus life-style drugs versus drugs that would be "nice to have" but are not essential?]**, *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. ***[F&C disagrees with this point as it is far-reaching and unrealistic. Companies should make such a commitment if it is in the interests of shareholders. Moreover, it would be***

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

impractical and inefficient to expect all companies to do this – starting up R&D from scratch in an area in which a company has no expertise is a waste of resources. We would suggest that governments need to incentivise and reward this behaviour in companies (e.g. by offering contracts or tax breaks to companies). This section could be re-worded to note that companies should respond to such initiatives considering their long-term shareholder interests and market positioning, not simply short-term returns.]

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 diseases; or both. In any event, it should disclose how much it invests in research and development for neglected diseases. ***[Does this include all small biotech and other health researchers such as hospital and university research programmes? Why are they excluded from this imperative as they are part of the drug development system? As per #15 above, this needs to be qualified and not universally applicable.]***

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. **[Clarifying accessibility is a very important point, particularly as it relates to countries with wide income disparity and a rapidly growing middle class.]** *(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* **[Suggest adding "in addition to respecting the legitimate rights to patents that enable companies to make financial returns that can be re-invested into their businesses."]**

[In general, we note that this section is extremely controversial, and requires governments to be responsible in their exercise of IP and TRIPS. We suggest that the responsibility of governments to understand the legitimate interests of companies and their shareholders is also referenced as part of the general context here].

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) ***[It seems extremely unrealistic to ask a company to not lobby on unknown proposals or changes related to a crucial industry standard. UN Guidelines would never ask advocacy organizations for a "blank cheque" promise not to lobby on a bread and butter issue, nor should it be asked of companies.]*** Also, the company should not, in practice, lobby for 'TRIPS-plus' standards.

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

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. ***[This lies beyond F&C's expertise to comment.]***

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. ***[It is unclear what the motivation behind this section is. of the general phrase "other treatments" seems like another potential "blank cheque". We believe a company should decide whether it wishes to manufacture itself or grant licenses to others to do so.]***

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. ***[As above, this seems too general and could be misinterpreted or misused. Specifically the reference to middle income countries gives concern, as that is where the debate becomes most complex and there is no one-size-fits-all solution. The Guidelines should not create broad obligations to participate in unsuitable mechanisms.]***

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. ***[There is a legitimate argument that bad practice in this area needs to be eliminated, but we find this point too sweeping to differentiate between legitimate extensions and bad practice. Is it the UN's position that all patent extensions are illegitimate? If so, that should be stated, but could not be supported by F&C.]***

[This is the most far-reaching and difficult section of the Guidelines. It is a long-list of unrealistic prohibitions rather than guidance for creative action or an analysis of constructive actions and practices a company could take. We also note that this is the section of the Guidelines that is most closely affected by existing legal frameworks, and would seek reassurance that the Guidelines have taken full regard of the legal position that governs companies' behavior.]

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. [***Does this mean on charitable terms? Automatic transfer of intellectual property may not be sensible in some markets.]***

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; ***[The price of a drug is not determined solely by the costs of manufacture – there are other inputs including tariffs, costs of transportation and storage, etc that might result in varied prices across markets. This area might provide an opportunity to discuss *disclosure* of pricing information rather than suggesting how prices should be set. Also, we suggest that this section should reference the MeTA project]***

    (iii) progressively extend its differential pricing and discount schemes to all medicines [***This is an enormous strategic ask of firms. What about companies making very high-end, targeted and expensive cancer drugs? What about firms making drugs that can enhance quality of life like allergy medicine, which are not life sustaining?];*** 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. ***[[This lies beyond F&C's expertise to comment.]***

31. The company should disclose the absolute quantity and value of its drug donations.[6] ***[We suggest that disclosure of value should be in a standardised format that allows for direct comparison across the sector.]***

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:

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

(i) as simple as possible e.g. the schemes should place the minimum administrative burden on the beneficiary health system; ***[While ensuring high quality and proper handling?]***

(ii) as inclusive as possible e.g. the schemes should not be confined to restrictive delivery channels ***[this seems like a very broad prohibition and entirely subjective]*** that, in practice, exclude disadvantaged individuals and communities.

We note that from this point on, the Guidelines become more generally about the behaviour and business conduct of pharmaceutical companies. We question whether it is appropriate to include these under the access to medicines banner, although we fully reognize the need to improve practices in many of these areas].

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.

[We suggest adding an additional point to refer to the principles of "clean data" as promoted by the Cochrane Collaboration. In other words, in both trials reporting and marketing data, data should be accurate, accessible and presented in a manner that is non-distortive. Distortions in the presentation of data has been a significant problem. In developed countries where direct-to-consumer advertising is common, particularly the US, it may be considered a barrier to access in the sense that the UN defines it – as it can lead to individuals making incorrect choices.]

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. ***[We agree completely that the board should be receiving regular reports, as this is a thorny set of strategic questions and part of proper risk management.]***

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).

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. ***[It is unclear how this latter point is substantively different from item #36 above.]***

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. ***[It is unclear how this point is different from #39 above?]***

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.

[These Guidelines periodically refer to Board oversight, but why not in this section?]

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.

[This is a very important section, and we support its aims. Such considerations about corruption are often left out of corporate responsibility guidance materials.]

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. ***[This seems overly directive. It may be that a trade association is excellent on other more relevant issues to the company. The Guidelines often verge on assuming that access to medicines is the *only* relevant issue that a company faces, which is unrealistic.]***

[We would suggest that this section be combined or appear in sequence with the section on political lobbying, as the trade associations play a very influential role in lobbying. We agree that there are important standards of good practice and transparency related to trade associations. We also agree with the supposition that companies must take more responsibility for their trade associations and not rely on them to conduct lobbying as a way to achieve unpopular ends without responsibility for the individual companies. We would suggest that this section would be more effective if it focused on processes to evaluate trade associations' positions and company disclosure related to trade associations rather than telling companies which associations they should not belong to.]

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: ***[In our view, a company should monitor its own programs and perhaps have the data verified or seek independent auditing for particular aspects of the program as a way to ensure proper internal control.]***

    (i) assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals and communities ***[Why especially to this group? Who else would access to medicine programmes be for?];***

    (ii) monitors, and holds the company to account in relation to, these Guidelines. ***[We are not entirely sure what kind of auditor is intended? Auditors and monitors don't usually "hold a company to account". They merely investigate facts and make a public report.]***

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.

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

19 September 2007

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