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EMA and EU national competent authorities agree on action plan to address medication errors

The European Medicines Agency and the National Competent Authorities of the European Union (EU) have agreed an action plan to address the issue of medication errors, a major public-health burden.

The overall objective of this plan is to facilitate the availability of tools to ensure that cases of medication errors causing harm are reported at national and EU level in compliance with the EU pharmacovigilance legislation and to optimise risk minimisation and/or prevention measures with regard to medication errors.

Medication errors are unintended errors in the prescribing, dispensing, administration or monitoring of a medicine by a healthcare professional, patient or consumer. They are the single most common preventable cause of adverse events in medication practice.

The EU pharmacovigilance legislation provides a clear legal framework for sharing data on medication errors causing harm. It requires reporting of all suspected adverse drug reactions resulting from medication errors to EudraVigilance, the EU database of adverse drug reactions.

In 2013, the EMA organised a workshop that brought together more than 240 participants from various stakeholder groups to determine a way forward for better reporting and prevention of medication errors.

Six key recommendations resulted from the discussions. The action plan published today foresees the development of guidance and other documents that aim to implement these recommendations for delivery by September 2015.

They include:

- a good practice guide focusing on the coding and reporting of medication errors, which will also define principles of data sharing between national patient safety authorities and national regulators. The assessment and sharing of signals of medication errors will also be addressed;
- a good practice guide on risk minimisation and prevention of medication errors, which will include aspects related to specific populations such as paediatric and geriatric patients.

The EMA and EU national competent authorities will co-lead the development of these two good practice guides.

As part of this action plan, the EMA is also developing a concept paper on the best use of the Medical Dictionary for Regulatory Activities (MedDRA) terminology to address medication-error specific coding, data retrieval and analysis issues. This paper will also consider the further development of Standardised MedDRA Queries (SMQs) and MedDRA's important medical events list, which are both used to support signal detection activities.

In addition, as part of the European Commission's Joint Action 'Strengthening Collaboration for Operating Pharmacovigilance in Europe (SCOPE)' coordinated by the United Kingdom's Medicines and Healthcare Product Regulatory Agency (MHRA), an awareness campaign on reporting requirements and communication tools in the context of healthcare delivery will be developed. The Agency will be involved as an observer in these activities.

All these developments will be undertaken in collaboration with the European Commission, through its Patient Safety and Quality of Care Working Group (PSQCWG).