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European Commission

European Medicines Agency

Closer ties on medicines safety between EU and Japan

The European Union and Japan will from now on be able to exchange confidential information about the authorisation and safety of medicines. Confidentiality arrangements were agreed between the European Commission and the European Medicines Agency (EMEA) on the one side and the Japanese Ministry of Health, Labour and Welfare (MHLW) and Japanese Pharmaceuticals and Medical Devices Agency (PMDA) on the other at a bilateral meeting in Tokyo. The partners will be able to exchange confidential information, for instance on safety issues with marketed medicines and products being developed or considered for authorisation.

Commission Vice-President Günter Verheugen responsible for enterprise and industry policy said: *"This closer cooperation with the Japanese authorities will provide earlier access to information and thus make it easier and quicker to take action to protect public health. Our close relationship will also allow us to tackle technical barriers to trade in medicines and help prevent new barriers occurring."*

EMEA Executive Director Thomas Lönngren said: *"We have been working closely with our Japanese counterparts for many years and I see these new confidentiality arrangements as an important step forward. Sharing information and expertise will help both the Japanese and EU to further strengthen public health protection."*

The European Commission's Directorate-General Enterprise and Industry, the European Medicines Agency (EMEA), the Japanese Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) have concluded confidentiality arrangements in the area of human medicine regulation during their bilateral meeting of 2 February 2007 in Tokyo.

The EU and Japan have been working collaboratively for many years in the area of human medicines regulation. This has included a mutual recognition agreement on manufacturing of medicines, through the International Conference on Harmonisation (ICH) and through bilateral meetings.

The new confidentiality arrangements build on the previous cooperation and will allow exchange of information between the parties as part of their regulatory and scientific processes, both before and after a medicine has been approved. The types of information covered include:

- advance **drafts of legislation** and/or regulatory guidance documents,
- **scientific advice** on product development given to companies **to promote innovation**,
- assessments of **applications for marketing authorisations** and
- information about the safety of marketed medicines to better protect public health.

The potential benefits of this exercise are expected to include:

- accelerated access of patients to **new and innovative medicines**;
- resource savings due to **reduced duplication of assessment** and
- improved performance and safety as a result of the involvement of the **best available regulatory expertise** from both the EU and Japan.

Background

The confidentiality arrangements cover human medicines subject to evaluation or authorised under the centralised authorisation procedure as well as medicinal products authorised at national level by the EU Member States that are subject to official EU arbitration and referrals.

The confidentiality arrangements are established by an exchange of letters which can be accessed here:
Letter from EC and EMEA:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm
Letter from MHLW and PMDA:
http://ec.europa.eu/enterprise/pharmaceuticals/pharmacos/new.htm
For more information on the work of the Commission's Pharmaceuticals Unit see: http://ec.europa.eu/enterprise/pharmaceuticals/index_en.htm
For more information about the EMEA see: http://www.emea.europa.eu
For more information about ICH see: http://www.ich.org

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