29 February 2008

Professor Paul Hunt
United Nations Special Rapporteur
C/o rkhosl@essex.ac.uk

Re: Comments requested on the Guidelines Draft of 19 September 2007

Dear Paul,

The subject of the development of and access to medicines (including vaccines and health-related products of biotechnology) is a serious one, and any policy prescription that hopes to address this issue effectively has to encourage the research-based pharmaceutical companies to carry out their unique societal mission to research and develop innovative pharmaceuticals, vaccines and biotechnology products. Therefore, I wanted to draw your attention to a number of relevant initiatives, facts and conditions that inform any discussion of the issues underlying your paper. The information provided here should help you to understand why the research-based pharmaceutical industry questions the relevance and utility of the types of "guidelines" that are contained in the draft paper. While not being able to tackle all of the problems in the draft paper, I hope that the information cited here will "guide" you in your future work on this and related issues.

I refer you to a few of the documents that IFPMA and its members have produced over the past several years, and which are and have been available on our website, at www.ifpma.org. First regarding access to health care and medicines, I would suggest that you cannot ignore the industry-backed partnership programs, which since 2000 have made available more than 1.3 billion positive health interventions in developing countries. The significant activities related to capacity building, not-for-profit sales, donations, etc. are documented in two reports found at http://www.ifpma.org/healthpartnerships/ and also at http://www.ifpma.org/pdf/2007_11_02_Release_Partnerships_Survey.pdf. As far as we can determine, no other industrial sector comes even close to matching the research-based pharmaceutical industry's voluntary contribution to helping achieve the Millennium Development Goals – indeed, no other sector appears to be even attempting to measure its collective contribution (see 2006 report by the London School of Economics Health and Social Care unit: http://www.ifpma.org/News/NewsReleaseDetail.aspx?nID=4467, which is currently being updated to reassess developments since then).

Second, with regard to R&D for Diseases of the Developing World (DDW's), a document indicating the upward trend in recent years is provided for all to see at http://www.ifpma.org/pdf/2007_11_02_Status_RnDforDDW.pdf. With regard to this issue, you may have noted the recent announcement by the US Administration of a program to provide over $300 million in support of the integrated treatment of seven of the most important neglected tropical diseases: lymphatic filariasis, schistosomiasis, blinding trachoma, onchocerciasis, and three soil-transmitted helminthiases. In

commenting on this positive development, the WHO stated that it welcomes the initiative and that" *Highly effective drugs are available, and many are being donated by industry in large quantities…Moreover, the drugs are safe and simple to administer and all at-risk populations can be treated …"* This suggests that industry has helped achieve much progress against DDW's without formulaic guidelines "from above", and the IFPMA document cited earlier in this paragraph shows the industry's continuing commitment.

Third, with regard to industry's overall focus on the critical challenges facing global public health – innovation, access and corporate good governance -- our position is outlined in an overall policy document that can be found at http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/2008_02_27_Contrib_2_Global_Health_Final_Industry_Focus_and_Actions_EN.pdf. I will just quote here the conclusion, which underlines industry's basic motives and actions:

> Industry is committed to its prime function of discovering and developing new medicines, vaccines and, increasingly, products of biotechnology for patients worldwide. The enormous mortality and morbidity burden in the poorest developing countries can only be addressed by improving access to health care via a *concerted, partnership-oriented strategy* that is supported globally with financial resources as well as know-how about good practices, and with national and community efforts to increase poor people's access to essential health services, regardless of where they live.
>
> It is obvious that single actors on their own will have a limited impact on global development and health problems. All actors in society - state and non-state - must contribute to solutions according to their obligations, abilities, and enlightened self-interest. All societal actors must make resources available and cooperate in a creative way in order to meet all the Millennium Development Goals. Industry commits to continue to act responsibly in its sphere of capability and is committed to work collaboratively to make its novel preventative and therapeutic products available and accessible to the global patient community.

I hope that these documents and references will inform your work as UN Special Rapporteur.

Finally, I would point out one other fundamentally flawed aspect of your September draft. Ostensibly, you are attempting to write guidelines for "pharmaceutical companies" that make and supply pharmaceutical "products". However, your paper does not address the great majority of conditions relating to companies and off-patent products that most patients in developing countries face every day of their lives. These conditions include: Companies marketing medicines made under non-GMP conditions, those marketing non-bioequivalent "similars" (i.e., not true generics), prescription medicines that have not been properly stored, counterfeit medicines and vaccines (all of which are substandard), products sold in uncontrolled marketplaces, medicines never tested for either safety or efficacy, and products diverted or stolen, mishandled, re-packaged and then re-sold. For

a look at merely one aspect of the "tip" of this "iceberg" see http://www.who.int/bulletin/volumes/83/1/64.pdf. (There is also no coverage of for-profit para-statal pharmaceutical companies owned by ministries of health, noting their importance and favored position in some developing countries.)

The exclusion of the issues, threats and challenges cited here in *any* analysis of developing-country pharmaceutical issues leaves open most of the pharmaceutical issues that people in developing countries face in the real world.

In closing, I would add a more general point. I would have hoped that a paper coming from you, given your important standing, knowledge and experience, would be a paper that encourages the further extension and development of public-private partnerships of the type that have emerged to address is very real ways the health-related UN Millennium Goals. Such a series of recommendations would have real benefit for the populations that that we all, including industry, care about helping. For this reason we rather support the focal points of action, stressing a partnership approach, outlined in the Industry Focus and Actions paper released earlier this week by IFPMA, and referred to earlier.

Best regards, Harvey

Harvey Bale
Director General
International Federation of Pharmaceutical
Manufacturers and Associations
Chemin Louis-Dunant 15
1211 Geneva 20
(T) 41 (0)22 338 3200
(F) 41 (0)22 338 3299