EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 2
Update on the Implementation of the Pharmacovigilance Legislation

Management Board
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An agency of the European Union

Introduction (1/2)

- MB on 15 December 2011 agreed on a stepwise implementation using the following criteria for prioritisation:
  - Public health activities
  - Transparency and communication activities
  - Simplification activities (primarily for pharmaceutical industry)
- A Press Release and Implementation Plan on activities for 2012 were published on 2 February 2012

Introduction (2/2)

- Activities have been grouped into 4 topic areas:
  - Collection of key information on medicines
  - Better analysis and understanding of data and information
  - Regulatory action to safeguard public health
  - Communication with stakeholders
- The status as of mid March 2012 is presented, in terms of the main deliverables

Collection of Information (1/4)

RMPs	
Main deliverables	Status
• New business process	• Ongoing
• GVP module	• Ongoing (public consultation launched 22 February 2012)

PASS	
Main deliverables	Status
• New business process for CAPs	• Ongoing
• GVP module	• Ongoing (public consultation launched 22 February 2012)

Collection of Information (2/4)

PSURs	
Main deliverables	Status
• New business process for CAPs	• Ongoing
• GVP module	• Ongoing (public consultation launched 22 February 2012)
• Establishment of list of “Union Reference Dates” for PSUR submission	• Ongoing
• Development of interim arrangements due to delay in the “EU single assessment procedure”	• Ongoing

Collection of Information (3/4)

Article 57(2) implementation	
Main deliverables	Status
• Agreement with pharmaceutical industry on revised approach	• Completed (30 January 2012 workshop)
• Information to the Network	• Completed
• Communication with stakeholders	• Completed (05 March 2012)
• Availability of data entry tool	• Completed (05 March 2012)
• Data validation	• Planned
• Agreement on next steps	• Planned

Collection of Information (4/4)

Patient reporting	
Main deliverables	Status
• Agreement with MSs on utilisation of standard reporting forms	• Ongoing
• Guidance for patient reporting	• Planned
• Preparation for publication of aggregated ADR data for CAPs on EMA website	• Ongoing

Analysis and Understanding of Data (1/3)

EudraVigilance and signal detection	
Main deliverables	Status
• GVP module	• Ongoing (public consultation launched 22 February 2012)
• New business process for signal detection / management of CAPs	• Ongoing
• Process for supplying MSs with EudraVigilance data for signal detection for NAPs	• Ongoing

Analysis and Understanding of Data (2/3)

Additional monitoring	
Main deliverables	Status
• Development of list of medicines subject to additional monitoring	• Planned
• GVP module	• Planned
• Agreement on standard wording of patient information / selection of black symbol	• Ongoing

Analysis and Understanding of Data (3/3)

IT systems to support processing / analysis of data	
Main deliverables	Status
• Electronic PSUR repository and tracking tool	• Delayed
• Enhanced ISO EudraVigilance database	• Delayed
• EU medicines web-portal	• Delayed

Regulatory Action (1/3)

Scientific Committees and decision-making	
Main deliverables	Status
• Establishment of the PRAC	• Ongoing
• PRAC Rapporteur appointment principles	• Ongoing
• Clarification of PRAC involvement for non-CAPs	• Ongoing
• Development of interaction PRAC-CHMP, PRAC-CMD(h)	• Ongoing
• Addressing the legacy issue of the PhVWP for non-CAPs	• Ongoing
• Review of the Early Notification System	• Planned
• Revision of CMD(h) mandate	• Ongoing
• Development / revision of business processes	• Ongoing

Regulatory Action (2/3)

Referral procedures	
Main deliverables	Status
• Redesigning Art. 107i procedure, including new business process	• Ongoing
• Idem for “residual” Art. 20 and 31 procedures	• Ongoing
• GVP module	• Planned

Regulatory Action (3/3)

Pharmacovigilance inspections	
Main deliverables	Status
• GVP module	• Planned
• Procedures for inspection and follow-up	• Planned

Communication (1/2)

Online publishing of information	
Main deliverables	Status
• Vision on transparency level in terms of types of documents to be published and the document content	• Ongoing

Coordination of safety messages	
Main deliverables	Status
• Development of coordination process	• Ongoing
• GVP module	• Planned

Communication (2/2)

Public hearings	
Main deliverables	Status
• Vision on concept of public hearings	• Ongoing
• Development of criteria and modalities	• Planned

In Conclusion

- The vast majority of deliverables is on schedule
- A number of more “controversial” issues are currently being debated within the governance structure
- There are delays in the ICT field (as per the prioritisation agreed in December 2011)
- The EMA will at regular intervals communicate on progress made with the implementation (recent HMA agreement on a joint HMA/EMA public campaign also to be taken into account)