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Dear Professor Hunt and Mr. Khosla,

Thank you for the major contributions you have made towards advancing the goal of the realization of the right to health through your work as the UN Special Rapporteur. I write to submit my comments on the Draft Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, in response to your call for public input. My comments are based on my academic work as well as my professional experience with Médecins Sans Frontières as a researcher and advocate on the issue of access to medicines; however, I would like to state clearly that I submit these comments in my personal capacity as an independent researcher currently based at Harvard University's Center for International Development.

I apologize for the lateness of my submission, and hope that it can nevertheless be considered along with other commentaries. Please do not hesitate to contact me if you would like further clarification, references, or any other information. Thank you for your work in this important area of human rights and I wish you success as it advances,

Sincerely,

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Comments on Draft Human Rights Guidelines for Pharmaceutical Companies In relation to Access to Medicines

Submitted by: Suerie Moon

Summary: The draft guidelines are an important initiative that can advance the objective of improving the global governance of access to essential medicines.[1] There are many elements of these guidelines that are urgently needed, such as the call for greater transparency regarding industry lobbying. However, there are also areas in which further specificity or a broader understanding of the access to medicines issue is required, such as with respect to neglected diseases, patents, and pricing. With some important revisions, these guidelines can make a critical contribution to the development of international norms regarding access to medicines and the right to health.

Public policy influence, advocacy and lobbying

Guidelines 12 & 13: I would like to express my strong support for Guidelines 12 & 13, which emphasize the importance of transparency in the drug industry's attempts to influence public policy through lobbying and advocacy. This is a critical governance issue that is often overlooked, and is likely to garner great resistance from the industry. I commend your team for highlighting it here.

Research and Development for neglected diseases

Guidelines 15-18: The guidelines rightly endorse a greater contribution from the pharmaceutical industry in investing in R&D for the neglected diseases. However, there are two important issues that have not yet been included. First, if and when the industry contributes to the development of new tools to combat neglected diseases, they ought to commit to policies that would make such tools rapidly available and affordable in the countries in which they are needed. Second, there is also a need for formulations of existing medicines that are adapted for use in resource-poor settings, whether for neglected diseases or diseases of global incidence. For example, fixed-dose combinations, pediatric and heat-stable formulations of AIDS medicines have long been urgently needed in developing countries, but lack of sufficient profit margins has hampered their development by the drug industry. Thus, it is not only medicines for neglected diseases that need to be adapted for use in resource-poor settings, but a much broader range of health tools.

Patents and Intellectual Property

Guideline 21: The wording of guideline 21 may cause undue confusion when it states that companies should 'support States' and 'issue compulsory licenses for exports,' since the current wording may be understood to mean that the companies ought to issue compulsory licenses, when in fact this right is reserved for public authorities. Companies that control patents on medicines that may fall under the Doha Declaration Paragraph 6 system may contribute to effective solutions by either quickly granting voluntary licenses

[1] I follow the Draft Guidelines in using the term 'medicines' to refer to a broad range of health tools, including active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other healthcare technologies.

enabling generic production and export, or publicly committing not to impede the government grant of compulsory licenses when these are necessary.

Guideline 23: This guideline unnecessarily restricts the scope of medicines to those related to HIV/AIDS, TB and malaria. Companies ought to negotiate licenses and conduct technology transfer in order to enable generic production of *all* essential medicines (national essential drug lists or the WHO model list could both serve as a reference), in order to encourage competition and/or economies of scale, as appropriate.

Guideline 24: Further details regarding the rationale behind this guideline would considerably strengthen it. For example, it could read: "The company should have non-exclusive voluntary license agreements to *enable generic production, which will decrease prices and encourage* increase*d* access to medicines in low-income and middle-income countries; the terms of such agreements should be *publicly* disclosed." [Suggested changes in *italics*.]

Guideline 25: This guideline would perhaps be stronger if it recognized that in some low/middle-income countries there is no law granting exclusive rights over test data. For example, it could read: "In low- and middle-income countries that do not grant exclusive rights over test data, companies should not lobby for such measures. In low- and middle-income countries where such laws are already in place, the company should *publicly commit not to block* National Drug Regulatory Authorities *from* using test data/override test data exclusivity for registration purposes." [Suggested changes in *italics*.]

Guideline 26: The language of this guideline is somewhat vague, and may benefit from more precision. For example, it could read: "The company should not *take measures that effectively extend* patent duration, *such as filing patent applications for new indications, formulations, or other incremental changes to* existing medicines, in low-income and middle-income countries." [Suggested changes in *italics*.]

Quality and Technology Transfer

Guideline 27: The current language stipulating that companies should manufacture medicines of the 'highest quality' is too vague; furthermore, sometimes very strict quality standards may be abused to unfairly exclude generic producers from important donor-financed markets. The current WHO pre-qualification standards for medicines production are very stringent and have been almost universally recognized by national authorities; at the same time, some pharmaceutical experts have noted that these criteria impose extremely high barriers to entry without concomitant benefits in quality. Therefore, language in the guidelines on product quality should be extremely carefully worded; terminology such as 'acceptable quality levels' may be more appropriate than 'highest quality.'

Guideline 28: The guidelines should recognize that technology transfer agreements may not always provide the best solution to an access problem, and therefore may not always be the recommended course of action. For example, local production in a low- or middle-income country may or may not offer economies of scale, and/or may entail unacceptably long delays that would hinder patient access. Some caveats may be warranted here.

Pricing, discounting and donations:
Guideline 29: This guideline may benefit from two further refinements. First, companies ought to announce their pricing policies clearly, specifying which countries are eligible for which prices and the rationale behind their pricing decisions. Second, companies are likely to move very slowly if the language of the guidelines encourages 'progressive' extension of differential pricing to all medicines. Today, most companies have implemented differential pricing only for AIDS medicines or a few other drugs such as Novartis' Glivec, which has come under public scrutiny particularly from cancer patients who cannot afford the medicine. The guideline should incorporate stronger language encouraging companies to implement affordable differential pricing – in other words, equitable pricing – for all their medicines as quickly as possible.

The negotiations over the price of Abbott Laboratory's AIDS drug Kaletra (lopinavir/ritonavir) illustrates the pitfalls of global differential pricing systems: for some period of time, Brazil had a lower price (~1300 USD per patient/year) than other middle-income countries (~3000-5000 USD per patient/year) for Kaletra because it had threatened to issue a compulsory license on the drug. Under heavy pressure from people living with AIDS, Abbott reduced the price for middle-income countries to 2200 USD per patient/year in August 2006 on the eve of the biennial international AIDS conference, but this price was still unaffordable for some governments. Abbott did not reduce its price further until after Thailand issued a compulsory license on Kaletra in January 2007, at which point it quickly dropped its price for all middle-income countries to 1000 USD/ppy. This experience illustrates that a country's negotiating power will be much more important than its income-level or public health need in determining the resulting price. It also demonstrates that differential pricing based on level of economic development does not necessarily lead to affordability or accessibility of a drug. Thus, the guideline would be considerably strengthened if it emphasized affordability, as well as the relative weakness of voluntary differential pricing as an access mechanism in the absence of strong country-level negotiating capacity.

Guideline 33: It is now widely recognized that drug donation programs are usually not a sustainable solution to an access problem. One of the key dangers of donations is that they may undermine the willingness of governments to consider more sustainable solutions that rely less on companies' largesse. Therefore, if companies do choose to offer donations rather than sell medicines at affordable prices (or allow others to do so), they ought to publicly provide a rationale for why donations are better than other alternatives, such as generic importation, for addressing access problems.

Clinical trials
None of the guidelines address the problem that companies are disinclined to report negative results emerging from clinical trials. The data regarding the increased risk of heart attacks linked to Merck's Vioxx is one example of this problem. There should be an additional guideline that asks companies to commit to publicly releasing all clinical trial data, a norm that would clearly serve the public interest but may be difficult to enforce in low- and middle-income countries.

General Comments: There are three further broad-ranging issues that the guidelines do not yet address:

1. **Availability**: one of key access problems that does not receive sufficient public attention is that companies do not register their drugs in low- and middle-income countries, or there are long delays in doing so. For example, for years Gilead has refused to submit the drug tenofovir, which is recommended by the WHO for AIDS treatment, to the drug regulatory authorities in China, while it has been in ongoing negotiations with the government over price. Companies may use drug registration as a negotiation chip in discussions with governments over prices, particularly in countries where governments are the largest purchasers of medicines. Furthermore, in some situations a drug may not be eligible for a patent, but will be granted a period of market exclusivity after it is registered – in such a case, a company will not register the drug until it is very close to marketing it, so that it will enjoy the longest possible monopoly period. The draft guidelines should include a provision that encourages companies to register drugs as quickly as possible in low- and middle-income countries after registration in the US, European Union or Japan (usually the earliest markets in which companies apply for registration); for example, the guidelines could suggest that companies submit registration dossiers no more than six months after receiving approval in one of the three markets mentioned above..

   Furthermore, registration can also be used as a political weapon. Abbott withdrew seven medicines from the registration process in Thailand after the government issued a compulsory license on Kaletra, as detailed above. This move was unprecedented and roundly condemned worldwide, but Abbott has yet to reverse its decision. The guidelines should suggest that companies do not use drug registration as a political weapon, but rather, that they ought to submit registration dossiers whenever a government requests that they do so and without undue delay.

2. **Country Categories**: Another difficulty with the guidelines is that it is not clear to which countries the guidelines refer. The reference to low- and middle-income countries suggests that the guidelines rely on World Bank classifications; if so, this should be made explicit, particularly since countries may move between these categories as conditions change. Also, it may be important to note that some of the biggest controversies are not occurring in the poorest countries, but rather in those where there is a small but profitable and growing pharmaceutical market at stake, such as Brazil, India, Thailand and South Africa. Ensuring that the guidelines cover not only the poorest countries, but also those that can have an impact on global generic pharmaceutical supplies and prices, is critical.

3. **Alternative R&D models**: Finally, there has recently been a flurry of creative activity around devising new R&D models that would reward innovation but also ensure access to new medicines. Companies can play an important role in identifying new systems for innovation by acting as willing partners in the policy experiments that may be necessary to identify new R&D models that can serve global health needs. One such idea is the use of prize funds, but there are many others worth considering. The guidelines should also embrace the exploration of new R&D

systems that do not pit innovation and rewards for inventors against access to essential medicines for the world. It may be appropriate to devise a guideline exhorting companies to act as bona fide partners in identifying systemic changes that would help address access problems.

Conclusions:

The draft guidelines are an important first step towards solidifying international norms that would influence the behavior of companies, and promote access to medicines and the right to health for all. However, they can and should be considerably strengthened to address a number of problems that continue to hinder the affordability and accessibility of many essential medicines today.