

Deputy Director General

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

Mr Paul Hunt
Office of the High Commissioner for
Human Rights
8-14 Avenue de la Paix
1211 Geneva 10

by e-mail:
rkhosl@essex.ac.uk

Berne, January 28, 2008

Direct line +41 31 377 72 01

Our reference 730.1-01 Schae/bep

Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines

Dear Mr. Hunt,

It was with great interest that we took note of your draft of 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine' that you have submitted for public consultation. We appreciate this opportunity to offer you our comments in the hope that you will take them into account when finalising the Guidelines for your upcoming report to the Human Rights Council.

The Swiss Federal Institute of Intellectual Property is the federal agency responsible for matters concerning intellectual property in Switzerland and, as such, represents Switzerland's interests in all legislative matters concerning intellectual property, both at the national and international level. Thus, these preliminary comments are limited to the paragraphs that relate to intellectual property. Also, they do not represent the position of Switzerland on the draft Guidelines, but are, in the context of this informal consultation, those of the Institute as one of the Swiss Government Agencies which has dealt intensively with the issues of the relationship of intellectual property rights and affordable access to medicines over the last couple of years and is involved in relevant discussions in WHO, WIPO and WTO.

We share your viewpoint that – despite the fact that the responsibility for realising the right to health lies with the respective governments – pharmaceutical companies also have an important role to play in providing access to medicines. Pharmaceutical companies invest in research, development and the registration of new medicines to make necessary medications available to prospective patients. We also agree that pharmaceutical companies, due to their knowledge-base and manufacturing capacities, have a social responsibility to help facilitate the access to medicines. We thus encourage our industry to continue its efforts to enhance access to medicines in developing countries in need and to engage in relevant public-private partnership programmes, as well as other actions promoted by the WHO global strategy and plan of action currently under negotiation – recommendations you might also consider including in your guidelines.

1. The draft Guidelines call upon pharmaceutical companies to not lobby for protection standards going beyond the standards provided by the TRIPS Agreement (paragraph 19).

This seems to imply that the protection of intellectual property rights – and patents in particular – are fundamentally hindering access to medicines. This is not an assumption that we share.

The contrary is true. In many instances the patent system is the primary incentive for pharmaceutical companies to invest in R&D of new medicines and vaccines. By granting patent holders the exclusive right to commercially market their invention for a limited time, the patent system allows the right holder to recoup investment made in the development of the drug. This allows making a profit which can be reinvested into further innovation. By thus creating incentives for R&D, which is particularly costly in the field of pharmaceuticals, intellectual property rights play a key role in innovation for public health and in long-term access to new and more effective medicines.

Neglected diseases can illustrate this because an economically viable market is lacking and thus the patent system alone cannot provide sufficient incentives for the research and development which is needed. This special case shows that without the incentive given by patents a significant research gap exists which would extend into other diseases were it not for adequate and effective levels of intellectual property rights.

Switzerland, like many other countries, has opted for a protection of inventions beyond the minimal standards of the TRIPS Agreement because we are convinced that this leads to more innovation. A generalising statement in the Guidelines of a UN Rapporteur implying that any intellectual property protection standards going beyond multilateral minimum standards are negatively influencing access to medicines would send a misleading message. Thus, we do not agree that pharmaceutical companies should be requested to stop defending their interests concerning the protection of intellectual property rights including fighting for higher levels of protection than those provided by the TRIPS Agreement.

2. The Guidelines call upon companies to consent to drug regulatory authorities to override test data exclusivity in low-income and middle-income countries (paragraph 25).

Similar to Recommendation 19, this implies that the protection of test data systematically hinders access to medicines. However, test data exclusivity is, for example, important for the development of paediatric formulas of existing drugs that are requiring new clinical trials. If this data is not protected, companies will not be able to get a return on their investment in the clinical trials and will lose the incentive to develop formulas which are, for example, specifically important for HIV/AIDS, and will not register their new medicines in countries that do not provide for test data protection.

We are also concerned about the extension of this recommendation to middle-income countries. According to the World Bank list of economies (July 2007), for example, Poland and Croatia both fall in this category (upper-middle income). However we do not think that the population in these countries has problems accessing the necessary medication. In addition, India – a country with an important pharmaceutical industry – is considered a low income country. The recommendation should thus either be limited to least-developed countries or reformulated. The same applies to paragraph 26.

3. The Guidelines call upon companies to respect the Doha Declaration as well as the right of countries to use the flexibilities provided by the TRIPS Agreement (paragraph 19 and 20) to the full extent.

We note here that the TRIPS Agreement as well as the Doha Declaration are addressed to WTO Member States and do not contain any obligations directed to pharmaceutical companies.

Therefore, it is unclear to us what is really meant when companies are requested to respect the right to use the flexibilities of the TRIPS Agreement and the Doha Declaration.

Does this mean that companies should refrain from advocating their interests when, for example, a country issues a compulsory license? The option of granting a compulsory licence is a right provided to WTO Members in the TRIPS Agreement and confirmed in the Doha

Declaration. Nevertheless, it is the legitimate right of a company whose patent is subject to a compulsory license to ask for judicial review of a national government or court decision.

It should be clear that this right is in no way being compromised by the Guidelines. Many companies already do refrain from depositing patents and/or defending their rights in the poorest countries and could be encouraged to do so. Again, a generalising recommendation could send a wrong signal.

4. The Guidelines request companies to enter into technology transfer arrangements and non-exclusive voluntary licensing agreements (paragraph 23 and 24).

We strongly encourage our industry to engage in such projects. However, pharmaceutical companies are very diverse. There are small companies and trans-national ones, research companies and generic ones, companies with a very disease-specific product portfolio and those that are active in the field of HIV/AIDS, tuberculosis or malaria. Licensing and technology transfer are not necessarily the best ways for all companies. There are others means to foster access to medicines in developing countries such as differential pricing or relevant public-private partnerships. The Guidelines therefore should simply request social engagement, propose a number of options regarding the form such engagement could take, and allow the individual companies to decide the best way for contributing to improved access to medicines in developing countries for themselves.

5. The Guidelines call upon every pharmaceutical company to provide either for in-house research on neglected diseases or to support external research (paragraph 17).

We support the goal of fostering research for neglected diseases and we are convinced that the industry plays a key role in the endeavour to fight such diseases. We actively work in the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property Rights to find mechanisms to increase research in this field and very much welcome any investment on the part of the industry in research on neglected diseases; the Novartis Institute for Tropical Diseases is an example of this kind of initiative. Both from a macro- and microeconomic perspective, however, it does not seem to be the task of private industry to finance the necessary research into neglected diseases. For the particular case of neglected diseases, this seems first and foremost to be the task of Governments and the international community as a whole. It is their/our responsibility to ensure that relevant research for neglected diseases take place. Thus, we support the underlying message of the Guidelines, but do not consider it appropriate to create a moral obligation of all pharmaceutical companies to invest in research on neglected diseases. Instead the Guidelines could encourage those companies which have the necessary know-how and the capacity to engage in such research to collaborate with their Governments and the international community or to help through other means such as by making their chemical compound libraries accessible to other researchers for identifying compounds with potential for fighting neglected diseases.

We sincerely hope that these comments can be received in the spirit in which they were given – namely, an effort to contribute to an important document which should serve all interests in the international community. We are looking forward to receive your report to the Human Rights Council. If you should have any comments or questions, myself or Peter Beyer from our Division of Legal and International Affairs (peter.beyer@ipi.ch; +41-31-377 72 02) are at your disposal.

Yours sincerely,


Felix Addor