Comments on the draft dated 19 September 2007

Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

South African Human Rights Commission (14/1/2008)

For Attention: The United Nations Special Rapporteur
Paul Hunt
By e-mail: rkhosl@essex.ac.uk
No. of pages: this cover page + 12 page annexure

Dear Sirs/ Mesdames

Submission from the South African Human Rights Commission ("SAHRC") on the United Nations Draft Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines

We refer to the draft Guidelines above and the correspondence between our Ms Jesseman and your Mr Khosla.

We have enclosed under cover hereof our submission to the United Nations Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental, on the draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

The SAHRC is compelled to make this submission in light of the impact of the actions of private actors, and specifically corporate actors, upon the fulfillment of human rights as entrenched in the Constitution of the Republic of South Africa, Act 108 of 1996. The SAHRC recognizes the importance of engaging with the corporate sector as community stakeholders, further evidenced by the establishment of the Human Rights and Business Special Programme.

The SAHRC trusts that its submission is in order, we thank you for this opportunity to contribute and participate in the process, and we look forward to any future engagement.

Yours faithfully

Jody Kollapen

Chairperson, South African Human Rights Commission

Introduction

The South African Human Rights Commission (hereinafter “”the SAHRC”) is pleased to participate in the process of considering and commenting on the United Nations (hereinafter “the UN”) draft Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (hereinafter “the Guidelines”), and commends the UN Special Rapporteur on the product and the processes thus far.

The Guidelines present an opportunity to consider the role of private actors in the pharmaceutical industry in facilitating access to medicines and thereby playing a role in the realisation of the right to the highest attainable standard of health. Moreover, this process provides pharmaceutical companies with an opportunity to engage with other role players in the health care sector in interrogating the challenges faced in facilitating access to medicines and, particularly, in stating the role that they currently play as well as shaping the role which they hope to play. This is surely reflected by their own aspirations as corporate citizens and community stakeholders, and dictated by their national and international legislative obligations and their Constitutional rights and obligations in a South Africa specific context.

As the SAHRC has consistently stated, we recognise that corporations are powerful and influential actors within national an international legal and economic paradigms. They exert influence beyond the predictable and either positively weave or negatively stamp their footprint into the socio-economic fabric of the societies within which they operate.

In September 2007 the SAHRC appointed a Co-ordinator for the Human Rights and Business Special Programme. The purpose of this position is to streamline, strengthen, co-ordinate and drive the activities of the SAHRC in relation to human rights and the corporate sector.

In accordance with its mandate in terms of section 184 of the Constitution and the Human Rights Commission Act, 54 of 1994, the SAHRC’s responsibilities include monitoring compliance by the corporate sector with its human rights obligations. The SAHRC seeks further to engage in developing policy options and practical strategies to facilitate such compliance. The SAHRC has and will continue to undertake research to assess the role of business and the corporate sector in the development and enjoyment of human rights, and continues with its key responsibilities of advocacy and public awareness.

Furthermore, the SAHRC reiterates that it is necessary to consider the human rights obligations of all actors in our Constitutional democracy in the broader sense. In this regard we consider it necessary to emphasise that in terms of the Application Clause (section 8(4)) of the Bill of Rights of the Constitution, juristic persons can be the bearers of rights to the extent that the nature of the right permits. However, they are also the bearers of obligations, and are bound by the provisions of the Bill of Rights “if, and to the extent that, it is applicable, taking into account the nature of any duty imposed by the right” (section 8(1)). In this instance, pharmaceutical companies bear obligations with regard to access to medicines. The SAHRC does not consider these obligations to exist to same extent as the obligations of the state, but the horizontal operation of the Bill of Rights is clear. It is this nuanced understanding of the Bill of

Rights and the rights and obligations of natural and juristic, private as well as state actors, which informs our consideration of these Guidelines.

Returning to the specific topic of the Guidelines, in the South African context, the right to health care is entrenched in section 27 of the Bill of Rights of the Constitution of the Republic of South Africa, Act 108 of 1996 (hereinafter referred to as "the Constitution"). The right to health care is placed in its appropriate socio-economic context in the Constitution, having been considered under the same socio-economic banner as food, water and social security, and is framed as follows:

"(1) Everyone has the right to have access to –
(a) health care services, including reproductive health care;
(b) sufficient food and water; and
(c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
(2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.
(3) No one may be refused emergency medical treatment."

However, in an era of the commodification of human rights, the socio-economic inequalities prevalent in South Africa exacerbate inequalities in the realisation of human rights. This is starkly illustrated by the lack of access to adequate health care more generally and access to medicines more specifically. These inequalities cannot effectively be addressed through a rights framework alone.

A holistic approach requires consideration of the Guidelines within the context of strengthening the health care system in its entirety. Furthermore, any holistic solution involves the engagement of the state with regard to the enforcement of the Constitutional obligations of private actors.

Encouraging Engagement

The publication of the Guidelines for comment and consultation provides an opportunity to engage with stakeholders in the pharmaceutical and broader health care industry within a country context and with reference to specifically situated challenges.

Accordingly, the SAHRC has attempted to engage numerous stakeholders for the formulation of a balanced and informed contribution to this consultation process. This has been undertaken through communications by our Co-ordinator for Human Rights and Business with pharmaceutical companies, industry bodies and special interest advocacy organisations. Specific and individually addressed communications were either telephonic, by e-mail, or both and the request for engagement and the text of the Guidelines were forwarded. An announcement was also made at a local conference where numerous pharmaceutical companies were present, and the SAHRC's intentions were published in a recent internet bulletin of a human rights portal and resource organisation. It is important to note that communications were directed at some, but by no means all, stakeholders in the sector.

Unfortunately, with the exception of one industry body, namely Innovative Medicines SA, the SAHRC has received no substantive input from those stakeholders who were

specifically contacted nor from other parties who may have been aware of the Guidelines through the various modes of publication through the UN processes and other organisations. The SAHRC has noted the comments made by certain pharmaceutical companies at an international level. However, the SAHRC is disappointed that an opportunity to consider South Africa's specifically situated challenges, with the sector stakeholders themselves, has not been fully utilised. It was not possible to contact all stakeholders personally, and the names of those stakeholders who specifically declined or failed by omission to make a contribution to the process will not be stated.

The reasons given, some undoubtedly valid while others are clearly contradictory, for the lack of engagement with the SAHRC include the following:

The industry body should be approached as opposed to individual companies;
The industry body cannot comment on behalf of individual companies;
The international head office of the industry body should be approached as opposed to the national office;
The international head office of the pharmaceutical company should be approached as opposed to the national office;
The international head office of the pharmaceutical company is already considering a submission and therefore the matter will not be dealt with at a national level; and
It is not useful to comment as the Guidelines contain nothing new or binding.
In some instances there was a failure to reply to telephonic or e-mail messages and in other cases the correspondents made a statement of intention to revert, but no input has as yet been received.

Specific Comments on the Guidelines

General
Although inclusion of the recognition of the importance of human rights in a company's mission statement is a point of departure, the dedication to such a declaration needs to be borne out in the internalisation and operationalising of human rights principles (Guidelines 1 and 2). Human rights principles require integration into the management processes of a company.

Furthermore, in a South African context, human rights obligations are entrenched in the Constitution and are not only aspirational principles, but legal obligations. The nature of pharmaceutical companies' human rights obligations need to be recognised as extending beyond corporate social responsibility to legislative compliance with Constitutional obligations as well as compliance with other national legislation. The necessary corollary is that companies need to proceed beyond strict legislative compliance in fulfilment of broader human rights principles and consider progressive realisation targets, possible collateral human rights damage and adding value to the human rights value chain. In addition, to return again to the formal Constitutional aspect, when interpreting the Bill of Rights in accordance with section 39, "a court, tribunal, or forum …(b) must consider international law". Therefore, when determining the nature and extent of companies' obligations, regard must be had to relevant international instruments.

The SAHRC has encouraged companies to join the Global Compact and is invited as a visitor to the local Global Compact Advisory Board meetings (Guideline 3). In this context the SAHRC wishes to emphasise that human rights are not only a multinationals issue, and small and medium sized enterprises need to be included in the consultative processes of the Global Compact in order to internalise human rights in these sectors and encourage ownership of initiatives as community stakeholders. The informal economic sector is another dynamic particularly prevalent in developing countries which needs to engaged with, although perhaps in a different forum.

A further challenge encountered concerning the Global Compact is that some multinationals exhibit resistance to local reporting, stating instead that they report in accordance with the Global Compact at an international level. However, the SAHRC submits that country specific challenges, such as the extent of HIV/AIDS pandemic in South Africa, combating TB and other infectious diseases and the exacerbation of the lack of access to medicines by socio-economic inequalities, would benefit from input and discussion at a national level between local stakeholders. This would also serve to include the communities involved for a more holistic approach based on engagement with the societies within which companies operate and encouraging community participation, ownership of responsibility. This concern also speaks to Guidelines 4 and 6, and hopes to address somewhat the dual operating standards of multinationals in developing countries with weaker regulatory systems.

Guideline 5 relates to a company's collusive behaviour, and in a country specific context may concern issues of corruption as well lobbying practices for the relaxation of legislative standards as is dealt with in other sections of the Guidelines.

Management
The SAHRC concurs that it is essential that human rights principles be concretised and commitment to the attainment of these principles confirmed through the establishment of appropriate accountability mechanisms. There are various levels of accountability, the primary mechanism being that put in place by the state to ensure legislative compliance and, thereafter possible industry and company initiated mechanisms.

Although there may be suggestions from within the South African pharmaceutical industry that self-regulation is the most effective means of control as it involves one competitor policing another, there are concerns that can be raised. One concern applicable to any industry, not just the pharmaceutical industry, is the possibility of anti-competitive practices and collusion between companies. The second concern raised is that of the possible lack of transparency of the process. Please see the further comments in paragraph 3.8 below concerning the draft code on ethical promotion and marketing.

Public policy influence, advocacy and lobbying
The SAHRC supports the proposals concerning accountability and transparency measures to be taken by pharmaceutical companies. In addition, within a South Africa specific context, the SAHRC wishes to emphasise the right of access to information as entrenched in section 32 of the Bill of Rights of the Constitution. Furthermore, the SAHRC urges compliance by pharmaceutical companies with the provisions of the

Promotion of Access to Information Act, 2 of 2000, which serves to facilitate the realisation of the right of access to information.

Research and development for neglected diseases

There appears to be little financial incentive for pharmaceutical companies to invest in research and development for neglected diseases. The SAHRC would encourage the incentivisation of companies in this regard. The SAHRC is not aware of any such proposals, emanating from the state or elsewhere in South Africa, but hopes that such initiatives may be effectively implemented and expanded if in existence, or otherwise considered for future development.

Patents and licensing

It is adding nothing new to the debate to state that this is the most contentious issue to be raised with pharmaceutical companies, but it bears repetition. While a measure of intellectual property protection is essential for the development of any market economy, the benefit of the development of new medicines is lost to those who need it most if patent protection is not balanced by the effective granting of sufficient licenses for production and distribution. This includes, by necessity, an obligation of affordable pricing as opposed to profit maximisation in developing markets. Secondly, this includes an obligation, especially with regard to HIV/AIDS drugs, to grant sufficient licenses for production and distribution to sustain patients' drug regimes without interruption once they are reliant on a specific medication which has been introduced into the market by that company.

The SAHRC is of the view that the approach to be taken should be informed by the protection and promotion of human rights as the over-riding primary guiding principle for the formulation of corporate action and strategy and not as a limiting principle curtailing corporate profit.

In October 2005 South African Pharmaceutical Trade Associations made a joint submission to the Department of Trade and Industry regarding compulsory licensing in national health emergencies. The conclusion on page five thereof summarises their views in this regard:

"We would recommend that the use of voluntary licensing as a first step where ever possible [sic] in cases of national public health emergencies. We also regard the inclusion of the Motta text and Menon statement in the TRIPS Agreement as providing the required balance between access to health care and protection of the rights associated with intellectual property in cases of national public health emergencies, were [sic] no other mechanisms are available domestically."

The SAHRC concurs with the Guidelines that pharmaceutical companies should not lobby for harsher restrictions in terms of the Agreement on Trade-Related aspects of Intellectual Property Rights, and should respect the exemptions granted to some least-developed countries and national human rights priorities in times of public health emergencies.

A matter related to the previous comments concerning the granting of licenses that may require future consideration is the complaint lodged with the Competition Commission South Africa by the Treatment Action Campaign against MSD (Pty) Ltd

and Merck & Co. Inc and related companies on 6 November 2007 (reference number 2007NOV3328). The Competition Commission is currently considering the complaint, the essence of which is that:[1]

> "12. The complainant alleges that the respondents have violated section 8(c) of the Competition Act 89 of 1998 ("the Act") by refusing to license –
>
> > a) Any existing company in South Africa (other than Aspen and Adcock) to import into, manufacture, use, offer to dispose of and/or dispose of in South Africa, generic EFV products; and
> > b) Any existing company in South Africa (including Aspen and Adcock) to import into, manufacture, use, offer to dispose of and/or dispose of in South Africa, co-formulated and/or co-packaged generic products containing EFV and at least one other ARV medicine."

Quality and technology transfer
The SAHRC concurs that technology transfer agreements should be, and it appears sometimes are in South Africa, part of intellectual property sharing arrangements, such as between Lilly and Aspen and Gilead Sciences and Aspen.[2]

Pricing and discounting donations
This is dealt with in paragraphs 3.3, 3.5 and 3.8.

Ethical promotion and marketing
Section 18C of the Medicines and Related Controlled Substance Act, 101 of 1965, requires that a code of ethics be prescribed by the Minister "relating to the marketing policies of pharmaceutical companies". The SAHRC was informed that although a draft was published several years ago for comment, no code had been promulgated. However, the pharmaceutical industry bodies have taken the lead in this regard and submitted a draft code to office of the Minister of Health for its consideration in December 2007. The SAHRC has received the body of the draft code, but has been informed that the section of the code dealing with the enforcement mechanism is still being finalised. The body of the draft code contains provisions concerning unethical business practices such as inappropriate incentivisation as well as medicine pricing control issues. It is hoped that this will be considered further once the document has been made public.

The industry bodies and their constituent pharmaceutical companies are to be commended for their commitment to this process and for taking the initiative in establishing a mechanism for the enforcement of ethical marketing practices.

What can be gathered from press sources is that the proposal puts forward an industry regulatory mechanism which is essentially one of self-regulation with an element of government enforcement. A report in the Business Day on 20 December 2007 states that the draft code provides for an industry funded Marketing Code Authority to

[1] Available at <http://www.wcl.american.edu/pijip/documents/complaint.pdf?rd=1> (visited on 22 November 2007), at paragraph 12 on pages 3 and 4 of the complaint.
[2] Sourced from the Joint Submission by South African Pharmaceutical Trade Associations to the Department of Trade and Industry (October 2005), at pages 4-5 (on file with Co-ordinator: Human Rights and Business Special Programme).

monitor pharmaceutical companies and enforce the code. Thereafter, unresolved matters would either be referred to the courts or the Medicines Control Council.

Two concerns which the SAHRC wishes to guard against concerning a self-regulatory proposal are, again, that of anti-competitive or collusive behaviour and also the transparency of the procedure. Transparency is essential in ensuring confidence in the regulatory process and the consequent legitimacy of the outcome.

Clinical trials

The SAHRC concurs with the content of Guidelines 36 to 38 which speaks to the right to security of person entrenched in section 12(2) of the Bill of Rights of the Constitution:

"Everyone has the right to bodily and psychological integrity, which includes the right…(c) not to be subjected to medical or scientific experiments without their informed consent."

On a related matter, the SAHRC wishes to make reference to alleged challenges brought to its attention concerning the obtaining of approval for clinical trials in South Africa resulting in possible missed opportunities. While emphasis in the Guidelines needs to be placed on pharmaceutical companies' compliance with strict guidelines and standards concerning clinical trials, the relevant state mechanisms need to be capacitated to deal with the administrative and regulatory aspects involved.

Public private partnerships

While the SAHRC concurs with the content of Guidelines 39 to 42, it is of the view that public private partnerships are an essential collaboration in an effective response to access to medicines issues in developing countries.

A possible incentive to be explored is that of public private partnerships capacitating local production in South Africa and other developing countries for export into Africa and elsewhere. However, the harmonisation of production standards remains a concern.

Corruption

Combating crime is a key challenge facing South Africa and corruption, collusion by companies in corruption and white collar crime are areas which require specific focus within this context. Companies also need to develop their own internal control mechanisms and continuously examine the effectiveness of existing mechanisms. In recognition of the importance of challenging crime in South Africa, the SAHRC has also appointed a Co-ordinator for Human Rights and Crime who will interact with the Co-ordinator Human Rights and Business where these portfolios intersect as is the case concerning alleged corruption in the corporate sector.

Where companies actions have a direct effect on individuals it is not acceptable for companies to state that they were not aware of the actions of their employees where illegal activities have taken place on a large scale and over a long period of time. This was clearly illustrated in the recent case of anti-competitive behaviour by Tiger Food Brands (Pty) Ltd as confirmed by the Competition Tribunal South Africa. The SAHRC has included reference to anti-competitive behaviour in this section

concerning corruption as it submits that such activities, whether or not criminalised by national legislation, should be considered in the same light as criminal findings of fraud and corruption.

Associations of pharmaceutical companies
The SAHRC concurs with the content of Guidelines 45 to 46. It is hoped that the SAHRC can have greater interaction with the various industry bodies in the future.
Monitoring and accountability

The SAHRC concurs with the content of Guidelines 47 to 48. However, the SAHRC submits that in developing countries with weaker regulatory systems there is a duty upon pharmaceutical companies to establish internal accountability mechanisms to compensate for any regulatory lacuna and also to play a role in encouraging and facilitating the establishment of external regulatory mechanisms, especially those comparable to existing mechanism in other jurisdictions within which the multinational may operate. This is linked to the concern of possible dual operating standards of multinationals in developing countries.

Conclusion
The SAHRC thanks the Special Rapporteur for the opportunity to comment on the Guidelines and hopes to be a part of this continuing process of engagement with the UN and the corporate sector.

United States Government Response to Request from the United Nations (UN) Office of the High Commissioner for Human Rights for Contributions to a Report on Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines (04/01/2008)

For Delivery to the UN Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

General Comments: The United States Government is committed to helping people of all countries expand access to safe and effective high-quality medicines. The United States also supports voluntary corporate social-responsibility initiatives in a variety of sectors throughout the world, because such initiatives complement the rule of law, and can help foster human dignity and improved living conditions, environmental safeguards, and good governance.

Along these lines, the United States believes that pharmaceutical companies, in enjoying the benefits of economic freedom and the rule of law within the countries in which they operate, can and should be good global citizens and engage in corporate philanthropy that improves living standards. Pharmaceutical companies, moreover, should exercise the due diligence required to protect the customer and promote access to safe and effective high-quality medicines. That said, it is the primary objective of private enterprises to be accountable to shareholders, including through the generation of profits, and utilizing those profits for reinvestment in research into new products.

The draft "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines" ("Draft Guidelines") makes a number of proposals for pharmaceutical companies to consider as guidelines for corporate behavior in accordance with the goal of the "realization of the right to the highest attainable standard of health." The Unites States recognizes that the Constitution of the World Health Organization (WHO) affirms that the highest attainable standard of health is a fundamental right of every human being without distinction as to race, religion, political belief or economic or social condition. However, the usefulness of a "rights-based" approach as a model by which to advance the objectives of public health, including greater access to medicines, is questionable. Public-health policies, whether of governments, international organizations, or civil society, including the private sector, are most effective if they are pragmatic, practical and rooted in evidence.

There is no international consensus on the nature and scope of health-related rights and obligations, and the attainment of economic, social and cultural rights -- including the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health" -- is a goal or aspiration to be realized progressively. With respect to the United States, which is not a party to the International Covenant on Economic, Social and Cultural Rights (ICESCR), this right does not give rise to any international obligations, nor is this right the basis of any domestic legal entitlements.

Further, the obligations established under international human rights treaties apply to States that are party to those treaties, not private-sector entities such as pharmaceutical companies. This notion of State responsibility is included in the Preamble of the WHO Constitution: "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health

and social measures." While the pharmaceutical industry can and certainly does help Governments attain health goals in many ways, including by developing life-saving medications, only States that have ratified the relevant treaties can be held accountable under international law.

The Draft Guidelines note States have the primary responsibility in this area (Introductory Note, E). However, the Draft Guidelines greatly exceed this traditional understanding in their approach, which appears to be based on General Comment 14, produced in 2000 by the UN Committee on Economic, Social and Cultural Rights. General Comment 14, like the Draft Guidelines, expresses the opinions of individuals acting in their personal capacities, and is not the result of deliberations among States; the U.S. Government does not consider these types of documents to have any legal standing in international fora. Indeed, a number of statements and assertions in General Comment 14 go beyond the ICESCR, and purport to create a panoply of health-related rights that are not found in the ICESCR. The U.S. does not accept such references -- some of which also pervade the Draft Guidelines -- as they are not found in international human-rights instruments. Such assertions of legal rights also raise profound questions as to how those rights would be implemented, and how compliance could be meaningfully assessed. (For instance, the pronouncement in section I.v., that "all health services, goods, and facilities, shall be available, accessible, acceptable, of good quality and safe" is a statement of aspiration, not a standard under which any entity could be held meaningfully accountable). Overall, the United States does not consider the "legal framework" of General Comment 14 -- or the "right to health" generally -- to be a viable foundation upon which to elaborate a set of guidelines.

Specific Comments

Definition

The Draft Guidelines do not define the term "pharmaceutical company," yet they purport to apply to any such company, regardless of the nature of a company's business. A diverse range of companies would fall under this umbrella. Accordingly, many of the Draft Guidelines will be inappropriate to certain companies or not feasible to implement. For example, it may not be appropriate that a small company have a "public *global* policy on access to medicines that sets out general and specific objectives." Similarly, it is not clear why "technology transfer agreements with local companies" in developing countries would be appropriate for all companies, since some companies are not engaged in technology transfer at all.

Right to Health Analysis (Introductory Note, I)

As with General Comment 14, many of the "key elements" of the so-called "right to health" analysis are not moored in international human-rights law. As expressed above, we do not consider the opinions of groups of experts on this subject to be an appropriate foundation on which to elaborate a set of "Guidelines."

Patents and licensing

Intellectual property (IP) protection, including that afforded through patent systems, is instrumental in providing incentives for innovative pharmaceutical companies to perform risky and costly research and development of new life-saving medicines. Businesses will not invest in new research efforts if they do not believe such research

will generate revenue that can be used to engage in further research and development. Effective patent systems are a key driver of research, because they provide some assurance that, if a new drug is successful, it will generate such revenue for the patent holder. Actions to reduce incentives to innovate will adversely impact research and development of vital new drugs, which is an unacceptable prospect at a time when resistance to some key medicines is on the rise. Therefore, the impact of IP protection on the availability and accessibility of medicines is highly positive, because it results in their creation and contribution to improving health care. This point is demonstrated by the fact that all 22 antiretroviral drugs were developed as a result of patent protection. Furthermore, the R&D-based industry developed most of the innovative drugs on the WHO Model Essential Medicines List.

Preventing companies from filing new indications patents for existing medicines would be detrimental to patients' welfare. Biomedical innovation often occurs through incremental advances that result in improvements such as fewer side-effects, better formulations and lower dosages. Incentives to engage in the research and development that underpins such improvements are especially important, for example, to develop heat-resistant and pediatric formulations of medicines for neglected diseases in poor countries.

To receive approval to market a new pharmaceutical or agricultural chemical product, most governments require companies to submit investigational studies in the form of data that prove that the product is both safe and effective for its intended use before it can be legally sold in that country. The time, effort and money invested in collecting such data are often very significant. Without effective data protection, the motivation to invest in research and development of new drugs is undercut.

Lack of protection for clinical-test data can lead to fewer innovative medicines in the marketplace and fewer opportunities to host clinical trials. The results include the loss of valuable improvements to health-care infrastructure through increased access to the latest medical technologies as well as training and employment of medical personnel.

Management

The Draft Guidelines state, "The company should have mechanisms that encourage and facilitate stakeholder engagement." It is unclear who these stakeholders would be. Private companies are accountable to their shareholders and not to any other "stakeholders." As previously stated, governments, not private industry, have responsibilities under treaties on international human rights law to which they are party.

Influence on public policy, advocacy and lobbying

The Draft Guidelines state, "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 on access to medicines." This standard is very broad and goes beyond both U.S. and international law. The ability of companies to lobby their country's government is subject to rules and laws within the relevant sovereign country and is not under international jurisdiction or oversight.

Quality and technology transfer
Agreements on technology transfer should be voluntary and serve to help those most in need, without providing disincentives for innovative pharmaceutical companies.

Corruption
States, private innovative pharmaceutical companies, generic manufacturers, and state-controlled public pharmaceutical companies should be encouraged to take all reasonable measures to combat all types of corruption, including counterfeiting.

Associations of pharmaceutical companies
It is unlikely that associations of companies (or "partnerships") could feasibly implement many of the Draft Guidelines. The United States strongly objects to the statements in paragraphs 41 and 45 that certain guidelines "shall" apply equally to associations or pharmaceutical companies. "Shall" is language denoting legal obligation. These Draft Guidelines are not an international treaty, nor are they the product of an inter-governmental negotiation. The document should not contain any language suggesting that legal obligations flow from the guidelines.

Monitoring and accountability
The Draft Guidelines call for an independent mechanism to hold each company to account in relation to the Guidelines. In addition to being prohibitively expensive, such a mechanism could contradict existing systems to measure accountability that companies have in place, and could hinder the economic freedom of and compromise the rule of law within the countries they operate.

Oxfam International (11/1/2008)

Dear Paul Hunt, *United Nations Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health,*

Oxfam welcomes the UN Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

These strengthen existing UN initiatives such as the UN Global Compact, which declare that companies should not be complicit in human rights violations and that they should support human rights including "the right to a standard of living adequate for health and well being, including food, clothing, housing, medical care, and to social services and security, …". While broad principles must be adhered to by companies, specific guidelines for each sector are urgently needed as they are essential to ensure compliance and the implementation of the principles. Further, they play an important role to hold companies to account and accurately measure their actual respect and support for human rights. This is why the relevance of the UN Human Rights Guidelines for Pharmaceutical Companies cannot be overemphasized.

The health crisis in developing countries, driven by a burden of old and new diseases, has been worsened by the lack of access to affordable medicines. Guidelines that can improve the pharmaceutical industry's performance are urgently needed. Pharmaceutical companies increasingly foresee many developing countries as the key to future market growth and the answer to internal and external pressures to reduce operating costs. More importantly, the social contract under which they operate has been globalised through the international property regime.

We believe these guidelines are important for three reasons. First, as companies increase their presence in developing country markets, the lack of regulation and enforcement, coupled with inferior technical capacity, enhances the need for international guidelines for issues such as clinical trials and ethical promotion and marketing. Secondly, the research-based pharmaceutical industry still sets the agenda for new drug development, and in many cases, is the key barrier that prevents the development of new medicines that would address diseases that predominantly affect poor people in developing countries. Thirdly, the introduction of the TRIPS Agreement in all countries delays the introduction of affordable, generic versions of new medicines. This leaves developing countries, and particularly least developed countries, wholly dependent on the goodwill of the pharmaceutical industry.

Developing countries' governments have the primary responsibility to promote the right to health, as the Guidelines introductory note clearly states. Governments need to ensure universal access to healthcare and thus universal access to medicines.

However these governments face numerous public health challenges alongside immense financial constraints. In order to fulfil their responsibility, governments need to obtain the lowest cost medicine available. When availability is constrained by patents, governments are obligated to use all tools available under international law to ensure lowest prices. Thus developing countries must use TRIPS flexibilities to ensure generic competition and lower prices. The relevance of the sections on public policy influence, advocacy and lobbying; patents and licensing; and pricing are therefore of central importance to the guidelines. Finally, as companies increasingly benefit from operating in these countries, the industry must address their specific needs on research and development, which includes medicines for the diseases that predominantly exist in poor countries, while also providing formulations of medicines appropriate for poor people in developing countries.

Oxfam has recently released a paper "Investing for life: Meeting poor people's needs for access to medicines through responsible business practices". In our paper, we highlight the need for companies to comprehend that access to medicines is a fundamental human right enshrined in international law, and the need to recognise their responsibilities in this context. Oxfam congratulates the UN Special Rapporteur for successfully completing this essential work that will contribute to improve the health of millions of people.

Yours sincerely,

Oxfam International

Submission by Oxfam International

Draft Human Rights Guidelines for Pharmaceutical companies in relation to Access to Medicines

Oxfam International welcomes this initiative to produce guidelines for the pharmaceutical industry that identify its human rights responsibilities on access to medicines. We believe that these guidelines will be very useful in articulating how provisions on the human right to health apply to the operations of pharmaceutical companies. We hope that the industry will respond to these guidelines constructively and recognise their value in helping individual companies adopt policies and practices on access to medicines that are effective and sustainable.

In this submission, we have chosen to focus our comments only on aspects of the guidelines that we believe could be improved by including further or more detailed stipulations on responsibilities.

Introductory note

i. In the introductory note the UN Rapporteur rightly points out that states hold primary responsibility for enhancing access to medicines. Oxfam believes that although developing countries' governments have the prime responsibility and obligation to ensure that their citizens realise their right to health care including access to medicines, developed countries also have responsibilities towards the realisation of the those rights in developing countries. There have been instances where developing countries have been pressured by developed country governments to implement stricter levels of intellectual property protection, including not using public health safeguards provided for under TRIPS. These situations affect these countries' ability to improve affordability and accessibility to medicines. Free-Trade Agreements (FTAs) are one example of such pressure. The UN Special Rapporteur has previously noted that a free trade agreement between the U.S. and Peru would introduce stricter levels of intellectual property protection and deny affordable medicines.

ii. On a separate point, all countries have a duty to ensure that companies behave in the highest ethical and transparent manner. Governments have an obligation to provide an adequate regulatory framework to ensure this.

Management

iii. This section needs to focus on ensuring an overall coherent policy for access to medicines is reflected in the core decision-making and operations of the company. For many companies, responsibilities for access to medicines are treated solely as philanthropic programmes and activities. Whilst such programmes can bring benefits, they neither negate nor overcome the negative impacts that core business practices can sometimes

have. The negative consequences, for example, of not introducing tiered pricing, or aggressive enforcement of frivolous patents, can far outweigh positive benefits of philanthropic programs.

iv. Furthermore, when evaluating a company's impact on access to medicines, companies need to include the impact of their overall activities as opposed to only assessing their corporate responsibility interventions. For example, price discounts for a least-developed country might not overcome the negative impact of undermining supply of inexpensive quality generics through enforcing a patent in the producing country.

v. Board-level responsibility and accountability should include a specific obligation not to block or hinder government's role in providing quality and affordable medicines.

vi. The introductory note rightly underlines the recognition that the right to health includes freedoms, such as freedom from non-consensual treatment and non-consensual participation in clinical trials. Companies should provide full and clear information to help realising the right to make informed decisions. Companies must implement comprehensive and clear reporting of access to medicines policies and practices. Companies should also institute greater transparency across all operations in developing countries – from registration policies to post-marketing monitoring, including clinical trials and their results.

R&D on neglected diseases

vii. With regards to the guideline on formulations for low-income and middle-income country that are appropriate for resource-poor settings and tropical conditions, Oxfam believes that there should be a specific provision highlighting the need for developing medicines suitable for poor settings including: paedriatic and child-friendly versions, and heat stable medicines.

viii. Oxfam also believes that companies need to facilitate access to their compound libraries to third parties to support R&D for medicines for diseases that primarily affect people in developing countries.

ix. Companies should also ensure that abandoned R&D projects that target diseases predominantly relevant to developing countries are placed in the public domain for other companies or non-for-profit organisations to complete the drug development process.

x. Oxfam recommends a greater degree of transparency with respect to R&D investment. For example, companies should disclose the amount and percentage of their R&D investment that is allocated for diseases that primarily affect developing countries.

Patents and Licensing

xi. Oxfam believes that the inclusion of data exclusivity and linkage amount to TRIPS-plus rule. These measures have the effect of denying access to medicines.

xii. The current draft guidelines emphasise the need to develop arrangements with other manufacturers for licenses and technology transfers to enhance access to medicines for HIV/AIDS, tuberculosis and malaria, and an increasing number of other treatments. Oxfam believes that these arrangements should extend to all diseases that are relevant to public health in developing countries - including infectious diseases and non-communicable diseases. Developing country governments' should be able to determine the diseases for which treatments should be considered for such licenses and technology transfers.

xiii. Oxfam notes that although voluntary licenses can contribute to price reductions, they are not the preferred solution to improving competition to solve access to medicines challenges in developing countries.

Evidence[3] shows that generics offered by Indian companies that are not under a voluntary license from the originator company, are often cheaper than a product produced under a voluntary license offered by a generic company, as well as the originator's product offered under differential pricing.

Ultimately, developing countries should be allowed to adopt TRIPS flexibilities within their intellectual property laws without pressure from developed countries. If rigorously regulated, however, voluntary licensing can play a role in promoting speedier and more affordable access to medicines (see appendix for Oxfam's proposed guidelines on best practice on voluntary licensing).

xiv. Provision 26 states: "the company should not extend patent duration, or file patents for new indications for existing medicines, in low-income and middle-income countries". Oxfam recommends that this provision should include 'or file patents for trivial modifications of existing medicines that extend the patent life beyond twenty years'.

Quality and technology transfers

xv. Provision 28 states; "the company should enter into technology transfer agreements with local companies". Oxfam believes that companies should also consider extending such agreement to those not-for-profit organisations dedicated to developing and/or providing medicines to low and middle-income countries e.g. OneWorldHealth.[4]

Pricing, discounting and donations

[3] See Medicines Sans Frontieres, *Untangling the web of price reductions – a pricing guide for the purchase of ARVs for developing countries* 9th Edition, (July 2006) http://www.accessmed-msf.org/
[4] www.oneworldhealth.org

xvi. In relation to pricing, Oxfam believes that companies should apply a systematic, global approach to pricing in developing countries, overseen by an international public health body. Such approaches should respond to the real purchasing power of developing countries and be applied to the entire portfolio of medicines beyond HIV and other higher-profile diseases. It should also address income disparaties within countries. This requires a flexible and innovative approach to both pricing and patenting policies.

xvii. Companies should also disclose their pricing rationale in developing countries so that developing country governments can make informed decisions when negotiating or setting prices for medicines. Price transparency is also vital because it allows society to hold governments' and drug providers accountable for charges (when governments levy taxes or public and private facilities profit from medicine sales), and to tackle abuses on mark-ups by intermediaries.

xviii. When reporting on donations, value should be expressed in cost terms and not market value. Many companies report their donations according to US retail prices for donations given to least-developed countries, thus inflating the value of donations.

Ethical promotion and marketing

xix. An additional provision could stipulate that specific cultural, socio-economic and literacy conditions should be taken into account.

xx. With regards to provision 34, usage instructions should be included alongside safety and side effects information.

Clinical Trials

xxi. Companies should not only conform to the WHO Guidelines for Good Clinical Practices, but also publicly register all clinical trials- both positive and negative – so that clinicians and decision-makers have access to all information regarding tested drugs.

xxii. The guidelines should specifically stipulate that, following the completion of clinical trials, treatment should be guaranteed as long as the patient needs it.

Public-Private Partnerships

xxiii. The company should disclose its objectives, timeline and contributions (whether financial, technical or know-how, assets e.g. compounds) to the partnerships. If the partnership involves a specific R&D goal for new medicines, the patent and pricing policies that will be applied to resulting drugs should also be made public. This is important to provide donors and other relevant stakeholders with transparent information for assessing the future impact of a particular partnership and to make informed decisions

with respect to funding. Transparency also empowers patients and poor country governments to negotiate fair terms for a promising medicines or vaccine with respect to pricing and IP.

Associations of pharmaceutical companies

xxiv. Industry associations must play a leading role in helping companies to improve their performance on access to medicines. Such leadership can enable companies to overcome the difficulties in undertaking measures on an individual basis, which may be seen as putting the company at a competitive disadvantage. By setting industry-wide standards, industry associations can greatly support such a process.

APPENDIX

OXFAM'S PROPOSED GUIDELINES FOR BEST PRACTICE IN ISSUING VOLUNTARY LICENSES (VLs)

1. VLs should not be used to undermine legitimate pre-grant opposition /observations processes. Where oppositions are in process, originator companies should allow such procedures to be completed before VLs are discussed.
2. VLs should not be issued without continuous public pressure, an epidemic or threat of pandemic. The lack of VLs on medicines for diseases other than HIV and Avian flu is a reflection of public pressure.
3. Any technology transfer should be of a nature that does not require the licensee to go back to the lab and delay marketing. All technology transfer should be royalty free.
4. Geographical restrictions should exclude only developed countries and not middle income countries where large populations are in need of access to medicines.
5. VLs should be permitted for both public and private sectors. This not only acts as an incentive for generic manufacturers but also helps to address the inadequacy public health systems in developing countries where medicines are often purchased privately.
6. Originators should not place restrictions on generic companies sourcing of API. Licensees should be permitted to seek out API from non licensed suppliers, provided such API meets standard good manufacturing practices.
7. Licensees should not be required to grant back any technology improving the originators technology on a royalty free basis. In order to provide incentives for R&D to generic companies with respect to further reducing manufacturing costs, generic companies should be allowed to receive a royalty.
8. VLs should be non-exclusive. in order to truly ensure competition.
9. VLs should not include any price controls or limitation on product output.

Anja Rudiger, Human Right to Health Program Director, NESRI (National Economic and Social Rights Initiative) NYC (21/12/2007)

Dear Professor Hunt,

Thank you for this opportunity to respond to your draft Human Rights Guidelines for Pharmaceutical Companies. I am submitting the following comments on behalf of the Human Right to Health Program, a collaborative program run jointly by the National Economic and Social Rights Initiative (NESRI) and the National Health Law Program (NHeLP), based in the United States.

I have had the pleasure of attending your briefing meeting at Human Rights Watch in New York City on October 23, 2007. I was grateful for your presentation of these valuable guidelines, and I would like to stress how much we welcome your efforts in this area. Your guidelines will be a useful tool for advocacy and for holding companies accountable for human rights violations.

As you know, the U.S. does not officially recognize the human right to health, which makes advocacy challenging. Our program, which started in October 2007, intends to inject human rights principles into the debate on health care reform in the U.S. by providing analysis and capacity building support to state-based health care reform efforts. In this context, our attention is focused on the governments' obligations vis-à-vis private heath insurance companies and investor-owned hospitals and other private health care providers. However, pharmaceutical companies clearly play an important role in our market-based and profit-driven health care industry, where violations of the right to health are ubiquitous. As our program activities progress, we are likely to come across specific issues involving pharmaceutical companies. At this point, I would like to share with you some more general concerns about the activities of pharmaceutical companies in the U.S. market, as they relate to your guidelines.

1. Pricing (Guidelines 19-33): Drug pricing is a key problem in the United States. Pricing is not transparent, and costs to patients are excessively high due to profiteering by both pharmaceutical companies and private insurance companies. High prices limit patients' access to essential medicines, including patients in public programs and those with private health insurance. Drug prices under public programs can be high; firstly because the largest public program (Medicare) is not allowed to negotiate drug prices, and secondly, because private insurers, contracted under a prescription drug benefit law (adopted in 2003), are effectively colluding with pharmaceutical companies to keep prices high and pass costs on to patients (through co-payments). A congressional study, conducted by the House Oversight and Government Reform Committee (*Private Medicare Drug Plans: Seniors and Taxpayers Hurt by High Expenses, Low Rebates,* *http://oversight.house.gov/documents/20071015093754.pdf)* found that despite the legal requirement that private insurers give Medicare beneficiaries access to their negotiated prices, including all discounts, insurers in fact failed to pass on these rebates to beneficiaries. There is clearly much need to provide oversight over pharmaceutical companies' financial relationships with health insurance companies, in addition to much greater transparency requirements for drug pricing and discounting.

→ As I suggested in October's briefing session, perhaps guideline 29 could be revised to take account of the situation in countries that are classified as high-income but where income is distributed extremely unequally and where the health care industry is driven by a profit motive. To that effect, guideline 6 (iv) could be integrated explicitly into guideline 29 (either in (ii) or as a separate point), adding a provision that requires drug pricing within high-income countries to be differential, through discount schemes or other measures, i.e. linked to low-income segments of the population, not generically to a country's median income level..

→ Guideline 29 could perhaps include a new point that specifically requires pricing transparency.

2. Marketing (Guidelines 33-34)
Marketing activities by pharmaceutical companies in the U.S. are subject to very little oversight, extremely costly, and often misleading. Stricter guidelines, which could be used to hold both companies and government to account, would be much welcomed. Three specific issues deserve to be addressed explicitly, perhaps also in your guidelines.

Firstly, the prevalence of aggressive direct-to-consumer advertising, which often contains incomplete and misleading information. There is a danger that such marketing practices influence medical assessment and drug approval processes, especially in the case of new drugs being advertised before they are approved by the relevant public agency (in the U.S., the Food and Drug Administration agency).

→ Guideline 34 could include specific restrictions on direct-to-consumer marketing.

Secondly, the relatively new phenomenon of marketing to the "payer" not the "provider" threatens drug safety and quality, as well as participation by patients and physicians. In the past, most pharmaceutical marketing has been directed at the providers of health care. Recent developments indicate a shift to focusing marketing efforts at payers, i.e. – in the U.S. market – private insurance companies. This is particularly troubling as it contributes further to a tendency whereby decisions about a drug regimen are no longer taken by patients and their doctors but shifted to insurance companies, i.e. corporate actors without medical expertise but with an interest in profiting from the prescribed regimen. For example, the pharmaceutical company Novartis has not only taken up marketing to insurance companies, but is also seeking to involve these companies in the development and clinical testing of new drugs (Wall Street Journal, *Novartis to Focus on Influence Insurers Wield Over Doctors*, December 14, 2007. http://online.wsj.com/article/SB119752894222426243.html). As a result, the principle of medical appropriateness is superseded by vested interests that strive to make a profit. Moreover, the participation of patients, and now also providers, in health-related decision-making is severely curtailed.

→ The marketing guidelines could include a provision that requires a strict separation between marketing and the drug development process.

Finally, in the U.S. patients are subject to a particularly disturbing violation of the rights to privacy and dignity, carried out solely for marketing and profiteering purposes. Pharmacies sell patient prescription data (including name, address, date of

birth and drug regimen), without having obtained consent or offered the right to opt out of this practice. According to an analysis by the organization Patient Privacy Rights, every day all 51,000 pharmacies in the U.S. transmit and sell personal data for every drug they disburse. This data is purchased by pharmaceutical companies, as well as insurance companies and underwriters.

→ The marketing guidelines could include a provision that requires all marketing practices, including the acquisition of data for marketing purposes, to respect the rights to privacy and data protection.

Thank you very much for your attention to our suggestions, and for all your valuable and important work to advance the human right to health. Please do not hesitate to contact me for any further information you may need.

We wish you and your team all the best for the New Year!

Kind regards,

Anja Rudiger
Human Right to Health Program Director

HelpAge International (20/12/2007)

MEMORANDUM -
Submission on the draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines

HelpAge International, December 2007

Introduction
This Memorandum sets out HelpAge International's recommendations on the draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines.

HelpAge International has a vision of a world in which all older people fulfil their potential to lead dignified, healthy and secure lives. HelpAge International is a global network striving for the rights of disadvantaged older people to economic and physical security; healthcare and social services; and support in their caregiving role across the generations.

HelpAge International has 23 years practical, research and policy experience of working with disadvantaged older women and men around the world.
We work in partnership with a range of national, regional and international academic, development and United Nations institutions. Our emphasis is on mainstreaming ageing as a development and public policy issue, to be reflected in national, regional and international policies, budgets and programmes for poverty reduction, HIV/AIDS, human rights and emergency assistance around the world.

Recommendations

Recommendation 1: Inclusion of older people in paragraph 6. Suggested additional wording:

6. (iv) give particular attention to the needs of older people

Rationale
In response to the rapidly ageing global population the importance of the increasing numbers of poor disadvantaged older people should be made explicit in these guidelines. By 2050, more than one in five people will be aged over 60, thanks to falling fertility rates and longer life expectancy. Older women will continue to outnumber older men.

Populations are ageing fastest in poorer regions. By 2050, nearly 80 per cent of older people will live in developing countries. The number of older people in developing countries will triple between 2007 and 2050, from 453 million to 1.6 billion.

Many older people experience discrimination, poor health and poverty. Data on older people's poverty is limited but studies show that older people are disproportionately poor. For example, in Uganda, 64 per cent of older people live in poverty, compared with 38 per cent of the population as a whole, in Vietnam 34 per cent of older people compared to 29 per cent of the total population and in Moldova 35 per cent compared

to 29 per cent. Households with older people and children only, and households headed by older people, are poorer than average in several African countries.

Older people with low incomes have little or no access to insurance for medication and often cannot afford to pay over the counter costs. Older people form a relatively high proportion of the population in rural areas, where access to medicines and other services is often more limited. Literacy rates among older people, especially older women, are often low. Low literacy levels and lack of identity papers make it difficult for older people to access to healthcare or free medicines, where the provision exists, that are theirs by right.

Population ageing is turning age profiles on their head. By 2050, there will be more adults over 60 than children under 14. This demographic shift is unprecedented and will have profound implications for society and the nature of health care provision. As the population ages the demand for medicines to prevent and treat chronic diseases will rise. This calls for an increased effort, including by pharmaceutical companies, to ensure affordable access to essential and safe medicines for older people and the appropriate and cost effective use of current or new drugs.

Recommendation 2: Inclusion of reference to chronic illnesses in paragraph 23. Suggested wording:

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

Rationale

HIV and AIDS are having devastating social, economic and financial consequences for older people. Large numbers of older people care for sick sons and daughters and orphaned grandchildren, often with little or no support. In southern Africa, more than half of orphans live with their grandparents. Older people are themselves at risk of infection although disaggregated data on prevalence rates of those over 49 and older people's access to ARVs are rarely available.

However whilst attention to HIV and AIDS, malaria and TB is vital, it can obscure the need for availability of medicines for chronic diseases, such as cardiovascular diseases, hypertension, stroke and diabetes. The 5 leading causes of death in developing countries are cardiovascular diseases, malignant neoplasms, injuries and respiratory infections and chronic respiratory diseases. As the population ages, demand for access to medicines for the treatment of chronic diseases will increase. Pharmaceutical companies and other health service providers must respond accordingly to ensure equitable access to health care for an ageing global population.

Joint Medact/Wemos submission (16/12/2007)

Comments and proposals for additions.

Public policy influence, advocacy and lobbying
Articles 12-14
Comments: Companies may declare their support to individuals & organisations, but the latter may *not* declare the support received at all, or in such a vague and non-specific manner that it becomes non-attributable and meaningless. Institutions and organisations have an obvious responsibility to be clear in this regard and require their own codes of conduct. In addition, it would enhance credibility, transparency and accountability if companies make it mandatory that individuals and institutions publicly declare the support they received.

The following addition is proposed:

Companies will insist that recipients of their sponsorships, reimbursement of expenses or other material rewards will publicly declare the support received at all appropriate occasions (e.g. as members of committees, as sponsor to health care events; writing articles and giving scientific or educational presentations and lectures etc).Recipients include (but are not exclusively) health professionals, researchers, officials and volunteers associated with patients' organisations, officials and others associated with government departments, health care organisations and non-governmental organisations.

Article 13.
Comment: as it is phrased now, companies may feel or state that they are not trying to influence policy, law or practice and, as a result, not feel obliged to declare their support.
A key issue regarding potential conflicts of interest, accountability and transparency is that it should be for the public to decide whether interests are important and/or conflicting or not. Judgments can only be made *after* companies and or other actors have published their interests. In this approach, the onus is on actors to publish all interests that might possibly be seen as important or potentially conflicting.

The following changes/additions are proposed for article 13 (bold italics):
… research centres and others, ***through which it could possibly be seen to influence*** public policy

Comment: Companies have been known to issue public statements that can be perceived as threatening to the welfare of vulnerable populations in vulnerable countries. An example of this was shown when Jon Pender, GSK spokesman, was reported as saying that industry might "wash its hands" of Africa, if "patent pooling", a modest improvement of the current arrangements regarding R&D and Intellectual Property Rights , was to be implemented[5].

[5] *"Jon Pender, GlaxoSmithKline's spokesperson, warns the system (of patent pooling) could discourage pharmaceutical groups from investing in future innovation, and might make them "wash their hands" of Africa " Source*: Patently Obvious. Patent pools spread ripples in research Financial Times; May 20, 2005

Proposed addition:
Companies will refrain from making public or private statements that can be perceived as threatening to the welfare of vulnerable countries and vulnerable populations. Companies shall take into account the relative lack of power of poor countries who try and develop policies aimed at improving access to pharmaceuticals to those in need.

Articles 19-26. Comment: .A fundamental problem regarding global and equitable access to pharmaceuticals access is created by the TRIPS treaty. In effect, TRIPS has extended pharmaceutical patents globally to twenty years, where they were shorter, or non-existent (e.g. India; Brazil;and into the 1990s, Finland). Furthermore, patents have now much more often been extended to processes and to discoveries. Until recently, there was a global consensus that discoveries such as life forms should not be patented; now, parts of genes can be patented.

Patents are monopolies, allowing the patent holder to set its price: Critics argue that extending its time span to 20 years is exorbitant. Indeed, the extension of patents is one of the most striking paradoxes in an era that is supposed to promote the lowering of barriers, innovation and trade. Industry argues that the higher costs of pharmaceutical development warrant a longer period; critics argue that it encourages industry to "sit" on patents, rather then to feel encouraged to innovate. Furthermore, many rich countries have allowed their pharmaceutical industry to grow and develop without, or under very lax patent regimes. Having reached the top, they kick away the ladder for other countries.

As a result, pharmaceutical prices are rising enormously, allowing for higher marketing and management expenditure and profit, hindering global access to pharmaceuticals. Furthermore, the move away from concepts of the public good [6] towards an emphasis on profitable patents ("Intellectual property rights) leads to acute problems in pharmaceutical R&D, including hindering vaccine development. A group of virologists [7] issued a warning and proposed a provisional arrangement to overcome the problems posed by patent holders that take a narrow view on intellectual property rights. Sadly, the proposed "patent pooling" was aggressively rejected by a key actor from the pharmaceutical industry[8].

[6] Half a century ago Jonas Salk led the team that developed the polio vaccine. When asked who owned the patent, he replied: "Well, the people, I would say. There is no patent. Could you patent the sun?" Source: Stolberg SG, Gerth J. In a Drug's Journey to Market, Discovery Is Just the First of Many Steps. New York Times, July 23, 2000. Accessed on: http://partners.nytimes.com/library/national/science/health/072300hth-drug-primer.html

[7] Simon JH, Claassen E, Correa CE, Osterhaus AD. Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling. Bull World Health Organ. 2005 Sep;83(9):707-10. Accessed at: http://www.who.int/bulletin/volumes/83/9/707arabic.pdf

[8] *Jon Pender, GlaxoSmithKline's spokesperson, warns the system (of patent pooling) could discourage pharmaceutical groups from investing in future innovation, and might make them "wash their hands" of Africa "* *Source*: Patently Obvious. Patent pools spread ripples in research Financial Times; May 20, 2005

Drahos and Braithwaite[9] describe the history of the development of the WTO TRIPS treaty and how it undermines fundamental human rights. Furthermore, the Commission on Intellectual Property Rights, advising the UK government in 2002, expressed serious concerns about TRIPS, suggesting that it should change to meet human rights concerns [10].

Governments in South East Asia are trying to respond to the challenges of vaccine development and the obstacles raised by intellectual property rights. Their responses may facilitate global improvements[11].

A variety of alternative frameworks and arrangements have been proposed with a view to improving global access to necessary pharmaceuticals and R&D for diseases in poverty. These include the right of governments, or government-appointed (inter)national agencies to acquire patents for the public good, prize systems, etc.[12]

Proposed additions:
Companies shall work constructively and transparently with other actors in the global policy arena to help overcome problems posed by current arrangements regarding research, development and Intellectual Property Rights and refrain from publicly rejecting limited proposals for reform.
These problems include the hindering and slowing down of the development of vaccines and other pharmaceuticals by fragmented ownership of knowledge and the lack of instant and easy access to such knowledge.
Companies shall not put direct or indirect pressure on governments and other actors in the national and international policy arenas to refrain from discussing or promoting alternative systems aimed at optimizing global access to pharmaceuticals. Such alternative systems include but do not cover exclusively voluntary or compulsory (inter)national arrangements for governments or government-approved agencies to acquire patents with a view to serving the public good.

Clinical Trials.

Articles 36-38.

Comment: Clinical trials and genome research in humans take place in a variety of settings. There may be an obviously commercial context, as in rich countries when

[9] Peter Drahos & John Braithwaite Who owns the knowledge economy?. Political Organising Behind TRIPS .The Cornerhouse , Devon, 2004. Full text at: http://www.thecornerhouse.org.uk/item.shtml?x=85821
[10] Commission on Intellectual Property Rights. Integrating Intellectual Property Rights and Development Policy. London Sep 2002. Accessed on 041107 through: http://cipr.org.uk/graphic/documents/final_report.htm
[11] Chan CK, de Wildt G. Developing Countries, Donor Leverage and Access to Bird Flu Vaccines..United Nations Department of Economic and Social Affairs Working paper nr 41. Accessed on 041107 at: www.un.org/esa/desa/papers/2007/wp41_2007.pdf
[12] See, for example: a) Dean Baker: Financing Drug Research: What Are the Issues? September 2004. Accessed at: http://www.cepr.net/index.php?option=com_content&task=view&id=149. ; b: Medical R&D Treaty (MRDT) at http://www.cptech.org/ip/health/rndtf ; and c) also the ongoing discussion on intellectual property rights, health and access to pharmaceuticals at: http://www.who.int/intellectualproperty/submissions/en/

trial participants receive a high fee. Alternatively, trials may be carried out against a background of poverty. Still, much pharmaceutical research involving humans continues to take place on the basis of not-for profit voluntary participation, without the pulls and pushes caused by poverty.
We raise two concerns regarding volunteers who participate in pharmaceutical including genome research.

1) Poverty and exploitation

.
Our first concern regards poor governance and potential exploitation , especially in developing countries[13].
While pharmaceutical R&D is increasingly outsourced to companies, a growing proportion of clinical trials take place in low-income and developing countries on a commercial basis. Clinical trials in developing countries are 10-50% cheaper and often subject to less stringent or less actively policed regulatory constraints.
Often, research protocols can be approved more easily, trials can be carried out more quickly, and drugs can be brought to market more quickly. Furthermore, many developing countries have large, concentrated populations (e.g India), which makes it easier to find patients suffering from rare diseases.

It is usually easier to find test subjects in developing countries, as earnings can be significant for test subjects. There are also instances where participation in a trial offers the only affordable access to medical care.
However, once marketed , a drug is often unaffordable for those people on whom it was tested.

At present there is no universal, compulsory registration system for these trials; nor is there any centralized, recognized, supervisory body. It is therefore impossible to know how many trials are taking place, where they are being held, or what methods are being used. Although a number of pharmaceutical companies post information on the internet, they are not formally obliged to publish it at all. This means that comparable clinical trials could be carried out at the same time by different companies, thereby exposing an unnecessarily high number of test subjects to the same risks. Therefore, pharmaceutical companies should register all clinical trials in a publicly accessible register, in accordance with WHO [14]guidelines.
Moreover, against a background of poverty, there is potential for undue pressure and conflicts of interests when health professionals receive material incentives for recruiting patients for drug trial and/or when material incentives for recruited patients are significant . Pharmaceutical companies should bear this in mind and develop credible, auditable guidelines and monitoring mechanisms that counteract this.

2) Patents or patients? Subverting the gift relationship in medical research

Our second concern regards the potential exploitation of volunteers' motives and the lack of informed consent in this context.

[13] SOMO briefing paper on ethics in clinical trials Updated version #1: Examples of unethical trials, SOMO/WEMOS, Amsterdam December 2006 . Accessed at: http://www.wemos.nl/Documents/examples_of_unethical_trials_dec_2006_nl.pdf
[14] WHO International Clinical Trial Registry Platform

Where pharmaceutical (including genome) research volunteers are not offered substantial material rewards, volunteers, usually recruited by health professionals, often join out of the goodness of their hearts and believe they are in a true "Gift Relationship"[15], contributing to the potential welfare of unknown strangers, without expecting reciprocity or anything in return.
In reality, research volunteers may contribute to the development of a useful pharmaceutical substance (e.g. a test, drug or vaccine) or the discovery of a biochemical substance (such as part of the genome) that can be commercialised through patents or otherwise. The end product or finding can become out of reach of the poor or uninsured, and even of themselves.

There is no evidence to suggest that those who recruit research volunteers are made aware of the potentially commercial trajectory of the research and its possible implications for access to pharmaceuticals or diagnostic or therapeutic interventions, Equally, there is no evidence that volunteers are always offered an informed choice in this regard. Recruiters are often health professional who are trusted by their patients and the public.
The FDA guidelines on informed consent, usually seen as the global standard for drug trials, do not clearly demand this[16]. Arguably, the declaration of Helsinki [17] does, even though it was developed before access to pharmaceuticals was complicated by the expansion of commercialisation of pharmaceutical R&D through TRIPS and other arrangements.

The following additions are proposed:

a) Pharmaceuticals companies, and others acting on their behalf , must inform research staff and recruiters of research volunteers of the potential commercial trajectory of the substance under study, including the possible claiming of Intellectual Property Rights and how these rights will be used vis-a vis global needs. Research staff and recruiters must make research volunteers aware of the potential commercial trajectory, in accordance with the Declaration of Helsinki ,

[15] Titmuss R. The Gift relationship
[16] US Food and Drug Administration (FDA) Good Clinical Practice; protection of human subjects. Section 50.25: Elements of informed consent. Accessed at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.25
[17] Declaration of Helsinki. Accessed on 30/10/07 at: www.wma.net/e/policy/b3.htm
Article 8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection.
The particular needs of the economically and medically disadvantaged must be recognized.
Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
Article 22 .In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely-given informed consent
Article 23. When obtaining informed consent for the research project the physician should be particularly cautious if the subject is in a dependent relationship with the physician or may consent under duress. In that case the informed consent should be obtained by a well-informed physician who is not engaged in the investigation and who is completely independent of this relationship.

and offer research volunteers an informed choice, including the choice for volunteers to only participate if all is done to make useful products or findings affordably available to all in need.

b) Pharmaceutical companies should register all clinical trials in publicly accessible registers, in accordance with WHO [18] guidelines.

c) Pharmaceutical companies must agree with the government of the country hosting the drug trial to make the relevant pharmaceuticals, once marketed, affordably available.

d) Pharmaceutical companies must bear in mind the vulnerable position of health professionals who recruit patients for clinical trials on the one hand and trial participants on the other. Financial incentives for either or both parties may create undue pressure and conflicts of interests and companies must develop credible and auditable guidelines and monitoring mechanisms to counteract this.

[18] WHO International Clinical Trial Registry Platform

Niels Ingerslev, MD, Copenhagen, Denmark Amnesty International (22/11/2007)

Dear Paul Hunt,

As a medical doctor engaged in human rights issues I have read the draft: "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines" with great interest.

I find it very timely that the UN defines clear ethical guidelines in this area. In my opinion the text will be very useful when working for the highest attainable standard of health in many countries in e.g. Africa and Asia.

For more than 25 years I have been working in a Medical Group under Amnesty International. The members are all physicians and the group's mission is to have the death penalty abolished and to stop medical participation in executions.

A focus for us, as medical doctors, has been the lethal injection, a method of execution that is used in USA, China and several other countries to an increasing extend and which involves the use of three drugs normally used for anaesthesia. We believe that medical involvement in executions is a grave misuse of medicine and medical technologies. This opinion is shared by numerous international and national medical organizations including the World Medical Association.

When the UN now prepares human rights guidelines for access to medicine, I think it would be of great importance to include for what purposes medicine is NOT supposed to be used.

Executions by lethal injection require medicine that is sold by pharmaceutical companies, who of course have not developed the drugs with the purpose to kill people. Nevertheless that is what is taking place today.

Misuse of their products cannot be totally prevented by the pharmaceutical companies, but in our opinion the companies must speak clearly out against this non-authorized use of their products. In this respect a clear statement from the UN undoubtedly would be a significant support to the companies.

I take the liberty to enclose a summery of a recent report prepared by Amnesty International on the use of lethal injection and a facts-and-figures paper on lethal injection. In case you should need more detailed material on the issue I should be happy to provide it to you.

I should be glad to have your opinion on these matters.

Yours sincerely

Niels Ingerslev, MD

http://www.amnesty-medicaldeathpenalty.dk

Beverley Snell, Senior Fellow, Centre for International Health, Australia (3/10/2007)

Please I would like to add the following - not just for drugs from neglected diseases. An example might be a rapid heat stable test for HIV.

Companies should develop a policy that products that are of prime importance to developing countries, be made available to the developing countries at realistically affordable prices (not donated - that undermines sovereignty and is not sustainable etc etc...).

New products including drugs, rapid tests and other biologicals such as vaccines are usually priced far beyond the reach of those who need them most.

Thank you very much

Beverley Snell

Professor John S Yudkin, Emeritus Professor of Medicine, University College London (1/10/2007)

Dear Rajat Khosla

I would like to make just one comment on the excellent Draft guidelines.

Having been working for the last 6-8 years on access to insulin in the world's poorest countries, I feel that there are major problems of equity pricing arrangements applying to the public, but not the private, sector. The NovoNordisk LEAD Initiative is maintaining prices insulin at 20% the average European/Japanese/US price in the 50 Least Developed Countries, but this applies only to government contracts. The theory is that the patients who buy their insulin in the private sector can afford to pay the full price. The reality, however, is that in the several such countries we have studied, the hospital drug budget runs out part way through the month/year, and in consequence the majority of patients have to buy their insulin in the private pharmacies.

I would thus propose that in Recommendations 29-33, Prof Hunt should include a comment about the need for such pricing systems to apply across all sectors.

Yours sincerely

John Yudkin

Robert Weissman, Essential Action (20/9/2007)

Dear Paul and Rajat,

Thanks very much for including me in Tuesday's review session, and putting up with my comments.

I've attached my comments. These reflect my interventions at the meeting, plus a few small additional points.

Two comments are not reflected in the attachment.

One is the issue of essential medicines. My recommendation is to do a search and replace, and use either important medicines or just medicines. Note, however, that the 2 billion figure at the top refers to the WHO's narrow definition of essential medicines.

This issue just came up in another document I was reviewing, prompting me to send this note:

This is a very tricky matter. The WHO list is based on cost effective interventions, so by definition includes almost exclusively generics. The only consequential exception is ARVs, because they are life-saving for a disease that is so pervasive in developing countries and for which there are no substitutes (and WHO was slow to put ARVs on the list).

Making things trickier is a terminological issue. For 25 years, WHO focused on "essential drugs," and the list was the essential drugs list (EDL). When we started campaigning on access/IP issues, Ellen t'Hoen (possibly Bernard Pecoul) innovated the idea of "essential medicines" as an attractive term we could use that would convey the idea of very important medicines, but which was distinct from WHO's more limited concept. Then, in 2002, WHO changed the name of the list to essential medicines, obliterating the terminological distinction we had drawn.

The second issue relates to 1-11. I know you're unlikely to follow the recommendation, but I'd still favor finding a way to incorporate that material in the introduction. I think those provisions are mostly empty, take up too much space, and, as the opening elements, frame the exercise in an unhelpful way.

Anyway, that's what I have. If I can be of any help along the way to finalizing this, please let me know.

Also, is the revised version available on the web somewhere for public comment? I'd like to send it around to relevant lists.

Best,

Robert Weissman (see also separate document)

David Dubins (see separate document)

Franciscans International (see separate document)

Health GAP (Global Access Project) (See attached document)

Health Action International HAI (see separate document)
