Welcome to the European MedDRA Users Group Webinar on ‘Update on Medication errors’

The session will be chaired by Ian Slack
Liz Thomas from the MSSO will provide technical support

Asking Questions

Using chat to ask questions during the presentation:
• Select Send to ‘Organizers & Panelists Only’
• Type your question into the chat box located at the bottom right corner of your screen.
• When finished typing your question click the ‘Send’ button.
• Questions will be collated and provided to the MSSO points to consider team for future consideration.

Frequently Asked Questions

• Will I be able to get a copy of these slides?
  YES

• Is this Webinar being recorded so that I or others can view it at a later time?
  YES
Welcome from the European MedDRA Users Group Steering Committee

Morell David  Barry Hammond  Jane Knight  Martin Menke

Ian Slack  Hilary Vass  Carol-Ann Wilson  Christina Winter

Agenda

• Introduction into EMA guidance/ Regulatory expectations
  - Victoria Newbould, EMA
• Amendments of MedDRA Term Selection: Points to Consider document
  - Hilary Vass, Biogen
• Medication error hierarchy in MedDRA v20.0 / New SMQ Medication errors
  - Tomás Moraleda, MSSO
• Group discussions – reviewing some previously submitted questions / examples
Introduction into EMA guidance/Regulatory expectations

Victoria Newbould
EMA

Amendments of MedDRA Term Selection: Points to Consider document

Hilary Vass, Biogen
Medication error hierarchy in MedDRA v20.0 / New SMQ

Medication errors

Tomás Moraleda
MSSO

Group Discussions
Group Discussions

• Patient reported that she was prescribed half a tablet daily and will be starting treatment soon. [Prescribing information states that slow release tablet should not be split.]

• Proposed Codes:
  – LLT Drug prescribing error (same PT)
  – LLT Tablet split incorrectly (PT Wrong technique in product usage process)

Group Discussions

• Only 50 ml was infused. Patient stopped infusion because site was leaking and drug run over skin. He decided to not finalize dosing as advised because he did not want to re-insert the needle.

• Proposed Codes:
  – LLT Infusion site leaking (PT Infusion site extravasation)
  – LLT Exposure via skin contact (PT Exposure via direct contact)
  – LLT Intentional underdose (same PT)
Group Discussions

• Doctor decided to prescribe higher than maximum recommended dose in label.

• Proposed Codes:
  – ????

• Options?
  – - Off label dosing
  – - Off label dosing and Intentional overdose
  – - Off label dosing and Prescribed overdose
  – - Intentional dose increase
  – - Intentional dose increase and Intentional overdose
  – - Intentional dose increase and Prescribed overdose
  – - Prescribed overdose

Group Discussions

• Patient called hotline and reported that she is intending to take OTC drug X for an indication that is not covered by the label. She did not take the drug yet.

• Proposed Codes:
  – ????
Group Discussions

• Patient received a contraindicated drug in error.
• Proposed Codes:
  – LLT Drug administration error (same PT)
  or
  – LLT Contraindicated drug administered (same PT)

THANKS
Group Discussions (Back-up slides)

- Mother gives vaccine X to her baby and is unaware the vaccine should be administered by a HCP.
- **Proposed Codes:**
  - LLT Drug administration monitoring procedure not performed (PT Drug monitoring procedure not performed)
  - LLT Drug administration error (same PT)

Group Discussions (Back-up slides)

- Patient was not weighed, dose was not calculated according to patient's body weight.
- **Proposed Codes:**
  - LLT Dose calculation error (same PT)
EU initiative on medication errors

- EU pharmacovigilance legislation requires:
  - Reporting of adverse reactions (ADR) associated with medication errors to EudraVigilance [DIR 2010/84/EU Recital (5) and (17), DIR 2001/83/EC Article 1(11) and 101(1)];
  - National competent authorities to liaise with national patient safety organisations [DIR 2001/83/EC Article 107a (5)] for exchange of ADRs caused by errors;
  - Facilitation of patient reporting [DIR 2010/84/EU Recital 21 and DIR 2001/83/EC Article 102];
- To support implementation of these provisions, the EU regulatory network organised a stakeholder workshop on medication errors in 2013 which resulted in key recommendations for tackling medication errors from a regulatory perspective;
- Based on these recommendations, a medication error action plan was agreed by EU Heads of Medicines Agencies (HMA);
Medication Errors Good Practice Guides

Good Practice Guide on recording, coding, reporting and assessment of medication errors


Good practice guide on risk minimisation and prevention of medication errors

Good Practice Guide on Medication Error - PRAC perspective

**Clear definition of medication error** including potential, intercepted errors relevant for regulatory decision making

**Recognition of patterns** or increased frequencies and of causes, contributing factors & clinical consequences of ME, including mitigating actions

**Expanded MedDRA terminology** version 19.0 in March 2016 and clarifications in PTC documents on coding conventions further increase granularity of ME reporting (ie. type of error, stage of medication use process can now be coded etc.)

**Electronic Reaction Monitoring Reports** made available to national competent authorities support signal detection activities via new SMQ for ME and separate ME reports (AMOMO)
Contents - GPG I Recording, coding, reporting, assessment

- Scope & legal basis
- Definitions and classification of ME
- Recording of medication error reports
- Coding medication error reports with MedDRA
- Reporting requirements for medication errors associated with adverse reactions
- Periodic reporting of medication errors without adverse reaction(s)
- Follow-up of medication error reports (typical parameters required for RCA)
- Rules of anonymisation of personal data and liability disclaimer
- Collaboration between national competent authorities (NCA) and patient safety organisations (PSO) for exchange of information on medication errors
- Annexes (templates, coding examples, business process for ICH E2B R3 etc.)

Definition

- Medication error
  - "A medication error is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient" (does not include lack of efficacy, process or human mediated failures) PTC more descriptive

- Potential error
  - "A potential error is the recognition of circumstances that could lead to a medication error, and may or may not involve a patient" (GVP Module VII.B.5.9);

- Intercepted error
  - "An intercepted error indicates that an intervention caused a break in the chain of events in the treatment process before reaching the patient which would have resulted in a potential ADR" (Good Practice Guide). The intervention has prevented actual harm being caused to the patient, e.g. a wrongly prepared medicine was actually not administered to the patient because the error was noticed by the nurse. PTC: 'medication error has occurred, but is prevented from reaching the patient or consumer. The intercepted error term should reflect the stage at which the error occurred, rather than the stage at which it was intercepted".
Feedback and comments on GPG

- Questions received GPG during public consultation
- Questions received in context of medication error info day October 2016 (to be considered at a later date)

5.2.2: General coding principles and MedDRA term selection

5.2.3.6. Ambiguous information

A report can only be best coded according to the information available. If the information is limited or ambiguous, attempts to follow up to ascertain missing or conflicting information should be made in line with GVP VI.B.3. If it is not possible to establish whether the event occurred due to an intentional decision made by the healthcare professional, patient or consumer, or whether it occurred unintentionally, it may be appropriate to use a more general MedDRA term from the HLT Product use issues NEC should be considered.
Unavailability

If a patient is unable to get a (repeat-) prescription (e.g. from pharmacy or from emergency supplies) or due to a manufacturing defect and as a consequence the patient experiences a deterioration of the underlying condition, this is not considered a medication error. In this context MAHs should consider notification of any withdrawal, suspension or cessation of marketing of a human medicinal product to the competent authority as applicable. A general product availability issue should be coded with the LLT Product availability issue, whereas if the product is unavailable due to supply chain issues the LLT Product supply issue may be more appropriate (Previous version: LLT Drug supply chain interruption).

Overdose

Overdoses are not necessarily considered to be medication errors unless unintentional overdose occurred as a consequence of an error. In this situation it is important to code both concepts in order to facilitate case identification in line with MTS:PTC, e.g. for an overdose as consequence of a prescribing error the LLT Accidental overdose and LLT Drug prescribing error should be used. Intentional overdose is not considered a medication error.
Quality issues vs error

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. This could be coded with the LLT Accidental underdose and LLT Product dropper calibration unreadable.

Examples in annex

Comment that the incorrect dose may be an assumption- clarification included:

<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient was switched to different insulin product without dose adjustment written on prescription and experienced hypoglycaemia</td>
<td>Drug prescribing error; Incorrect dose administered; Hypoglycaemia;</td>
<td>ADDED: The LLT Incorrect dose administered is provided based on the sender's knowledge of the product. This information may be provided in the Sender’s diagnosis or Sender’s comments data element.</td>
</tr>
</tbody>
</table>
Examples in annex

Comment - doesn’t say it was a product for child only

<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>A three-month-old baby was inadvertently given an ibuprofen syrup quantity measured prescribed for a 3-year-old child.</td>
<td>Child product given to infant; Incorrect dosage administered; Drug administered to patient of inappropriate age, <strong>Drug prescribing error</strong></td>
<td>Cannot assume an overdose although the inadvertent concept should be represented with an error term.</td>
</tr>
</tbody>
</table>

Comments on GPG and proposed revision

Examples in annex

Removal of example

<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient well-controlled on antiepileptic medicines failed to get repeat or emergency supply and was hospitalised with partial seizures</td>
<td><strong>Drug-supply chain interruption, partial seizures</strong></td>
<td>Removed example- not a medication error also see dose omission concept description</td>
</tr>
</tbody>
</table>
### Comments on GPG and proposed revision

#### Examples in annex

<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient noticed tablets didn’t look like usual but took anyway and passed out. Later found it was the wrong formulation</td>
<td>Wrong active ingredient in product; <strong>Tablet physical issue</strong> Incorrect product formulation administered Passed out;</td>
<td>(Wrong active is an assumption may be wrong formulation with same active- Tablet physical issue? Otherwise product formulation issue but then have 2 formulation codes?)</td>
</tr>
</tbody>
</table>

#### More specific LLTs available:

<table>
<thead>
<tr>
<th>Verbatim</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Box contained 2 vials of low strength instead of 1 of high, one of low. Patient used wrong strength and had increased intraocular pressure</td>
<td>Wrong and correct product strengths in same container; Wrong dose administered <strong>Accidental dose decrease</strong>, Increased intraocular pressure</td>
</tr>
<tr>
<td>Child swallowed up to 12 tablets due to faulty cap and vomited</td>
<td>Failure of child resistant mechanism for pharmaceutical product; <strong>Accidental drug intake by child</strong>, Accidental exposure to product by child; Vomiting</td>
</tr>
</tbody>
</table>
Proposal for process for using E2B (R3)

- E2B is electronic standard for reporting ICSRS and SUSARS in ICH region, E2B (R3) to be implemented towards end 2017

- Once implemented, the ICH E2B (R3) data element G.k.10.r ‘Additional information on drug (coded)’ should always be populated with the respective code for medication error at drug level (i.e. code 7) if the primary source has indicated that any type of medication error may have occurred

- The advantage of using the G.k.10.r flag is to identify medication error cases at drug level rather than only at case level

E2B (R3) and Medication errors - senders diagnosis

**E2B (R2)**

**B.5.3 Sender's diagnosis/syndrome and/or recategorization of reaction/event** This section provides the sender with an opportunity to combine signs and symptoms that were reported into a succinct diagnosis and the reasoning would be included in section B.5.4. MedDRA terminology.

**B.5.4 Sender's comments** This section provides information concerning the sender's assessment of the case and can be used to describe disagreement with, and/or alternatives to the diagnoses given by the initial reporter.

**E2B (R3)**

**H.3.r.1.b Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)** This data element provides the sender with an opportunity to combine signs and symptoms that were reported into a succinct diagnosis. Supporting rationale for the term selection is included in Section H.4.A MedDRA LLT code should be used.

**H.4 Sender's comments** This data element captures the sender's assessment of the case and can be used to describe disagreement with, and/or alternatives to the diagnoses given by the reporter(s).
EudraVigilance reporting trends

- Medication error reporting trends are increasing, 1.6% of all EEA and 2.3% of globally reported ICSRs in EudraVigilance are related to medication errors* by end of 2015;

*based on Narrow SMQ Medication Errors

Global top 10 PTS (from N SMQ list)
Summary/next steps

- Discussion ongoing how to address questions/comments and updates to GPG-MedDRA examples are out of date (Q&A, PTC companion document, revised GPG with/without public consultation?)

- Numbers of reports coded with a term from the Narrow SMQ medication error have steadily increased since 2008 with a peak around 2012

- Analysis of EV data can be used as a baseline to assess the impact of GPG in future including MedDRA (term availability and coding guidance)

- Potential further analysis:
  - Case review for data quality- are there gaps in coding guidance?
  - Case review for root cause analysis
  - Assess public health impact in order to identify any proposals for signal management prioritisation
THANK YOU
ICH MedDRA Term Selection: PtC Changes relating to Medication Errors in MedDRA 19.1

Hilary Vass
ICH M1 PtC Rapporteur
November 2016

ICH Points to Consider Working Group remit

- Author and update Points to Consider (PtC) documents for consistent use of MedDRA
  - Term Selection (MTS:PtC)
  - Data Retrieval and Presentation (DRP:PtC)
- Update PtC documents with each MedDRA version (twice a year) - based on user feedback
- Agree concept descriptions used only in the context of MedDRA
- Representatives from FDA, EU (MHRA, Italian Regulator), Health Canada, MHLW, WHO, PMDA, EFPIA and PhRMA together with EU, MSSO and JMO
ICH Points to Consider Working Group - June 2016 meeting

- Changes implemented in PtC: Term Selection MedDRA 19.1 - Sept 2016 were intended to clarify appropriate term selection
- Reviewed proposed revisions to the Medication error and Product use issues hierarchy
  - Proposals were posted as complex changes in July for implementation in MedDRA 20.0 (March 2017)
- Agreed further clarifications to be provided once complex hierarchical changes are available
- Produced condensed versions of PtC documents to be available in all MedDRA languages (except English and Japanese) in 2017

Intercepted Medication Errors (new concept description)

For the purposes of term selection and analysis of MedDRA-coded data, an intercepted medication error refers to the situation where a medication error has occurred, but is prevented from reaching the patient or consumer. The intercepted error terms reflect the stage at which the error occurred, rather than the stage at which the error was intercepted.

<table>
<thead>
<tr>
<th>Example</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>The physician prescribed the wrong dose of the drug; the error was identified at the time of dispensing</td>
<td>Intercepted drug prescribing error</td>
</tr>
<tr>
<td>The pharmacist dispensed the wrong drug but the patient realised the error and did not take the drug</td>
<td>Intercepted drug dispensing error</td>
</tr>
</tbody>
</table>
Drug dose omission (3.15.1.2)

- Dose omission is failure to administer an ordered dose but **excludes** patient’s refusal, clinical decision or other objective reason not to administer *

<table>
<thead>
<tr>
<th>Example</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient failed to receive his scheduled dose of drug X while in the hospital</td>
<td>Drug dose omission</td>
</tr>
</tbody>
</table>

* See Concept Description in Appendix B of the MedDRA Introductory Guide

Medication Error Terms - Labelled Interactions

<table>
<thead>
<tr>
<th>Reported</th>
<th>LLT</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient with renal failure is accidentally prescribed a drug that is contraindicated in renal failure</td>
<td>Labelled drug-disease interaction medication error</td>
<td>Product is labelled for this drug-disease interaction. The prescribing error term provides additional information about the nature of the labelled interaction medication error.</td>
</tr>
<tr>
<td>Patient with known sulfa allergy is administered a sulfonamide-based drug and experienced wheezing</td>
<td>Documented hypersensitivity to administered drug</td>
<td>This medication error refers to the situation when a patient is administered a drug that is documented in the patient’s medical file to cause a hypersensitivity reaction in the patient.</td>
</tr>
</tbody>
</table>
3.16.1 Misuse

For the purposes of term selection and analysis of MedDRA-coded data, misuse is the intentional use for a therapeutic purpose by a patient or consumer of a product - over-the-counter or prescription - other than as prescribed or not in accordance with the authorised product information.

<table>
<thead>
<tr>
<th>Example</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient deliberately took the medication twice daily instead of once daily</td>
<td>Intentional misuse in dosing frequency</td>
</tr>
</tbody>
</table>

Example LLT: Intentional use by incorrect route (PT Intentional product use issue) provides additional information about the nature of the drug abuse

Abuse

For the purposes of term selection and analysis of MedDRA-coded data, abuse is the intentional, non-therapeutic use by a patient or consumer of a product - over-the-counter or prescription - for a perceived reward or desired non-therapeutic effect including, but not limited to, “getting high”(euphoria). Abuse may occur with a single use, sporadic use or persistent use of the product.

<table>
<thead>
<tr>
<th>Example</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient deliberately ingested the topical medication for its psychoactive effect</td>
<td>Drug abuse</td>
</tr>
<tr>
<td></td>
<td>Intentional use by incorrect route *</td>
</tr>
</tbody>
</table>

* LLT: Intentional use by incorrect route (PT Intentional product use issue) provides additional information about the nature of the drug abuse
3.27 - Off Label Use

For the purposes of term selection and analysis of MedDRA-coded data, the concept of “off label use” relates to situations where a healthcare professional intentionally prescribes, dispenses, or recommends a product for a medical purpose not in accordance with the authorised product information.

When recording off label use, consider that product information and/or regulations/requirements may differ between regulatory regions.

3.28 - Product Quality Issues

Product quality issues are defined as abnormalities that may be introduced during the manufacturing/labelling, packaging, shipping, handling or storage of the products. They may occur with or without clinical consequences. Such concepts may pose a challenge for term selection.

<table>
<thead>
<tr>
<th>Example</th>
<th>LLTs</th>
</tr>
</thead>
</table>
| Patient reported severe burning in his nose after using nasal drops that had a cloudy appearance. An investigation by the manufacturer revealed that impurities were found in the batch of nasal drops and that these had been introduced by a faulty piece of equipment. | Nasal burning  
Product appearance cloudy  
Product impurities found  
Manufacturing equipment issue |

Specific product defects and issues with manufacturing systems may be reported subsequently as part of a root cause analysis.
Looking forward

- Aim for the changes made in this PtC version to not conflict with future changes to MedDRA hierarchy
- Eva will talk more about the complex changes
- ICH PtC Working Group are looking at ways to provide further examples outside of the PtC Term Selection document
  - Term selection is already quite large
  - Too many example can cause confusion and are difficult to translate and maintain
- Please send any comments, suggestions or feedback relating to the PtC documents directly to the MSSO

Thank you
Medication errors (SMQ) and revisions to the medication errors and product use issues hierarchies

Tomás Moraleda, International Medical Officer MSSO
15 November 2016

Agenda

- Medication errors (SMQ)
  - Background
  - Definition
  - Scope
  - In/exclusion criteria
- Revisions to the medication errors and product use issues hierarchies
  - Background to hierarchy revision
  - Overview of new hierarchy
  - Impact on coding medication errors
  - Retrieval considerations
Medication errors are defined as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing, order communication, product labeling, packaging and nomenclature, compounding, dispensing, distribution, administration, education, monitoring and use.*


**Medication errors (SMQ)**

- This SMQ is comprised of narrow and broad scope terms.
  - Term inclusion criteria was determined on the basis of test results to retrieve or be associated with cases of medication errors, including potential and intercepted cases.
- Testing was performed in:
  - Three regulatory databases across all products
  - One industry database using three different types of products with different delivery routes, including a device
- In production as of MedDRA Version 19.0
Medication errors (SMQ) (cont)

• Exclusion criteria

- Intentional/deliberate use terms: by definition these are not medication errors
- Product contamination terms
- Transmission of infectious agent terms
- Off label use terms, Drug interaction terms
- Counterfeit product terms, Drug incompatibility terms
- Exposure terms that do not refer to product or drug exposure such as PT Exposure to body fluid
- Terms for non-specific and broad concepts that might produce substantial “noise” in data retrieval, e.g. PT Device issue, PT Product quality issue, PT Poisoning, PT Treatment noncompliance

• Inclusion criteria

- Terms referring to a medication error according to the concept description*. These terms are included as narrow scope terms.

- Terms which do not specifically represent a medication error, but have a significant potential to identify medication errors for their frequent association with them, such as product label issue terms, product exposure terms, and terms referring to administration of contraindicated drugs or other unapproved uses. These terms are generally included as broad scope terms.

Medication errors (SMQ) (cont)

With MedDRA v19.1 there are 89 Narrow and 41 Broad PTs in this SMQ

<table>
<thead>
<tr>
<th>Narrow</th>
<th>Broad</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accidental device ingestion</td>
<td>Complication of drug implant insertion</td>
</tr>
<tr>
<td>Accidental device ingestion by a child</td>
<td>Contraindication to medical treatment</td>
</tr>
<tr>
<td>Accidental exposure to product</td>
<td>Contraindication to vaccination</td>
</tr>
<tr>
<td>Accidental exposure to product by child</td>
<td>Device adhesion issue</td>
</tr>
<tr>
<td>Accidental exposure to product packaging</td>
<td>Device connection issue</td>
</tr>
<tr>
<td>Accidental exposure to product packaging by child</td>
<td>Device difficult to use</td>
</tr>
<tr>
<td>Accidental overdose</td>
<td>Device infusion issue</td>
</tr>
<tr>
<td>Accidental poisoning</td>
<td>Device use issue</td>
</tr>
<tr>
<td>Accidental underdose</td>
<td>Device-device incompatibility</td>
</tr>
<tr>
<td>Accidental use of placebo</td>
<td>Difficulty removing drug implant</td>
</tr>
<tr>
<td>Booster dose missed</td>
<td>Exposure to contaminated device</td>
</tr>
<tr>
<td>Circumstance or information capable of leading to device use error</td>
<td>Exposure via contaminated device</td>
</tr>
<tr>
<td>Circumstance or information capable of leading to medication error</td>
<td>Exposure via ingestion</td>
</tr>
<tr>
<td>Contraindicated device used</td>
<td>Exposure via inhalation</td>
</tr>
</tbody>
</table>

References

- Introductory Guide for Standardised MedDRA Queries (SMQs) 2.60 Medication errors (SMQ)

- ICH MedDRA Data Retrieval and Presentation: Points to Consider. (See section 4, Standardised MedDRA Queries)

http://www.meddra.org/how-to-use/support-documentation
New MedDRA Hierarchy for Medication Errors in v20.0

Evolution of Medication Error(s) in MedDRA

- v 2.1 - LLT Medication error to PT Drug maladministration
- v 2.3 – PT Medication error to HLT Maladministration and accidental exposure
- v 8.0 – HLGТ Medication errors with 5 HLTs incl. HLT Overdoses
- v 18.0 – HLGТ Product use issues with 4 HLTs incl HLT Overdoses NEC
• Hierarchy advantages
  – Medication errors, misuse, off label use, overdoses, underdoses in same SOC
  – Miscellaneous product use issues
    • Intentional
    • Neutral/unspecified

• Hierarchy concerns
  – Addition of HLGT *Product use issues* has caused confusion for some users
    • Forces distinction between MEs and product use issues, but
    • Some terms in HLGT *Medication errors* don’t specify error or accidental vs intentional (e.g. “wrong” “incorrect”)
    • Neutral terms in HLT *Product use issues NEC* that could represent medication errors, misuse, or off label use e.g., PT *Drug administered to patient of inappropriate age*
New Hierarchy

- Discussed with expert groups
  - Points to Consider Working Group
  - MedDRA Expert Panel
- Posted complex change proposal for comments from MedDRA users (July-September 2016)
  - Majority of feedback in favor
- To be implemented in MedDRA Version 20.0 (March 2017)

Advantages

- Avoids force-classification of MEs vs. product use
- Classification by stage in the medication/product process (EMA Good Practice Guide Section 5.5.1)
- Intercepted medication errors under relevant stage HLTs
- Intentional concepts separated from errors/unspecified issues
- “Product” covers medication and other product concepts such as device use/error terms
Preview of New Hierarchy

Medication errors and other product use errors and issues
- HLT 1 Accidental exposures to product
- HLT 1 Medication errors, product use errors and issues NEC
- HLT 1 Product administration errors and issues
- HLT 1 Product confusion errors and issues
- HLT 1 Product dispensing errors and issues
- HLT 1 Product monitoring errors and issues
- HLT 1 Product preparation errors and issues
- HLT 1 Product prescribing errors and issues
- HLT 1 Product selection errors and issues
- HLT 1 Product storage errors and issues in the product use system
- HLT 1 Product transcribing errors and communication issues

Preview of New Hierarchy (cont)

Off label uses and intentional product misuses/use issues
- HLT 1T Intentional product misuses
- HLT 1T Intentional product use issues
- HLT 1T Off label uses
- HLT 1T Overdoses and underdoses NEC
- HLT 1T Overdoses NEC
- HLT 1T Underdoses NEC
Merged HLGT/HLTs

The following HLGTs and HLTs were merged (removed) in favor of the new hierarchy:

- HLGT *Product use issues*
- HLGT *Medication errors*
- HLT *Intercepted medication errors*
- HLT *Maladministrations,*
- HLT *Medication errors NEC,*
- HLT *Medication monitoring errors*
- HLT *Product use issues NEC*

- PTs re-allocated according to the stage of medication process where the error occurred

Data Retrieval Considerations

- New HLGT combines medication (product) errors and unspecified use issues
  - Advantage: Retrieve true errors and use issues often associated with MEs
  - Disadvantage: May be “noisy” if want to retrieve only true MEs
- Other terms that aren’t specifically MEs but have potential to identify MEs because of frequent association
  - Product quality issues
  - Device issues, e.g., malfunctions
  - Exposures
  - Compliance issues
- Hierarchy alone is not sufficient to retrieve potential cases
  - *Medication errors* (SMQ) may be supportive
Code list available in E2B (R3)

G.k.10.r Additional information on drug (coded) Especially helpful for “neutral” reports

- 1 = Counterfeit
- 2 = Overdose
- 3 = Drug taken by the father
- 4 = Drug taken beyond expiry date
- 5 = Batch and lot tested and found within specifications
- 6 = Batch and lot tested and found not within specifications
- 7 = Medication error
- 8 = Misuse
- 9 = Abuse
- 10 = Occupational exposure
- 11 = Off label use

Summary

- *Medication errors* (SMQ) implemented in March 2016
- New hierarchy to be implemented in March 2017
- Addresses issues identified by users
- Supports regulatory requirements for coding and reporting medication errors
Thank you