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For Attention: The United Nations Special Rapporteur
Professor Paul Hunt
By email: rkhosl@essex.ac.uk

Dear Professor Hunt:

***Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines,* prepared by United Nations Special Rapporteur, Paul Hunt**

Response from Merck & Co., Inc.

Merck & Co., Inc[1]., is in strong agreement with Paul Hunt's objective of ensuring broader access to medicines and vaccines for those living in the developing world. Merck believes that responding to global health challenges is a strategic and humanitarian necessity. Our approach is founded upon the belief that pharmaceutical companies have a responsibility to offer assistance when social, political and economic conditions make it impossible for patients to receive life-saving therapies and that Merck and others should leverage their expertise to help remove the barriers that stand between patients and the therapies they need.

However, we feel the approach to define guidelines specific to the pharmaceutical industry is misguided and will not result in meaningful improvements given that they do not directly address the underlying issues that prevent achieving the highest attainable standard of physical and mental health (i.e., the need for health system development in developing countries by increasing the numbers of health professionals, building capacity for procurement, storage and distribution of medicines, and improving the rational use of drugs through training). Rather, we are concerned that the current guidelines will lend an unproductive aspect to the debate around access to medicines (ATM) and divert attention and resources from the real problems and challenges that urgently need to be addressed. Several of the guidelines also are impractical and would place undue burden on companies, while not advancing the overall goal of improving access.

We believe that true solutions to the access to medicines challenge will come from focusing on the entire international community -- including governments, donors, international agencies, non-governmental organizations and the private sector (including generic and state-owned companies) -- and examining and having a meaningful dialogue on all barriers to achieving the highest attainable standard of physical and mental health. Given that attainment of this right is a joint responsibility of all stakeholders, a more constructive approach might be to consider establishing a set of balanced principles that all players would be asked to endorse. Once there is agreement on the principles, specific indicators could be developed by an independent third party – such as the Global Reporting Initiative – to measure organizations, institutions and government's compliance and performance. To be most effective, these indicators should be pragmatic, practical and rooted in evidence.

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[1] *Merck & Co., Inc., (Whitehouse Station, NJ, USA) operates as Merck Sharp & Dohme (MSD) in many countries outside the United States.*

For example, one way to help ensure access to affordable medicines would be for countries to eliminate import tariffs and value-added taxes to medicines that increase price to consumers. It also would be revealing if, through this process, the international community were to analyze countries' efforts to set up effective delivery mechanisms to ensure that medicines and vaccines actually reach patients in need, rather than be left to expire in government warehouses or improperly diverted. An assessment of developing countries' relative investments in health would also be revealing. Another more illuminating analysis would be certain countries' failure to live up to existing commitments in the Harare and Abuja declarations. There is much that can be done to improve access if we all work together and focus on the real barriers.

An additional concern is that we feel the guidelines could have the unintended consequence of supporting arguments for weakening intellectual property protection (IPP). IPP, 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 IPP 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 antiretroviral drugs to treat HIV infection 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.

We also think it's important to point out that the guidelines set a negative and alienating tone by failing to recognize the major contributions that individual companies *are already* making in the developing world. We believe, for example, that our activities and those of others in the research-based pharmaceutical industry have had a meaningful impact on access to care. In particular, Merck is proud of our record of success in developing important medicines and vaccines using the best scientific understanding of disease and taking important steps to promote access to our discoveries.

While we feel that Mr. Hunt's approach of focusing exclusively on the pharmaceutical industry is unlikely to achieve the changes he envisions, we would be open to discussing with him the specific guidelines attributed to the industry in more detail, particularly if this could be part of a broader discussion on how to broaden this exercise to include additional stakeholder groups.

Thank you for the opportunity to comment on the draft guidelines. Merck looks forward to the opportunity to discuss these important points further.

Best regards,

John L. Skolnik