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Medication Errors - Follow-up Actions from Workshop
Implementation Plan 2014 - 2015

1. Introduction

Medication errors with medicinal products are a major public-health burden and generally refer to mistakes in the processes of prescribing, dispensing, administering or monitoring medicinal products in clinical practice. Table 1 shows the incidence of medication errors in Europe[1]. An estimated 18.7 - 56% of all adverse drug events among hospital patients result from medication errors that would be preventable and are thus a concern at all stages of health delivery in European health care systems.

Table 1: The incidence of medication errors in Europe

Stage in the medication use system	Ambulatory care	Hospital settings	Comments
Prescribing	7.5%	0.3 – 9.1%	% of medication orders
Dispensing	0.08%	1.6 – 2.1%	% of medication orders
Administration	Not available		*Direct observation studies:*
		49.3%	IV medicines dose prepared on wards
		5.1 – 47.5%	Traditional floor stock or ward stock systems
		2.4 – 8.6%	Ward stock system with original prescription and daily ward visits by pharmacists
		7.2 – 9.1%	Patient prescription distribution systems
		10.5%	Unit dose drug distribution manual system
		2.4 – 9.7%	Unit dose drug distribution computerised or automated system

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[1] 'Creation of a better medication safety culture in Europe: Building up safe medication practices', Council of Europe Expert Group on Safe Medication Practices (2006).

2. Background

Since July 2012, the EU pharmacovigilance legislation [Directive 2001/83/EC, Recital (5) and (17), Article 1(11) and 101(1)] explicitly includes medication errors in the definition of a reportable adverse drug reaction (ADR). Article 107a (5) of Directive 2001/83/EC explicitly foresees liaison between national authorities for medicines and national patient safety organisations to improve public health. These new legal provisions present an opportunity for national and European collaboration to reduce the burden of harm from medication errors.

The European Medicines Agency (EMA) organised a workshop in February 2013 whose primary objective was to raise awareness among the stakeholders involved in the reporting, evaluation and prevention of medication errors of the new legal provisions at EU level with the aim to facilitate their implementation. It highlighted the need to address medication errors as a global concern in the broader context of patient safety and the need for collaboration and synergies to be leveraged with different stakeholder groups at both national and EU level.

The workshop concluded with six key recommendations:

- Systematic assessment and prevention of the risk of medication errors during the product life-cycle;

- Establishment of collaborative relationships between national patient safety authorities, national regulators, the EMA and the European Commission;

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

- Harmonisation and further development of terminologies and definitions at EU and international level;

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

- Support to research into safe medication practices.

The full workshop report is published on the EMA website.

The potential for medication errors in the context of benefit-risk balance and risk minimisation measures is also the subject of a CHMP position paper published on the EMA website in June 2013.

3. Current pharmacovigilance activities in relation to medication errors

In accordance with EU legislation the European Medicines Agency coordinates the scientific resources and expertise put at its disposal by Member States for the performance of pharmacovigilance activities, in particular the pharmacovigilance tasks performed by the Pharmacovigilance and Risk Assessment Committee (PRAC). The PRAC is responsible for providing recommendations in relation to the detection, assessment, minimisation and communication of risks of adverse reactions, including adverse reactions caused by medication errors. During its monthly plenary meetings the PRAC evaluates and provides recommendations to the Committee for Human Medicinal Products (CHMP) or the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) for regulatory action on safety issues arising through errors associated with the use of medicines authorised in the EU. The mandate of the PRAC also covers all aspects of risk management in the use of medicines, including the monitoring of the effectiveness of specific measures to minimise the risk of medication errors. The EU-RMP template contains a specific section (in Part II - Safety Specification) on the potential for medication errors based on pre- and post-authorisation data, including a review of

preventive measures for the final product being marketed. Accordingly, Periodic Safety Update Reports (PSUR) assessed by PRAC also include a dedicated section on medication errors that occurred during the reporting period. This information is taken into consideration in the continuous evaluation of the benefits and risks of a medicinal product.

The potential for medication errors associated with the name of a medicine is routinely assessed by the EMA's Name Review Group, whose mandate includes the assessment of medicinal product names from a safety and public health point of view prior to marketing authorisation.

4. Scope of proposed actions

Medication errors are a major public burden affecting key stakeholders such as patients, healthcare professionals, pharmaceutical industry and regulators, as well as health insurance companies and national patient safety organisations.

Several initiatives to tackle medication errors proposed during the workshop are closely related to patient safety, which is a Member State responsibility. The Heads of Medicines Agencies and the EMA have agreed an action plan with the overall objective to optimise risk minimisation and prevention of medication errors through the existing regulatory framework and to facilitate the availability of appropriate tools to ensure cases of medication errors causing harm are reported at national and at EU level in compliance with the legislation.

The coordination of EU activities to support Member States in reducing the public health burden caused by medication errors is also a major opportunity for national and European collaboration and will help

- To broaden the scope of pharmacovigilance with a focus on the entire medication process, including aspects of healthcare delivery;

- To further strengthen the EU regulatory network through facilitation of collaboration with patient safety organisations at national and EU level, i.e. through collaboration with the European Commission's Patient Safety and Quality of Care Working Group (PSQCWG);

- To strengthen the evidence base in pre- and post-authorisation phase to enable better regulatory decision-making for the prevention of medication errors;

5. Deliverables endorsed by HMA

Heads of Medicines Agencies (HMA) agreed on 28 November 2013 to the following deliverables being developed through existing development fora over a time period from January 2014 to September 2015. An overview of the deliverables and development frameworks is provided in Annex I.

5.1. Concept paper on a working group for best use of terminologies

This concept paper includes the establishment of a working group to address medication error specific coding issues and to develop search criteria with a Standard MedDRA Query (SMQ) and input in the important medical events (IME) list. This objective will be delivered through the existing MedDRA Points to Consider Expert Group in consultation with Joint EMA/EU Member States Project Team 1[2] for the implementation of the pharmacovigilance legislation and PSQCWG.

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[2] Joint EMA/EU Member States project team for the collection of key information on medicines set up for the implementation of the pharmacovigilance legislation.

5.2. Good practice guide on coding and reporting medication errors

This deliverable will be developed as a stand-alone guidance focusing on coding and reporting of medication errors and related terminologies from a patient safety and pharmacovigilance perspective. Confidentiality aspects of reporting systems and a policy on general principles of liability aspects for healthcare professionals reporting medication errors will be developed. Principles of data sharing between national patient safety and pharmacovigilance organisations and the assessment and sharing of signals of medication errors will be elaborated. The technical best practice guide may subsequently be integrated in GVP module VI on management and reporting of adverse reactions to medicinal products.

This good practice guide will be delivered by Project Team 1 through the existing governance structure for the pharmacovigilance legislation in collaboration with PSQCWG.

5.3. Good practice guide on risk minimisation and prevention of medication errors

This deliverable will be developed as a stand-alone guidance on risk minimisation and prevention of medication errors, including population specific aspects in paediatric and geriatric patients. The best practice guide may subsequently be integrated in GVP module V on risk management systems and/or module XVI on risk minimisation measures: selection of tools and effectiveness indicators.

The stand-alone good practice guide will be delivered by Project Team 2[3] through the existing governance structure for the pharmacovigilance legislation in collaboration with PSQCWG.

5.4. Awareness campaign on reporting requirements

This awareness campaign will delivered through the European Commission's Joint Action SCOPE[4] (formerly Joint Action on Pharmacovigilance) in consultation with Project Team 1.

5.5. Communication toolbox in context of healthcare delivery

This paper will delivered through the European Commission's Joint Action SCOPE in consultation with Project Team 3[5].

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[3] Joint EMA/EU Member States project team for better analysis and understanding of data and information set up for the implementation of the pharmacovigilance legislation.
[4] European Commission's Joint Action SCOPE is an EU wide pharmacovigilance project 'Strengthening Collaboration for Operating Pharmacovigilance in Europe' coordinated by the UK Medicines and Healthcare Products Regulatory Agency.
[5] Joint EMA/EU Member States project team for the communication with stakeholders set up for the implementation of the pharmacovigilance legislation.

Annex 1 – Deliverables and development frameworks

HMA Medication Errors Action Plan 2014-2015

Legend:
- ■ Lead Development (solid blue)
- ▢ Consultation/Input (dashed light blue)

Framework ▼ \ Deliverable ▶	Good Practice Guide — Coding & Reporting	Good Practice Guide — Risk Minimisation & Prevention	Concept Paper — Working Group	Awareness Campaign Reporting	Communication Toolbox
European Commission Joint Action SCOPE (Strengthening Collaboration for Operating Pharmacovigilance in Europe)	Consultation/Input			Lead Development	Lead Development
EMA / EU-Regulatory Network (Joint Project Team for Pharmacovigilance Legislation Implementation)	Lead Development	Lead Development	Consultation/Input	Consultation/Input	Consultation/Input
MedDRA Points to Consider Working Group	Consultation/Input		Lead Development		
European Commission Patient Safety & Quality of Care Working Group	Consultation/Input	Consultation/Input	Consultation/Input	Consultation/Input	Consultation/Input