Dear Mr. Hunt,

Thank you so much for inviting me to the UN consultation process on draft human rights guidelines regarding access to medicines. It was a very useful and at the same time, constructive process.

As I mentioned to you at the end of consultation meeting, I would like submit a brief comments regarding the guidelines as well as the consultation. Sorry for the last minute submission.

First, I would like to say I share some comments raised by some participants. The guidelines should not be equally applied to all companies given the geographical and market cap differences. For instance, there has been tremendous advantages are given to large-cap and mega-cap size corporations, including financial resources to conduct R&D or launching new products for specific countries or at the global level. Some companies simply have no such capacities.

I would like to emphasize geographical differences and company's sphere of influence not only the location of its headquarters or where it is incorporated but also locations of operations. Social needs differ among each countries or societies.

For instance, Many Japanese companies (pharmaceutical) have rather limited operational capacities in terms of its global reach given the fact that their operations are almost exclusively focusing on Japanese market and the US market or EU market in some cases. Their R&D is basically looking at Japanese social needs, of course. In these markets, it would not make business sense to focus or emphasis on diseases such as TV, which is not going to sell much in Japan, their largest market. Also, it is difficult to ask to expand their R&D or products beyond these individual companies' current capacity.

Thus, I also agree participants' comments regarding the companies regarding companies focusing on specific products should not be punished for not manufacturing products needed for meeting specific social/country needs.

Likewise, I would like to address the fact pharmaceutical industry in emerging markets are often 'mystified' though their focus on generic drug might rather be strategic choice than the act of being altruistic acts to increase access to medicines. As you know substantial increase in production of patented/branded drugs among some of the oldest companies in emerging markets supports such strategic choice among companies. Such increase in production of patented drugs should not be punished.

To summarize, areas of R&D regarding neglected diseases are the one, which can be strongly encouraged through this guidelines as it is or through various dialogues and joint programs. I understand that even these limitations, there are spaces for them to further emphasizing their commitments, but such efforts may be realized as collectively together with other companies as a joint initiatives or programs. However, such commitments would go beyond the level of social programs or extra-efforts and would not become core business, at least for a short-term.

Regarding Patent and Lobbying/Advocacy Issues

I would like to thank you for making clear statement for these issues in the guidelines since patent issues and lobbying issues are different from putting more effort to emphasize neglected diseases.

Regarding these matters, I might disagree with some other participants who emphasize the perspective of business interests. We need to keep ourselves the fact that public good/social needs and business interests could collide or even contradict to each other and the issues of access to medicines is one example of such cases.

Given the context of your appointment and the current UN framework, the single most important role for the guidelines, I believe, is to set out a series of clear expectations of 'what should' and 'what should not' based on social needs or to disseminate information regarding the current social norms and perceptions regarding access to medicines while clearly identifying challenges in the current pharmaceutical industry rather than trying to be overtly sensitive regarding what pharmaceutical industry want, agree or even what kinds of guidelines make business sense.

We need to readdress the fact that necessary measures to address social needs do not always match with the business interests, particularly in terms of profits, since meeting such social needs might mean bearing additional costs or even internalizing some externalities pharmaceutical industry creates to the society. I understand that such a gap between business interests and social needs has created needs for the guidelines.

Many participants in the consultation would agree that follow-ups or discussions regarding concrete steps are necessary for each section of guidelines involving multi-stakeholders to address issues laid out by the guidelines.

However, drawing lines between respecting ordinary business and violations of one's rights to 'highest attainable standards of health' are difficult in practice.

Thus, the guidelines need to be practical in a sense to capture the concrete issues and challenges while it does not necessary to be practical in terms of processes to ensure such business conducts since such issues should be considered for the follow-up mechanisms or frameworks.

Comments for Individual Sections

Regarding General Section 6:
Given the fact some societies in Asia or Europe are facing serious aging issues, thus it would be reasonable to include not only children but also elderly for the guideline's emphasis, particularly since there often are cases needs of elderly have not been met or being neglected in terms of access to medicines. If the guideline will focus at the global scale, such issues need to be addressed.

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