

Risk Management for Medicinal Products in the EU

Over the last few decades many important pharmacovigilance issues have been identified through spontaneous reporting of adverse drug reactions. At the same time, consideration has been given to ways in which the current reporting systems might be augmented and strengthened. A strong contender is that planning of pharmacovigilance activities might be improved if it were more closely based on product specific issues identified from pre- or post-authorisation data and from pharmacological principles. Such planning would also guide the use of routine electronically collected data within health services to provide rapid investigation of predicted or emerging safety concerns.

In 2005, new Community Legislation introduced a requirement for the submission in the application for authorisation of a medicinal product, of the risk management system, when appropriate, by applicants and/or marketing authorisation holders.

A risk management system is as a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to medicinal products, including the assessment of the effectiveness of these interventions. A risk management system for an individual medicinal product or a series of medicinal products can be presented to Competent Authorities in the form of an EU Risk Management Plan. Information on the format, contents and when it should be submitted can be found in the Guideline on Risk Management System for Medicinal Products for Human Use (see below).

Risk management is a continuing process throughout the life-cycle of a medicinal product. A medicine is authorised on the basis that in the specified indication(s), at the time of authorisation, the benefit-risk is judged positive for the target population. However, not all actual or potential risks may have been identified when an initial authorisation is sought. In addition, there may be subsets of patients for whom the risk is greater or different than that for the population as a whole.

The management of a single risk consists of four steps, risk detection, risk assessment, risk minimisation and risk communication. However, a typical individual medicinal product will have multiple risks attached to it and individual risks will vary in terms of severity, and individual patient and public health impact. Therefore, the concept of risk management must also consider the combination of information on multiple risks with the aim of ensuring that the benefits exceed the risks by the greatest possible margin both for the individual patient and at the population level.

More information about Risk Management in the EU can be found in:

- **Guideline on Risk Management Systems for Medicinal Products for Human Use** (will be integrated in Volume 9)
- **EMA template for EU risk-management plans**
- **Action Plan to Further Progress the European Risk Management Strategy Rolling Two-Year Work Programme** (Mid 2005 - Mid 2007) February 2006
- **European Risk Management Strategy (ERMS) Facilitation Group** (Press release , December 2005)
- **Action Plan to Further Progress the European Risk Management Strategy** May 2005
- **Establishing a European Risk Management Strategy** (January 2003)