European Medicines Agency

London, 26 July 2007
Doc. Ref. EMEA/308167/2007

European Risk Management Strategy: Achievements to date

Reviewing the status of implementation of the European Risk Management Strategy (ERMS) during their meeting in Lisbon on 10 July 2007, the European Medicines Agency (EMEA) and Heads of Medicines Agencies (HMA) expressed their satisfaction with the progress made to date and had a first discussion on the priority areas for the next two years.

No effective medicine is without risk and the benefits of a medicinal product always need to be balanced against its risks. While it is acknowledged that medicines regulation cannot protect the public from every risk, the ERMS aims to provide for a more coherent approach to the detection, assessment, minimisation and communication of risks of medicines in Europe. This should lead to a more proactive approach to safety monitoring of medicines throughout their life-cycle.

Achievements to date
Achievements made between 2005 and 2007 are described in the 'Public Status Report on the Implementation of the European Risk Management Strategy'. Some of the achievements have been:

- Implementing the legal tools for monitoring the safety of medicines and for regulatory actions provided for by revised EU pharmaceutical legislation, with particular emphasis on the systematic implementation of risk management plans;
- Strengthening the spontaneous reporting scheme through further improvements to implementation of electronic reporting of adverse drug reactions to the EudraVigilance database;
- Launching the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) project to strengthen the monitoring of medicinal products by facilitating the conduct of multi-centre post-authorisation safety studies;
- Contributing, in collaboration with the European Commission, to the conduct of research in the field of pharmacovigilance and safety of medicines in the context of the Health Theme of the 7th Framework Programme;
- Strengthening the organisation and the operation of the EU Pharmacovigilance System.

Priority areas for the next two years
Building on the achievements to date, the EMEA and HMA are in the process of finalising a work programme on activities to be undertaken over the next two years to further implement the ERMS. A number of environmental changes will impact on this work programme, such as the European Commission's Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance. Two main areas will be covered by the ERMS during the next two years: further improving the operation of the EU Pharmacovigilance System and strengthening the science that underpins the safety monitoring of medicines for human use. It is envisaged for this work programme to be published following the November 2007 HMA meeting.

-- ENDS --

Notes:
1. In autumn 2002, the Heads of Medicines Agencies (HMA) agreed on the outline of a European Risk Management Strategy (ERMS). A summary report prepared by the HMA Ad Hoc Working Group on ERMS was subsequently published in January 2003

7 Westferry Circus, Canary Wharf, London, E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 09
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

(MCA/PL/JM/HoASummaryReport.doc on http://heads.medagencies.org). The aim of the ERMS is to strengthen the safety monitoring in the EU of medicinal products for human use.

2. The 'Public Status Report on the Implementation of the European Risk Management Strategy' is available on the EMEA website.
3. The final version of the work programme to further implement the ERMS in the next two years will be presented at the November 2007 Heads of Medicines Agency Meeting.
4. The European Commission's Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance can be found at: http://ec.europa.eu/enterprise/pharmaceuticals/pharmacovigilance_acs/index.htm
5. This press release, together with other information on the work of the EMEA, can be found on the EMEA website: www.emea.europa.eu

Media enquiries only to:
Martin Harvey Allchurch or Monika Benstetter
Tel. (44-20) 74 18 84 27, E-mail press@emea.europa.eu