Implementing good practice – industry experience with medication errors

Jo Emmott
Physician Support, Office of the EU QPPV
Merck Sharp & Dohme Ltd.

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Agenda

- Introduction
- Implementation of the Good Practice Guides: industry considerations
  - Recording
  - Coding
  - Reporting
  - Assessment, Risk Minimisation and Prevention
- Conclusions

Introduction

- Medication errors:

a major public health burden

Introduction

Good practice guide on recording, coding, reporting and assessment of medication errors

- ‘a key deliverable of the EU regulatory network’s medication error initiative to improve reporting and learning from medication errors for the benefit of public health’

Good practice guide on risk minimisation and prevention of medication errors

- ‘includes population-specific aspects in paediatric and elderly patients, as well as guidance on the systematic assessment and prevention of the risk of medication errors throughout the product life-cycle’

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015

EMA Good practice guide on risk minimisation and prevention of medication errors EMA/606103/2014; Nov 2015

Good Practice Guide Implementation: Industry considerations

- Recording
- Coding
- Reporting
- Assessment, Risk Minimisation and Prevention

Industry considerations: Recording

Medication Errors pre 2015:

- GVP Module VI (Rev 1)

> The guidance provided in this Module does not address the collection, management and reporting of events or patterns of use, which do not result in suspected adverse reactions (e.g. asymptomatic overdose, abuse, off-label use, misuse or medication error) or which do not require to be reported as individual case safety report or as emerging safety issues. This information may however need to be collected and presented in periodic safety update reports for the interpretation of safety data or for the benefit risk evaluation of medicinal products. In this aspect, guidance provided in Module VII applies.

- GVP Module VII (Rev 1)

> ***VII.B.5.9 2. PSUR sub-section "Medication errors"***
>
> This sub-section should summarise relevant information on patterns of medication errors and potential medication errors, even when not associated with adverse outcomes. A potential medication error is the recognition of circumstances that could lead to a medication error, and may or may not involve a patient. Such information may be relevant to the interpretation of safety data or the overall benefit-risk evaluation of the medicinal product. A medication error may arise at any stage in the medication use process and may involve patients, consumers, or healthcare professionals.

GVP Module VI Management and reporting of adverse reactions to medicinal products (Rev 1) EMA/873138/2011 Rev 1; Sep 2014
GVP Module VII Periodic safety update report (Rev 1) EMA/816292/2011 (Rev 1); Dec 2013

Industry considerations: Recording (new guidance concept)

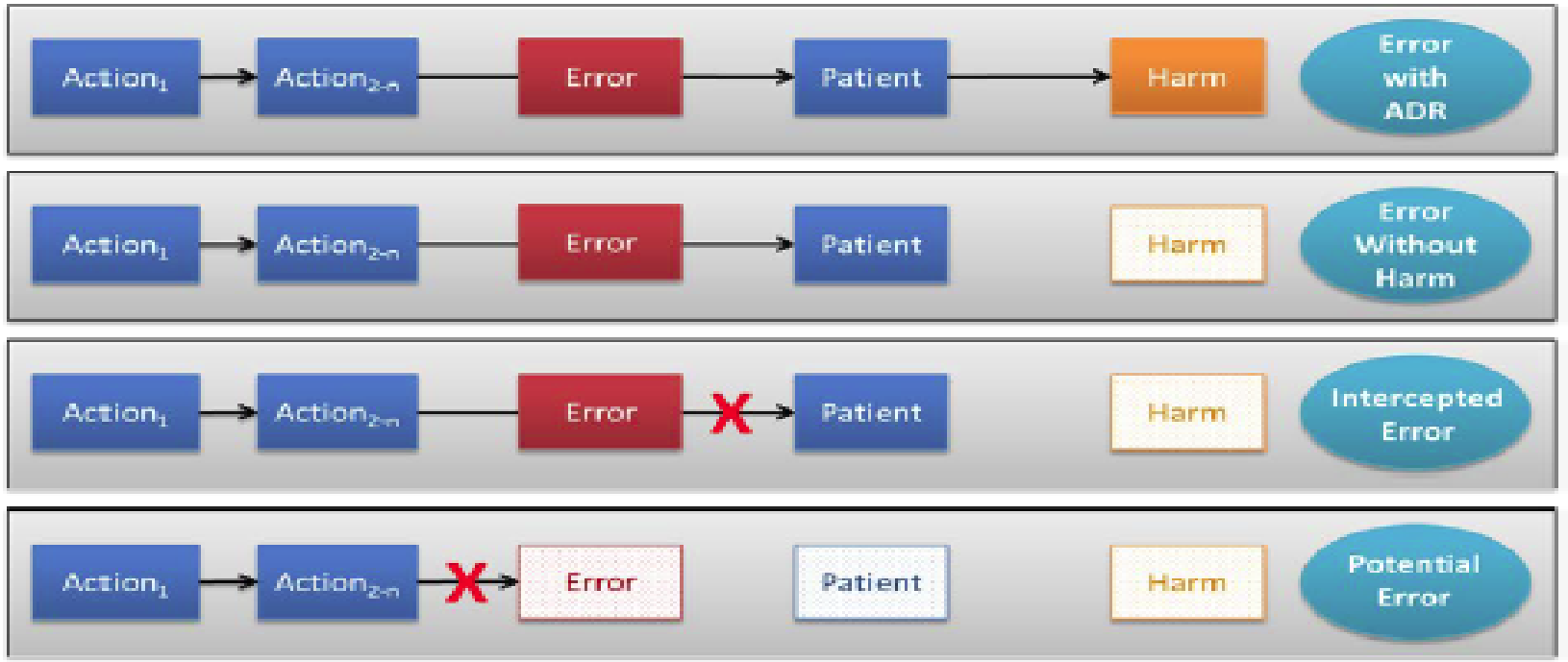

Figure 2: Concept for the classification of medication error reports for pharmacovigilance purposes. Depending on the break in the chain of events (represented by X), medication errors may be classified as error with ADR, error without harm, intercepted error and potential error.

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015.

Industry considerations: Recording (new guidance concept)

prescribing

storing

dispensing

preparing for administration

administering

Industry considerations: Recording

- Is everything that should be captured by drug safety being captured?

- Awareness and understanding of medication errors classification and reporting responsibilities by internal personnel
  - Customer facing staff
  - Staff facilitating 3rd party interactions
  - Staff involved in intake process

Industry considerations: Recording

- Decisions at the point of intake
  (Potential) medication error vs PQC vs customer feedback

5.2.8. Product quality issues versus medication errors

Product quality issues are abnormalities that may be introduced during the manufacturing, labelling, packaging, shipping, handling or storing process of a medicinal product. They should be distinguished and carefully evaluated if they fall in the definition of a medication error provided in chapter 4.3. For example, an underdose of antibiotic was administered because the lines on the dropper were hard to read which led to a medication error (accidental underdose).

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015

Industry considerations: Recording

- Education and training
  - Tailored to role/responsibilities
  - Working examples/scenarios
- Quality Management System

Industry considerations: Coding

- Education and training in medication error ‘concepts’ (with example scenarios) to ensure accurate interpretation of information and in turn, accurate coding

  Stage of medication error

  Intercepted vs potential medication error

  Intent of prescriber/patient

  ? off-label use, misuse, overdose, product use issue

- Above reflected in internal safety database manual for reference
- Availability of internal designated support network for discussion of complex cases (with sharing of learnings)

Industry considerations: Reporting

- Individual case level

  Disclaimer inclusion (in sender's comment or narrative) suggested in guidance, to address potential conflict between potential HCP liability and MAH's pharmacovigilance obligations

> *This suspected adverse reaction report is submitted and classified as a medication error solely and exclusively to ensure the marketing authorisation holder's compliance with the requirements set out in Directive 2001/83/EC and Module VI of the Good Pharmacovigilance Practices. The classification as a medical error is in no way intended, nor should it be interpreted or construed as an allegation or claim made by the marketing authorisation holder that any third party has contributed to or is to be held liable for the occurrence of this medication error.*

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015

Industry considerations: Reporting

- Disclaimer continued:
  - ‘Pros’ per guidance
  - Potential ‘cons’ include potential for data entry error (ie missed inclusion of standardised text/included in error), Rest of World impact

- ? include statement on follow up form (eg in medication error specific section)
- ? include statement in PSUR (in view of potential freedom of information requests etc)

Industry considerations: Reporting

- Aggregate reporting - PSURs

  Education and training of group/s involved in assessing case data/requesting/delivering data outputs (and internal authoring template updates) to enable:

  - Application of the concepts outlined in the good practice guidance
  - Use of the new tables A2-1 and A2-2 (including information on the Medication Errors SMQ)

Industry considerations: Reporting

Table A2-1: Template summary tabulation - numbers of Preferred Terms (PT) in the HLGT Medication errors reported with serious or non-serious adverse reaction(s) from post-authorisation sources* for <(invented) name>.

HLGT Medication Errors[1]	Spontaneous, including competent authorities (worldwide) and literature					Non-interventional post-marketing study and reports from other solicited sources **	
	Serious		Non-serious		Total Spontaneous	Serious	
	Interval	Cumulative	Interval	Cumulative	Cumulative	Interval	Cumulative
<HLT 1>							
<PT>							
<PT>							
<HLT 2>							
<PT>							
<PT>							

[1] Consider MedDRA HLTs such as *Accidental exposures to Product*, *Maladministrations*, *Medication Errors NEC*, *Medication Monitoring Errors* and other relevant HLTs as applicable.

* Non-interventional post-authorisation studies, reports from other solicited sources and spontaneous ICSRs (i.e., reports from healthcare professionals, consumers, competent authorities (worldwide), and scientific literature)

** This does not include interventional clinical trials conducted in accordance with Directive 2001/20/EC.

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015.

Industry considerations: Reporting

Table A2-2: Template listings of individual cases of medication errors of special interest and medication error not associated with adverse reaction(s) from post-authorisation sources*** for <(invented) name>.

Medication error of special interest (MedDRA Preferred Term(s) *or* class of error)	Reported adverse reaction(s) MedDRA Preferred Term(s) *or* brief description	Medication stage (prescribing, storing, dispensing, preparation, administration, monitoring)	Contributing factors (e.g. human behaviour, system related, transition of care, external beyond HCP/patient control)	Patient risk factors (e.g. paediatric, elderly, pregnancy, lactation, disease)	Ameliorating factors and corrective action(s)
<PT 1>					
<case 1>					
<case 2>					
Subtotals					
<PT 2>					
<case 1>					
<case 2>					
Subtotals					
Errors without harm					
<case 1>					
<case 2>					
Subtotals					
Intercepted errors					
<case 1>					
<case 2>					
Subtotals					
Potential errors					
<case 1>					
<case 2>					
Subtotals					

*** Reports from non-interventional post-authorisation studies and other solicited sources, reports from healthcare professionals and consumers and the scientific literature brought to the attention of the marketing authorisation holder

EMA. Good practice guide on recording, coding, reporting and assessment of medication errors EMA/762563/2014; Nov 2015.

Industry considerations: Reporting

- Module VII guidance consistent:

VII.B.5.9 2. PSUR sub-section "Medication errors"

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GVP Module VII Periodic safety update report (Rev 1) EMA/816292/2011 (Rev 1); Dec 2013

Industry considerations: Assessment, Risk Minimisation and Prevention

Good practice guide on risk minimisation and prevention of medication errors

This good practice guide is one of the key deliverables of the Agency's medication error initiative and offers guidance on risk minimisation and prevention of medication errors. The guidance includes population-specific aspects in paediatric and elderly patients, as well as guidance on the systematic assessment and prevention of the risk of medication errors throughout the product life-cycle.

- GVP Module V update awaited

EMA Good practice guide on risk minimisation and prevention of medication errors EMA/606103/2014; Nov 2015

Industry considerations: Assessment, Risk Minimisation and Prevention

Education and training of applicable internal group/s (and updates to internal template authoring guidance) to enable:

- Application of the concepts outlined in the good practice guidance documents (pre and post MA)
- Analysis/discussion of detailed examples of medication error scenarios eg those included in Annex 1, and the measures applied to minimise risk

Optimization of follow up information collection to enable:

- Determination of the root cause of the error
- Development of appropriate risk minimisation measures

Conclusion

- A clear understanding of the concepts within the Medication Error good practice guidance documents is crucial for their correct application and, to enable determination of the root cause of errors to be made. This in turn allows a more accurate assessment of a product's benefit-risk balance and the introduction of measures to minimize risk where needed.

- Communication at all levels is integral to the success of efforts to address this public health burden.

Ask