EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emerging Safety Issues

Sixth Stakeholders Forum on the implementation of the new Pharmacovigilance legislation, 8 November 2012

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What is new?

- GVP modules VI (ADR reporting) introduces Emerging safety Issues (ESI)
- MAHs to notify forthwith in writing MS and EMA of any ESI (as of July 2012)
- *Objective:*
  - ✓Ensure most appropriate management of new information which may have an impact on the risk benefit balance of the medicinal product or on public health
  - ✓Ensure efficient operation of the EU Regulatory Network

Emerging Safety Issues – examples 1/2

Module VI.C.2.2.6. Emerging safety issues

Events may occur, which do not fall within the definition of reportable valid ICSRs, and thus are not subject to the reporting requirements, even though they **may lead to changes in the known risk-benefit balance of a medicinal product and/or impact on public health.**

Examples include:

- major safety findings from a newly completed **non-clinical study**;
- major safety concerns identified in the course of a **non-interventional post-authorisation study or of a clinical trial**;
- safety issues published in the **scientific and medical literature**;
- safety issues arising from the signal detection activities (see Module IX);

Emerging Safety Issues examples 2/2

Examples include cont'd:

- signals of a possible **teratogenic effect**;
- safety issues related to the use within or **outside the terms** of the marketing authorisation;
- safety issues due to **misinformation in the product information**;
- marketing authorisation **withdrawal, non-renewal, revocation or suspension outside the EU** for safety-related reasons;
- **urgent safety restrictions** outside the EU;
- safety issues in relation to the **supply of raw material**;
- **lack of supply** of medicines.

Emerging Safety Issues – exchange of information

- Emerging Safety Issues should be communicated in writing to the competent authorities in **Member States** where the medicinal product is authorised and to the **Agency** via email (P-PV-emerging-safety-issue@ema.europa.eu); this should be done immediately when becoming aware of them.
- The document should indicate the points of concern and the actions proposed in relation to the marketing application/authorisation for the concerned medicinal product.
- ESI should also be analysed in the relevant sections of the periodic safety update report of the authorised medicinal product.

Thank you!