EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Implementation of the New Pharmacovigilance Legislation

2012 Implementation Plan

Stakeholder meeting
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In this presentation

- Reminder: objectives and scope of measures
- Prioritisation
- Focus on 2012 implementation

Reminder – background to the new legislation

- Excellent public health protection and promotion requires:
  - Law
  - Science
  - Resources

Background - Making of New Legislation

- 2003: EC decision to undertake an assessment of the Community system of pharmacovigilance
- Both **Regulation (EC) 1235/2010** and **Directive 2010/84/EC** published on 31 December 2010
- July 2012: new legislation will apply
- Some transitional provisions:
  - ADR reporting to EMA only,
  - PSUR reporting to EMA only,
  - Pharmacovigilance System Master File

Reminder: High Level Objectives

Promote and protect public health by reducing burden of ADRs and optimising the use of medicines:

- Clear roles and responsibilities / robust and rapid EU decision-making
- Engage patients and healthcare professionals
- Science based - integrate benefit and risk
- Risk based/proportionate
- Increased proactivity/planning
- Reduced duplication/redundancy
- Increase transparency and provide better information on medicines

Reminder: Scope of Changes

- Coordination / lists of medicines
- Authorisation requirements
- Risk Management Plans
- Post-Authorisation Studies (Safety and Efficacy)
- Effectiveness of risk minimisation
- Adverse Drug Reactions reporting
- Signal detection
- Periodic Safety Update Reports
- Scientific Committees / PRAC / decision-making
- Transparency and communication
- Coordination of inspections
- Pharmacovigilance Audits
- Fees charged and payments for assessments / services

Reminder: Impact

- Biggest change to the legal framework for human medicines since 1995
- Entire product life-cycle

Introduction

- Prioritisation of the implementation of the new legislation – stepwise implementation over the next years
- Criteria for prioritisation:
  - Firstly, public health activities
  - Secondly, transparency and communication activities
  - Thirdly, simplification activities (primarily for pharmaceutical industry)

2012 Implementation Plan (1/7)

4 main areas of activity

- Collection of key information on medicines
- Better analysis and understanding of data and information
- Regulatory action to safeguard public health
- Communication with stakeholders

2012 Implementation Plan (2/7)

Collection of key information on medicines:

- Risk Management Plans
  - Strengthening of the procedure
  - Operation of the revised procedure
- Periodic Safety Update Reports (PSURs)
  - Implementation of new procedure for CAPs
  - Preparation of a harmonised list for PSURs and publication of harmonised birthdates to support submission

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Collection of key information on medicines (cont'd):

- Post-Authorisation Studies
  - Implementation of the Post-authorisation safety study (PASS) procedure for protocol approval and results management for CAPs
  - Consultation on scientific guidance for Post-authorisation efficacy studies (PAES)
- Electronic submission of core medicine information by pharmaceutical industry and start validation of received information (Article 57)
  - Revised legal notice and guidance in the coming days

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Better analysis and understanding of data and information:

- EudraVigilance and signal detection
  - Operation of the revised process for CAPs
  - Support Member States to operate the new EU signal detection processes for NAPs
  - Start signal management through the Pharmacovigilance Risk Assessment Committee
  - Continuation of maintenance work for the current Eudravigilance system including data quality
  - Implementation of web publishing of adverse reaction data (further to the EudraVigilance Access Policy)

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Regulatory action to safeguard public health:

- Scientific Committee and decision-making
  - Establish the new Committee (PRAC)
  - Revise the mandate of the current CMD(h)
- Strengthening referral procedures
  - Operate the urgent Union procedure
- Additional monitoring
  - Develop and publish the list of medicines with additional monitoring status
- Finalise business requirements for enhanced IT systems

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Communication with stakeholders:

- Online publishing of information
  - Publication of CHMP and PRAC agendas, minutes, recommendations, opinions
- Coordination of safety messages
  - Operation of the coordination of Member States' safety announcements for NAPs
- Public hearings
  - Introduction of the novel concept of public hearings in the frame of the urgent Union procedure

2012 Implementation Plan (7/7)

- Continued development of detailed guidance on all aspects of the new pharmacovigilance legislation through GVP modules

Current Status

- Currently on target
- EMA intensifying the communication with stakeholders

Conclusion

- Excellent public health promotion and protection needs:
  - Science
  - Law
  - Resources
- New EU legislation on pharmacovigilance will deliver for health promotion and protection

Discussion