1/03 '08 16:53 FAX 001

MISSION PERMANENTE DU JAPON
AUPRÈS DES ORGANISATIONS INTERNATIONALES
GENÈVE-SUISSE

MM/UN/108

The Permanent Mission of Japan to the International Organizations in Geneva presents its compliments to the United Nations Office of the High Commissioner for Human Rights and, in reference to the latter's note verbal dated 15 October 2007, has the honour of transmitting herewith the comments of the Government of Japan in response to the Draft of "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines" as contribution to the request by the Secretary General.

The Permanent Mission of Japan to the International Organizations in Geneva avails itself of this opportunity to renew to the United Nations Office of the High Commissioner for Human Rights the assurances of its highest consideration.

Geneva, 27 March 2008

Enclosure mentioned.

MISSION PERMANENTE DU JAPON AUPRÈS DES ORGANISATIONS INTERNATIONALES GENÈVE

OHCHR REGISTRY

- 1 AVR. 2008

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The Government of Japan's Comments in response to the Draft of "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines"

The Government of Japan recognizes the field of Global Health as one of the crucial challenges for achieving the Millennium Development Goals (MDGs) and has implemented various forms of international cooperation including the Health and Development Initiative. "The Right of everyone to the enjoyment of the highest attainable standard of physical and mental health" makes a contribution to the issue, and Japan expresses support for the movement from the standpoint of promoting economic and social rights. In particular, the enhancement of medicine development and access to medicines to tackle the diseases deeply affecting developing countries is an important task which requires a global commitment. Japan has been proactively engaged in international cooperation in collaboration with the private sector, as exemplified by WHO activities such as the WHO/TDR, by providing technical cooperation such as the provision of training and dispatch of experts, and by contributing to the Global Fund to Fight AIDS, Tuberculosis and Malaria which supports activities that include the securement of medicines against these three major infectious diseases.

Meanwhile, research-based pharmaceutical companies have been engaged in activities to improve public health on a global scale through the development of safe and effective innovative medicines for the treatment of diseases threatening patients' health.

In order to improve access to medicines, it is necessary to maintain sustainable activities on a global scale and establish a framework to cope with the challenge under a public-private partnership, promoting active participation from private corporations.

The captioned draft guideline describes 48 items of request to pharmaceutical companies to improve access to medicines.

It is explained that this draft guideline was based on the international discussion on the right to health; however, international consensus has not yet been built with respect to the nature or scope of the right to health, and it is irrelevant to practically restrict the activities of pharmaceutical companies by imposing the argument on private corporations despite the fact that it is the government of each member state which shall assume the primal responsibility bound by the international human rights treaties.

Furthermore, the contributions which pharmaceutical companies have made to improve healthcare in developing countries or various activities which pharmaceutical companies have carried out to solve the issue of access to medicines are not adequately reflected in the recommendations of the guideline. The contents of the guidelines should be written appropriately based on discussions with pharmaceutical companies and a correct understanding of the current situation.

At present, global strategies/action plans have been discussed in the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) based on the report released by the WHO Commission on Intellectual Property Rights, Innovation and Health (CIPIH Report), and these deliberations should be adequately reflected in the preparation of the guideline.

1. Scope of application of the guideline and definition of pharmaceutical companies

The issue of access to medicines has been discussed for years but no conclusion has been reached yet. The issue of access to medicines refers to both the absence of necessary medicines and the inaccessibility to existing medicines. The research and development of medicines for neglected diseases represents the former case and the problem regarding the supply of medicines represents the latter case. In this guideline, patented medicines are grouped into the latter case, but between 94 and 98% of medicines on the WHO's Model List are off-patent. Various generic products are available in these countries but such important issues are scarcely mentioned in the discussions.

In the guideline, various measures are described under the precondition that pharmaceutical companies are all research-based pharmaceutical companies without a clear definition of "pharmaceutical companies". However, there are globally operating generic product manufacturers that supply various generic products around the world. To correct the supply-related problem in access to medicines, the supply of generic products included in WHO's list of essential medicines is extremely important as mentioned above. In the guideline, not only research-based companies but generic product manufacturers should be included in the subjects.

2. Research and development for neglected diseases

It is also highly important that research-based companies with advanced knowledge and experience in medicine development participate in research and development for neglected diseases. For this purpose, WHO/IGWG is expected to hold constructive dialogues about the enhancement of the public-private partnership to invite active participation of private pharmaceutical companies.

Also to increase the motivation of the companies, practical discussions should be made to secure an investment scheme or protect intellectual property rights for research and development of new medicines for neglected diseases under the collaboration of not only the WHO but other international organizations such as the WTO or WIPO.

3. Patents and licensing

The issue of patents and licensing should be carefully considered based on not only the discussions in WHO/IGWG, but deliberations and specialist knowledge of the WTO and WIPO as well. It has not been clearly verified that the issue of access to medicines has a direct relationship with intellectual property rights, and it is duly necessary to recognize the risk that the international proposal to easily weaken intellectual property rights may impair research & development of medicines necessary for humans. Regarding the description about the flexible use of the TRIPS Agreement, in particular, this Agreement partly has the aim of ensuring smooth international trading, and it is necessary to understand that the compulsory licensing schemes based on the precondition of a national emergency should not be easily approved.

Also as for the description of the period of data protection, data protection is one of the important incentives for continuing research and development of new medicines, and this issue should be sufficiently discussed based on such point.

4. Ethical promotion and marketing (Securing the transparency of pharmaceutical industry activities, Part 1)

To secure proper promotional activities for medicines, the international marketing code was revised by the International Federation of Pharmaceutical

Manufacturers & Associations (IFPMA) and came into force on January 1, 2007. In Japan, the Japan Pharmaceutical Manufacturers Association (JPMA) revised the promotion code based on the said revision.

5. Disclosure of clinical trial data (Securing the transparency of pharmaceutical industry activities, Part 2)

In 2005, the association of Japan, U.S., and European research-based pharmaceutical companies and the IFPMA prepared a joint guideline by four organizations for the disclosure of information about the clinical trials performed for research and development of medicines necessary for healthcare, and companies have proactively provided information. The disclosed data are searchable on the IFPMA portal site. Japan has also opened a portal site for the disclosure of information obtained from clinical trials sponsored by coordinating investigators.