European Commission

Health Canada

European Medicines Agency

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Closer ties on medicines safety between European and Canadian regulatory authorities

The regulatory experts from the European Union and Canada 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 Health Products and Food Branch of Health Canada on the other at a bilateral meeting in Brussels in December 2007. The partners will be able to exchange confidential information, for instance on safety issues with marketed medicines and therapeutic products being developed or considered for authorisation.

This closer cooperation between the authorities will provide earlier access to information and thus make it **easier and quicker to take action to protect public health**. Sharing information and expertise will help both the Canadian and EU authorities to **further strengthen public health protection**.

The European Commission's Directorate-General Enterprise and Industry, the European Medicines Agency (EMEA), and the Health Products and Food Branch of Health Canada have concluded confidentiality arrangements in the area of medicines and therapeutic product regulation during their bilateral meeting of 7 December 2007 in Brussels.

The EU and Canada have been working collaboratively for many years in the area of medicines and therapeutic product regulation. This has included a mutual recognition agreement on manufacturing of medicines, through the International Conference on Harmonisation (ICH) and the International Conference on Harmonisation of Technical Requirements for Registration of Veterinary Products (VICH).

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:

- position papers on **future 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**;
- improved performance and safety as a result of the involvement of the **best available regulatory expertise** from both the EU and Canada.

Background

Scope of products covered in Europe: The confidentiality arrangements cover human and animal 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.

Scope of products covered in Canada: includes pharmaceuticals, radiopharmaceuticals, biologics and natural health products.

The confidentiality arrangements are established by an exchange of letters which can be accessed here:
Letter from EC and EMEA
Letter from Health Canada

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 Health Canada see:

http://www.hc-sc.gc.ca/ahc-asc/branch-dirgen/hpfb-dgpsa/index_e.html

For more information about ICH see: http://www.ich.org

For more information about VICH see: http://www.vichsec.org