EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Report on Medication-errors (ME) workshop

Patients/Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) joint meeting, 5 June 2013

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Pharmacovigilance and Risk Management

Background

- **New EU pharmacovigilance legislation** requires
  - Reporting of suspected adverse reactions associated with ME to EudraVigilance [DIR Recital 5 and 17, Art 101(1)]
  - Member States to liaise with National Patient Safety Organisations [DIR Art 107a(5)]
- The aim of the workshop was to **facilitate the implementation** of these new legal provisions at EU level
- Other on-going activities**:**
  - WHO draft report on reporting and learning systems for ME
  - CHMP draft position paper on ME
  - FDA draft guidance for industry for product design to prevent ME

GVP Modules V and VI Definitions

- An **adverse reaction** is a response to a medicinal product which is noxious and unintended [DIR Art 1(11)]. This includes adverse reactions which arise from:
  - the use of a medicinal product within the terms of the marketing authorisation;
  - the use outside the terms of the marketing authorisation, including overdose, off-label use, misuse, abuse and **medication errors**;
  - occupational exposure.
- A **medication error** refers to any unintended error in the prescribing, dispensing or administration of a medicinal product while in the control of the healthcare professional, patient or consumer.

First EU Regulatory Workshop on ME

- 28th February – 1st March 2013, EMA premises, London
- Organised by the EU Regulatory Network and EMA
- Live broadcast to NCAs
- More than 240 participants (170 + 70 remotely)

The Programme

- *Session 1* Medication errors in the product lifecycle and special populations
- *Session 2* Reporting
- *Session 3* Analysis of medication errors resulting in harm
- *Session 4* Regulatory tools for managing the risk of medication errors
- *Session 5* Implementation of preventive measures
- *Session 6* The way forward (panel discussion)

Objectives of the workshop

- **Primary objective**: raise awareness amongst the stakeholders involved in the reporting, evaluation and prevention of medication errors to facilitate the implementation of the new legal provisions at EU level
- **Secondary objectives**:
  - Common understanding of what constitutes a medication error and the new legal requirements for reporting cases of medication error at EU level
  - Better understanding of how medication errors are managed at national level
  - Sharing best practice for the prevention of medication errors
  - Proposals to facilitate stakeholder co-operation at national and international level

Stakeholder representation

- Regulatory bodies: EU National Regulatory Agencies, European Medicines Agency, other international regulatory bodies (34)
- Public health bodies: National Patient Safety Organisations, European Commission's Directorate General for Health & Consumers Working Group for Patient Safety and Quality of Care, WHO (18)
- Healthcare professional organisations (16)
- Patient consumer organisations (6)
- Academia/learned societies (13)
- Pharmaceutical industry and their service providers (35)

Outputs of the workshop

- Press release and 'special topic' on EMA website ✓
- Presentations and broadcast published ✓
- **Meeting report with proposed action plan** for recommendations ✓
- **Publication** in a peer-review journal (Q2 2013)
- Concept paper for **regulatory and scientific guidance** on best practice for medication errors, including coding in EV (Q3 2013)
- Development of a **communication strategy** to enhance exchange of information between national competent authorities, pharmacovigilance centres and patient safety organisations
- Strategy to streamline EU (regulatory) **network resources**

Key findings of the workshop I

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1. ME may have serious impacts on patient safety (especially children, elderly).
2. Systematic assessment of the potential for ME during product development and post-authorisation is critically important.
3. Consider methods used by industry to contribute to the assessment of ME potential: failure mode and effects analysis (FMEA) and simulated user testing.
4. Tackling ME is complex since different organisations are involved in the collection of ADR reports and ME reports.
5. Need for closer collaboration between national patient safety authorities, national competent authorities, the EMA, and the European Commission.

Key findings of the workshop II

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6. Need for sharing and pooling information with other stakeholders to tackle ME earlier.
7. Need to improve reporting of ME by patients and HCPs by further engaging them.
8. Need to clarify legal implications of reporting systems.
9. Shortcomings in existing pharmacovigilance systems:
   a) Lack of an operational definition of ME which impairs a common approach to reporting, detection, classification and prevention
   b) Shortcomings in coding terminologies (e.g. MedDRA) cause problems for signal detection
   c) ME not resulting in harm (‘near misses’) are not captured

Recommendations for action

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I. Harmonisation and further development of terminologies and definitions at EU and international level.

II. Establishment of collaborative relationships between national patient safety authorities, national regulators, EMA and the EC.

III. Development of new methods to identify medication errors from a patient safety and pharmacovigilance perspective through data pooling and analysis.

IV. Systematic assessment and prevention of the risk of medication errors during the product life-cycle including prior to granting marketing authorisation through the EU risk management planning process.

V. Active engagement and capacity building with patient consumer groups and healthcare professionals to improve safe medication practices.

VI. Support to research into safe medication practices.

Conclusion

- The objective to raise awareness about the new reporting requirements for adverse reactions resulting from ME was achieved.
- There was broad consensus that ME are a global concern and need to be addressed in the broader context of patient safety.
- Such a vision requires the need for collaboration and synergies to be leveraged with different stakeholders and calls for action at different levels (national, international).
- The recommendations for actions (see **action plan**) suggest *Report page 14*
  - coordination of actions at EU or MS level, and
  - frameworks for implementation that leverage existing groups, guidance, committees and resources thereby allowing for the public health benefit without having to identify any new resources.

→ A prioritised action plan will be made public in Q4/2013

Any questions?

Legal basis I

Directive 2010/84 (EC) Recital (5)

For the sake of clarity, the definition of the term 'adverse reaction' should be amended to ensure that it covers noxious and unintended effects resulting not only from the authorised use of a medicinal product at normal doses, but also from medication errors and uses outside the terms of the marketing authorisation, including the misuse and abuse of the medicinal product.

Directive 2010/84 (EC) Recital (17)

Member States should operate a pharmacovigilance system to collect information that is useful for the monitoring of medicinal products, including information on suspected adverse reactions arising from use of a medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, including overdose, misuse, abuse and medication errors, and suspected adverse reactions associated with occupational exposure.

Legal basis II

Directive 2001/83/EC Article 1(11) - Definition

Adverse reaction: A response to a medicinal product which is noxious and unintended.

Directive 2001/83/EC Article 101(1)

Member States shall operate a pharmacovigilance system……to collect information on the risks of medicinal products as regards patients' or public health. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation….

Directive 2001/83/EC Article 107a (5)

Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations and/or institutions, responsible for patient safety within that Member State. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 25 of Regulation (EC) No 726/2004.