EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 November 2015
EMA/787897/2015
Stakeholders and Communication Division

Streamlining EMA public communication on medication errors

1. Introduction

1.1. Background

Medication errors cause a large number of adverse drug reactions with negative patient health outcomes each year and have been highlighted worldwide as a major problem affecting the lives of patients with significant financial cost implications to healthcare systems.

There is no standard definition of a medication error which varies widely in the scientific literature. The good practice guide on recording, coding, reporting and assessment of medication errors (EMA/762563/2014) defines a medication error as “unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient”..

Medication errors fall broadly into four categories:

- Wrong medication
- Wrong dose (including strength, formulation, amount)
- Wrong route of administration
- Wrong patient

Medication errors do not always lead to adverse reactions but if they do these are considered preventable adverse events. The percentage of these types of adverse reactions rated potentially harmful is small, and although death or serious injuries occur only infrequently, any preventable adverse event has a cost to the healthcare system and the patient.

Reporting errors is fundamental to error prevention and improving patient safety. However, medication errors often go unreported especially if there is no harm associated. With the 2010 pharmacovigilance legislation, the system for monitoring the safety of medicines on the European market has been strengthened and now requires all adverse reactions resulting from medication errors at European Union (EU) level to be reported as part of the safety monitoring of each medicine.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

In particular, the term 'adverse reaction' has been amended and broadened 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.

1.2. Impact of medication errors

Though estimates vary across studies and countries, medication errors are responsible for millions of adverse events worldwide. Reported medication errors are only a small fraction of what really happens and the real rate is estimated to be between 2 and 14% of patients admitted to hospital, with estimations of around 1–2% of patients being harmed as a result.[1]

1.3. Actions taken to prevent medication errors

Recognition of the problem has led to increased efforts by national and international policy makers to find solutions to improve patients' safety. As a latest initiative the EU regulatory network has developed a good practice guide for pharmaceutical industry and regulatory authorities in Member States aimed to improve the reporting, evaluation and prevention of medication errors throughout the European Union (EU). This good practice guide is complementary to the guideline on good pharmacovigilance practices (GVP) and other existing guidelines published by the Agency. The guide can be found here.

Regulatory Authorities, the pharmaceutical industry as well as other stakeholders such as patient safety organisations and health authorities have an important role to play in reducing and preventing harmful medication errors, such as those that result from a medicine's name, package or label. Prevention strategies require actions in the pre-authorisation and the post-marketing phase of a medicine and involve collaboration between regulators, industry, medication error reporting programmes, healthcare practitioners and patients. Preventive actions can be taken at the level of the medicine (labelling packaging and nomenclature) or at the level of the medicine administration process (administration route and dosing regimen), and target the patient (patient engagement and disclosure), caregiver (education, teamwork and checklists), local workplace (culture and workplace changes) and the system (information technology and incident reporting systems).

Reporting is fundamental to detecting medication errors and improving patient safety. A variety of medication error reporting systems have already been established at national level to assess safety and to improve the medication use system to patients, on patient safety standard and a common definition of quality of care. Reports of suspected adverse reactions arising from errors associated with the use of a medicine will be reported to EU regulatory authorities and will also be made available to organisations responsible for patient safety. The fact that both patients and healthcare professionals are able to report suspected adverse reactions will further help to improve the detection of medication errors.

1.4. Existing communication tools and channels and benefits of effective communication

Education and communication are key elements in tackling medication errors. Currently, there are a number of communication tools and channels that authorities at national and European level can use to

[1] Medication errors have been estimated to harm 1.5 million people every year in the US (United States Institute of Medicine 2006), kill 7,000 patients per annum and account for nearly 1 in 20 hospital admissions in the US. The incidence is likely to be similar Europe.

alert and inform healthcare professionals and where necessary patients of the risks of medication errors and of the measures to prevent them from occurring. These include educational material, direct healthcare professional communications (DHPCs), newsletters, etc.

Proactive and effective communication on medication errors will help to meet the following objectives:

- contribute to the safe use of medicines;
- increase public awareness and recognition of medication errors;
- promote the reporting, discussion, understanding and prevention of medication errors;
- increase awareness and recognition of the important role of Regulatory Authorities in the prevention of medication errors;

So far, EMA has not consistently communicated on important issues related to medication errors assessed by its committees and when it has sporadically communicated so, this was following reports of medication errors with adverse events in the post-authorisation phase.

In this context, EMA is now proposing to streamline its current 'safety communications' to consistently capture key information related to medication errors which are assessed by its scientific committees.

2. Improving communication on medication errors

EMA will streamline current '(PRAC/CHMP) safety communication' so that *key* issues related to medication errors evaluated by the PRAC/CHMP (i.e. when non-routine measures are recommended) are consistently captured.

Any communication on medication errors issued centrally should be seen as complementary to any communication issued at national level, for which established tools and channels (mainly DHPCs, specific communication from national competent authorities, educational material, initiatives taken by national patient safety organisations, etc.) already exist.

Although research on the impact of communication on medication errors is limited, the research available suggests that given the high prevalence rates of medication errors and the role patients and consumers can play in identifying and preventing errors, there is a clear argument for increasing public awareness and understanding of issues relating to medication safety[2] and any information provided additionally to already existing communication may therefore be helpful. It is hoped that increasing awareness on medication errors will not only prevent errors from occurring but also promote the reporting of medication errors that do occur. Medication errors are still widely underreported and better reporting of medication errors is fundamental to making improvements in patient safety.

2.1 When will EMA issue safety communications relating to medication errors?

EMA will use current communication tools to communicate on medication errors for medicines assessed by the PRAC if either one of the following situations apply:

- Where additional risk minimisation measures are recommended (i.e. introduced in the assessment report and in the RMP) to reduce the risk of medication errors for a medicine.
- Where a DHPC has been agreed at EU level which specifically addresses medication errors.

[2] Hinchcliff R, Westbrook J, Greenfield D, Baysari M, Moldovan M, Braithwaite J. Analysis of Australian newspaper coverage of medication errors. Int J Qual Health Care. 2012 Feb;24(1):1-8. doi: 10.1093/intqhc/mzr067. Epub 2011 Nov 24.

2.2 Format of EMA communication

The communication will be presented in the format used for other EMA safety communications known as “EMA Public Health Communication”.

The information will target healthcare professionals and patients if appropriate (some safety briefs may be very technical and more targeted at healthcare professionals, i.e. medication errors related to the reconstitution of a medicine). The documents will contain a brief description of the medicine and the identified risk of the medication error; it will also highlight the measures introduced to prevent the error. They may contain links to relevant information such as updated product information, RMP summaries and presentation mock-ups where feasible and considered helpful.

EMA will update its website with general information on medication errors, which will be linked to relevant communications issued. It will also describe general activities undertaken by national competent authorities and EMA to reduce the risk of medication errors. For centrally authorised medicines, any communication issued will also be published on the EPAR page of the medicine concerned (displayed in the right hand menu).

2.3. Preparation of EMA communication

Preparation will follow the same steps as for other EMA safety communications, with close collaboration between EMA secretariat, CHMP and PRAC. Patient and healthcare professional organisations as well as external experts in communication on medication errors should be involved in the preparation of these documents to ensure that the information they deliver is useful, adapted to the target audience and aligned and complementary to related communication activities at national level. Communication will be systematically sent prior to publication on EMA website to the European Regulatory Network detailing the timelines for dissemination to ensure that national competent authorities can align their communication. Any communication will also be disseminated to relevant European healthcare professional organisations and European patient organisations to ensure that they reach the target audiences.

3. Impact evaluations

The impact of communication and whether it meets the desired objectives will be measured using standard tools such as website analysis and feedback from stakeholders based on regular surveys. The EMA Patients’ and Consumers’ Working Party (PCWP) and Health Care Professionals’ Working Party (HCPWP) will be involved in obtaining such information as well as feedback from national competent authorities.