Basic Attitude of the Japan Pharmaceutical Manufacturers Association towards the Convention on Biological Diversity (CBD)

The Japan Pharmaceutical Manufacturers Association (JPMA) has put many ideas into practice to deliver innovative and safe drugs to patients. Traditionally, it also respects the spirit of the CBD in its promotion of drug development, taking the importance of technologies based on genetic resources into consideration.

The tenth meeting of the Conference of the Parties (COP10) to the CBD will be held from October 18th to 29th, 2010, in Nagoya, Japan. JPMA expects that the Japanese government will take efforts as the host country to make a success of this meeting. A possible international framework for access to genetic resources and benefit sharing (ABS) may greatly influence related businesses depending on the content. JPMA expresses its basic attitude towards the key issues of interest below, from the standpoint of the pharmaceutical industry. We sincerely request your consideration and review of these points.

[Basic attitude toward CBD/ABS]

- The JPMA expects that a principle will be established on access to genetic resources and the sharing of benefits from their use, respecting the goal of the CBD.
- The JPMA cooperates with stakeholders in CBD, to discuss an international framework for ABS, so that it will be achieved effectively.
- The JPMA expects that an international framework will be established, without changing the pre-agreed points, for example, that "such a new framework should not be applied retrospectively," and that "the exclusion of human genetic resources in the Bonn Guidelines will be retained." Although pathogens are not human genetic resources in the strict sense, they are hazardous and have to be excluded from an environment containing humans. Therefore, the JPMA believes that that pathogens should be excluded from the meaning of "conservation of species diversity" and "sustainable use of biodiversity" as the goals of the CBD, and thus from its scope.
- The JPMA opposes legally binding requests for the disclosure of sources of patent applications, because they can cause great uncertainty concerning the value of patents.
- The JPMA hopes that a fair method of access and benefit sharing will be established, in accordance with the basic principle of the CBD that genetic resources will only be collected based on mutually agreed terms (MAT) that are reached at the point of access to such resources. Considering that a desirable state of access and benefit sharing is not necessarily the same in all the technological fields and industrial segments, the JPMA hopes a flexible approach will be possible, taking into account the characteristics of the respective fields and segments, instead of fixed, across-the-board conditions for MAT.
- Member companies of the JPMA comply with the guidelines formulated and published by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA)*, to which the JPMA belongs.

* http://www.ifpma.org/Issues/fileadmin/templates/ifpmaissues/pdfs/2008_05_22_Guidelines_Genetic_Resources_EN.pdf

[Background of the basic attitude]

- The CBD is a convention on the conservation of biodiversity and the sustainable use of genetic resources, to which Japan became a signatory on May 28, 1993. An international framework has been discussed in the CBD on how to define a scheme for promoting access to genetic resources, and for sharing benefits from their use. COP10 will be held in Nagoya from October 18th to 29th, 2010. It has been decided to complete negotiations concerning an international framework for ABS in this Nagoya round.
- There are some important concerns about the proposed specifications of an international framework, and JPMA considers the following points particularly critical, with regard to the scope of the CBD and the application of such a framework.
    1) An international framework should not extend the pre-agreed scope of the CBD. In other words, its scope shall be limited to "genetic resources," and shall not extend to a wider range of "biological resources," nor to products originating from genetic resources, their derivatives and/or pathogens. The key reason is that such coverage will lead to the inclusion of unforeseeable materials into its scope, which will result in extremely uncertain terms and conditions and extremely unstable business situations.
    2) An international framework shall, in principle, apply to the conducts after the enforcement of such a framework, and shall not apply retrospectively to the transfer of genetic resources that occurred before it.
- Legally binding requests for the disclosure of sources of patent applications are, by nature, independent of patentability. In addition, they are not considered effective against the conduct of "biopiracy" (even though a still unclear definition of this term has been put aside). This is because patent applications are only made for a very small part of the outcome of research, and, even if applications are made only an extremely small portion of them lead to execution. The JPMA thinks that a more direct means for securing benefits of genetic resource providers is to establish a scheme for promoting the respective ABS contracts with genetic resource owners, and to prevent the unauthorized export of genetic resources through exit controls at borders.
- If source disclosure for patent application is required in a legally binding manner, great uncertainty would be placed on the value of patents. In particular, concerns about competitors' utilization of such a requirement as a means for invalidating patents would be serious. Invalidation of patents would lead to lost benefits from the use of genetic resources for both patent holders and genetic resource owners, resulting in economic loss. At the same time, a considerable negative impact is expected on the progress of research and development using genetic resources and related R&D investment, because motivation would be lowered for sound and effective use of genetic resources due to the elevated risk of patent invalidation and uncertainties of patentability, caused by the requirement of source disclosure. The JPMA is afraid that such negative impact could deprive patients of opportunities for receiving more innovative and safe drugs.