



European Medicines Agency
Press office

London, 8 April 2009
Doc. Ref. EMEA/220316/2009

PRESS RELEASE

European Medicines Agency, European Commission and Health Canada agree implementation plan for confidentiality arrangement

The European Medicines Agency, the European Commission and Health Canada, the Canadian regulatory authority for medicines, have agreed on an implementation plan for their confidentiality arrangement.

The implementation plan details the process for both regular and ad-hoc exchanges of information, and describes the process for monitoring the progress of the implementation plan. It also foresees an exchange programme for staff to promote mutual learning and sharing of regulatory experience.

The terms of the confidentiality arrangement, signed in December 2007, allow the parties to share non-public information on all human and veterinary medicines – already authorised or still under review - that fall within the scope of the agreement. It also allows the exchange of information on legislation under development or draft regulatory guidance documents.

In the initial implementation phase, emphasis will be given to exchange of information on medicines used in oncology and on veterinary medicines.

The implementation plan with Health Canada follows largely the plan in place for implementation of the confidentiality arrangements with the United States Food and Drug Administration (FDA). The regulatory agencies will explore potential joint implementation activities with the FDA to avoid duplication of efforts.

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Notes:

1. The implementation plan can be found here:
http://www.emea.europa.eu/pdfs/general/direct/internationalcoop/implementation_plan-en.pdf
2. More information on the international work of the European Medicines Agency can be found here: <http://www.emea.europa.eu/htms/general/direct/internationalcoop.htm>
3. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

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