European Medicines Agency

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European Risk Management Strategy: 2008-2009 work programme adopted

The Heads of Medicines Agencies (HMA) and the European Medicines Agency (EMEA) agreed on a rolling two-year (2008-2009) work programme to further progress the European Risk Management Strategy (ERMS) at their November 2007 meeting in Funchal (Portugal).

No effective medicine is without risk and the benefits of a medicinal product always need to be weighed up against its risks. The challenge for regulators is to find the right balance between timely availability of new medicines and the fact that knowledge on the safety profile is limited at the time of marketing authorisation. The ERMS aims to provide for a more proactive conduct of pharmacovigilance by putting in place measures that allow for the early detection, assessment, minimisation and communication of risks of medicines in Europe throughout their lifecycle.

The ERMS workprogramme during the next two years will focus on two areas: further improving the operation of the EU Pharmacovigilance System and strengthening the science and methodology that underpins the safety monitoring of medicines for human use.

Some of the key initiatives, which aim to improve the implementation of the current legal framework, relate to:

- Further developing the EudraVigilance system through the introduction of additional functionalities, hence leading to a fully operational system
- Optimising the functioning of the EU Regulatory System Network, and in particular its pharmacovigilance component
- Reinforcing operational and scientific quality assurance
- Increasing transparency and improving communication on the safety of medicines
- Implementing the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) project in order to broaden the access to and optimise the use of pharmacoepidemiology resources
- Exploring methodologies in the conduct of pharmacovigilance

The activities to be undertaken over the next two years build on the progress already made, but also take into account a number of environmental changes which will impact on the implementation of the ERMS, such as the European Commission's Strategy to Better Protect Public Health by Strengthening and Rationalising EU Pharmacovigilance, the implementation of new European Union (EU) legislation on paediatric medicines and on advanced therapies, and the increased regulatory cooperation with non-EU regulatory authorities.

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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 (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 by providing for a more coherent approach to the detection, assessment, minimisation and communication of risks of medicines.

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2. The rolling Two-Year Work Programme (2008-2009) to further progress the ERMS is available here: http://www.emea.europa.eu/pdfs/human/phv/28008907en.pdf
3. A 'Public Status Report on the Implementation of the European Risk Management Strategy', published in July 2007, is available on the EMEA website here: http://www.emea.europa.eu/pdfs/human/phv/16895407en.pdf
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

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