European Medicines Agency

Heads of Medicines Agencies

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Implementation of the Action Plan to Further Progress the European Risk Management Strategy: Rolling Two-Year Work Programme (Mid 2005 – Mid 2007)

I Introduction

Reference is made to the document "Action Plan to Further Progress the European Risk Management Strategy" (hereafter called "Action Plan"), which was adopted by the Heads of Medicines Agencies during their meeting on 2 May 2005 and subsequently published on 11 May 2005. Such "Action Plan" provides an important contribution as regards the ultimate deliverable of the European Risk Management Strategy (ERMS), i.e. to achieve high standards of public health protection for all medicines available on the European Union (EU) market.

The "Action Plan" states that the initiatives to be taken during the second implementation phase of the ERMS relate to three priority areas, i.e. the implementation of new Community legislation, complementary implementing initiatives to arrive at the envisaged intensive drug monitoring system, and a further strengthening of the EU Pharmacovigilance System as part of the EU Regulatory System.

The aim of this document is to describe how the further implementation of the ERMS will be undertaken, by providing information on the initiatives envisaged for the period mid 2005-mid 2007.

II Working Methodology

The working methodology applied during the further implementation of the ERMS is based on 3 pillars: (1) introducing a targeted approach by providing a further level of prioritisation in order to adequately tackle the wide range of activities to be undertaken stemming from the "Action Plan", (2) making the best use of the available resources and established discussion fora, hence avoiding duplication of work, and (3) involving all relevant stakeholders of the EU Pharmacovigilance System.

Such working methodology will allow to give priority to these initiatives which are expected to provide the most significant contribution to the further improvement of patient safety, whilst adhering to imperative deadlines in particular as regards the timeframe for the implementation of the new legislative provisions, and whilst not neglecting the cost-efficiency aspects of the whole operation. In addition, appropriate stakeholder involvement will be assured.

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III Key Initiatives Envisaged During the Period Mid 2005 – Mid 2007

Using the above-described working methodology a wide range of initiatives will be undertaken for the period up to mid 2007 to implement the "Action Plan". Such initiatives should allow the EU Regulatory Authorities to make an important contribution in achieving the requirements necessary to enhance drug safety in the 21st century, i.e.

- moving–up the evidence (best evidence concept);
- applying a more proactive conduct of pharmacovigilance;
- finding the right balance between timely access for patients to medicines and the knowledge needed on the safety profile of medicines at the moment of licensing, along with the most robust post-licensing programme.

The key initiatives that are envisaged for the reporting period mid 2005 - mid 2007 are described below.

Area of risk detection

Initiatives in the field of risk detection will focus over the next 2 years on achieving intensive drug monitoring, building on the principles of best evidence. This should allow to establish a framework which facilitates the earliest possible detection of important safety signals.

Key initiatives

- Speeding-up the implementation of electronic reporting to EudraVigilance in accordance with ICH standards, at the level of both the National Competent Authorities and the pharmaceutical industry.
- Taking due account of experiences gained with such electronic reporting and addressing the needs for remedial actions through the newly established structure of the EudraVigilance Steering Committee and the EudraVigilance Expert Working Group.
- Further developing the EudraVigilance database by introducing additional functionalities, especially in the field of signal detection and data mining.
- Progressing the best evidence concept by developing a Concept Paper on best evidence based on the principles described in the 2003 ERMS.
- Identifying which areas require research with respect to the development of novel methodologies through participation in the Innovative Medicines Initiative.
- Publishing a list of medicines requiring intensive drug monitoring.
- Developing a network of academic centres to be involved in intensive drug monitoring.
- Exploring other methods of risk detection by taking due account of various initiatives undertaken by Regulatory Authorities.

Area of risk assessment

Building on the achievements attained during the first implementation phase of the ERMS, initiatives over the next reporting period will concentrate on further organisational and operational improvements of the EU Phamacovigilance System. In addition, the quality and scientific and regulatory consistency of the scientific evaluation processes will be further strengthened and should lead to an increased consistency of decision-making.

Key initiatives

- Establishing the "new" Pharmacovigilance Working Party (PhVWP) with its revised mandate covering all medicinal products on the EU market, and reinforcing its scientific expertise taking into account the outcome of a gap-analysis.
- Optimising the interaction between the Committee for Human Medicinal Products (CHMP) and the PhVWP, and establishing the interaction between the PhVWP and the newly created Co-ordination Group for Mutual Recognition and Decentralised Procedures-Human (CMD(h)), building on the work already undertaken through the Best Practice Guide on the cooperation between the Mutual Recognition Facilitation Group (MRFG) and the PhVWP.
- Strengthening the existing peer review systems for the scientific work undertaken at the level of the CHMP and the PhVWP.
- Improving the methodology for benefit/risk analysis through the development of a Concept Paper which will be subject to public consultation.

Area of risk minimisation

The focus on risk minimisation activities will relate to initiatives aiming at arriving at a real Risk Minimisation Toolbox, characterised by reliable tools with measurable effects and criteria for their use. The introduction of risk management plans will be a first step in achieving such Risk Minimisation Toolbox.

Key initiatives

- Fully implementing the new legal concept of risk management plans submitted by pharmaceutical companies as part of their marketing authorisation applications.
- Monitoring such implementation and taking any remedial action, where considered necessary.

Area of risk communication

Risk communication activities over the next reporting period will concentrate on initiatives to arrive at an EU wide Transparency and Communication Strategy on safety related information which should lead to effective communication between all EU Regulatory Authorities and the pharmaceutical industry. The ultimate outcome should be effective and timely risk communication at EU level.

Key initiatives

- Initiating discussions with all involved parties on further increasing the transparency and streamlining the communication in the field of safety of medicines.
- Developing the component of an EU Transparency and Communication Strategy dealing with safety related information, including a Code of Conduct between the EU Regulatory Authorities and the pharmaceutical industry.

Other areas

Additional activities over the time period up to mid 2007 will target the full implementation of other new legal provisions, strengthening insufficiently developed fields of pharmacovigilance and further reinforcing the EU Pharmacovigilance System, leading to the establishment of a network of excellence at EU level.

Key initiatives

- Fully implementing all other new legal tools to further strengthen the safety monitoring and to further increase transparency in the field of safety of medicines, monitoring such implementation and taking remedial action, where necessary.
- Applying a more proactive approach in the field of paediatric pharmacovigilance by developing a Guideline on paediatric pharmacovigilance and by establishing an inventory of all sources of data collection at EU level.
- Reinforcing pharmacovigilance in the area of vaccines by developing a Concept Paper on vaccinovigilance and by initiating discussions with the European Centre for Disease Prevention and Control (ECDC) on the development of methods and processes for the conduct of high-quality post-authorisation studies.
- Optimising the utilisation of scarce resources by fully implementing established work-sharing concepts (i.e. in the field of Periodic Safety Update Reports (PSURs)) and by identifying additional fields of work-sharing.
- Enhancing the overall quality of the EU Pharmacovigilance System by ensuring the availability at EU level of top quality scientific expertise through the establishment of an EU-wide up-to-date inventory of the available scientific expertise (including expertise from academia and learned societies), through the reinforcement of competence development and through adequate workload and resource planning at EU level.

IV Reporting

Information on the follow-up to all initiatives will be provided in a yearly status report which will be made publicly available. The first status report (2006 ERMS Status Report) will be published at the beginning of 2007. The next rolling two-year work programme will also be made available during the first quarter of 2007.