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European Risk Management Strategy: Progress to date and next steps

Two key documents on the European Risk Management Strategy were published today. The result of a collaboration between the Heads of the National Medicines Agencies across the EU and the European Medicines Agency (EMA), the two documents set out what has been delivered to date and what the priorities will be for the collaborative European Union (EU) system of monitoring the safety of medicines in the future. Their publication comes at a time when the profile of safety issues, in relation to medicines, across the EU has never been higher.

The impact of this collaborative work is set out in the 'Progress report of the *ad hoc* working group on the implementation of the European Risk Management Strategy'. This includes implementation of measures designed to strengthen the safety monitoring of medicines in the EU. By enabling authorities to better identify, assess and manage risks as they emerge, more effective, coordinated actions and communications across the EU regulatory system can be delivered.

It is widely recognised that no effective medicine is without risk. But strong regulation, based on robust scientific decision-making should clearly assess the balance of benefits against the known risks. Pharmaceutical industry, healthcare professionals and patients all have their part to play as well. The two reports acknowledge that medicines regulation cannot protect the public from every risk; the Strategy aims at putting in place a coherent approach to the detection, assessment, minimisation and communication of risks in Europe.

The next steps of the Strategy are set out in an 'Action plan to further progress the European Risk Management Strategy'. This builds on the progress made and takes into account the need to respond to public concerns over the safety of medicines. The action plan focuses on three priority areas:

- **Implementation of new EU pharmaceutical legislation**
From November 2005 onwards, new EU pharmaceutical legislation gives authorities additional tools for monitoring the safety of medicines, as well as greater scope for urgent regulatory action once the benefit/risk balance of a medicinal product becomes unfavourable. The legislation will also result in increased transparency on safety issues and facilitate communication, with the provision of timely and targeted information to healthcare professionals and the public.
- **Supporting initiatives**
Complementary initiatives to put in place an intensive drug-monitoring system will focus on risk detection, risk assessment, risk minimisation and risk communication.
- **Further strengthening of the EU pharmacovigilance system**
The action plan also highlights the need to make best use of scientific resources and expertise available at EU level, and on enhancing quality assurance. This should lead to a further strengthening of the EU regulatory system overall, resulting in the establishment of a 'network of excellence' for medicines regulation.

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- Links to:
 1. Report of the Ad Hoc Working Group: Progress on Implementation of the European Risk Management Strategy
 2. Action plan to further progress the European Risk Management Strategy
 3. [Establishing a European Risk Management Strategy. Summary report of HoA ad hoc working group January 2003](#)