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On 11 June 2015, the CPME Executive Committee adopted the ' CPME response to the EMA Good practice guides on medication errors (CPME 2015/062 FINAL)

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The Standing Committee of European Doctors (CPME)[1] represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.

CPME welcomes the opportunity to comment on the EMA:

- good practice guide on recording, coding, reporting and assessment of medication errors (Guide 1 available here)
- good practice guide in risk minimisation and prevention of medication errors (Guide 2 available here)
- risk minimisation strategy for high strength and fixed combination insulin products, addendum to the good practice guide on risk minimisation and prevention of medication errors (Addendum available here)

Comments to the Good practice guide on recording, coding, reporting and assessment of medication errors (Guide 1 available here):

In January 2015, CPME had commented on a preliminary draft of Guide 1 in the framework of the Patient Safety and Quality of Care Working Group (PSQC WG) of the European Commission.
Part of these comments were taken into account, therefore CPME reiterates the following points that have not been included into the new draft version of Guide 1:

Line 199 – Adverse event often refers to as "medication related adverse event" - to make a difference with other kind of adverse events (eg. falls, infections, wrong side surgery). The document should make the distinction between "adverse events" and "medication related adverse events".

Line 206 – The categorisation of off-label use as a potential adverse drug reaction is questionable. If the possible negative effects are taken into account from the very beginning, they should not be considered as adverse reactions.

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.

Line 236 – The definition of medication error as proposed in the current draft document is as follows: *"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"*. In a previous draft document, the definition included a reference to medications errors caused by either omissions or commissions. We would advise to keep this reference to omissions and commissions. The definition should read: "*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. It can include an act or acts of omission or commission."* Indeed, omissions are among the most serious medication errors (for example omission of anti-coagulants) therefore the last part of the sentence should not be deleted.

Line 328 – The EMA document refers to Root cause analysis (RCA). Different methods are used for the analysis of medication errors and RCA is not always the most appropriate method. A systems analysis or a patient safety analysis may in some cases be more appropriate.

Line 401 - The guide envisages that Marketing authorisation holders (MAH) should learn from errors which come to their knowledge, but it does not envisage anything about how MAH should try to find those error reports. The national authorities should forward all reports (after anonymisation) to the companies, when they can be identified. For generics or other situations where MAH cannot be identified, the national authorities should publish anonymous trends for the use of the MAHs. This is important for the staff and patients who report- to know that the reports will then be used.

Line 547 - The Eudravigilance coding on medication errors should be revisited and amended to European work flows. We welcome categorisation of medication errors in a common database. The categories for medication errors in the Eudravigilance database is to our knowledge mainly based on pharmacist work flows. Other workflows should be covered so that the database categories reflect relevant error types.

Line 706 – Table 2 outlines the parameters to be followed when reporting medication errors. The table doesn't provide with the possibility to code into the reporting process that the substitution of a drug was done. Due to substitution, the actual product cannot always be identified. This should be taken into account when coding.
Furthermore, the coding list is very long. Neither clinical staff nor hospital administrative staff will or can spend too much time on reporting and classifying. The most important is a good and simple system for harm reporting, including potential harm.

Line 1066 - The role of PRAC: Since medication errors is a problem with the same magnitude as other adverse reactions, PRAC should include members with this expertise. The same goes for EMA staff and staff in national authorities.

Comments to the Good practice guide in risk minimisation and prevention of medication errors (Guide 2 - available here)

In addition to the draft Guide 1, CPME has the following comments to draft Guide 2 on good pratice guide in risk minimisation and prevention of medication errors:

Line 1292 - Suggestion for addition to the paragraph on Products for IV use or parenteral administration: Instructions for calculating when robots are dispensing should be part of SPC. This has to do with how the whole bottle content is expressed – is it the actual content or is it the content, that can be extracted from the bottle (assuming some medication is left behind). In Denmark for instance, this has caused a major incident.

Line 1307 – General considerations: Educational material and/or SPC should, when relevant, include calculation tablets in which dose is calculated from mg per weight or per Body surface or per renal function into actual dose. This is particularly relevant for pediatrics and for orphan drugs.

Annex 2 – The following information could be added:

- Numbers like 12,5 mg vs 125 mg 1 mg vs 10 mg, 2 mg vs 20 mg, can easily be mixed up. Suggestion to use numbers that differ more, i.e. 3 mg vs 20 mg, 2 mg vs 10 mg etc.
- Establish agreement among companies on colour coding for particular forms or medications dealing with the same disease – for the safety of the patient.
- Point out clearly in the SPC when particular errors are known to have caused serious harm. For instance methotrexate causes serious harm if given daily for two weeks.

Comments to the risk minimisation strategy for high strength and fixed combination insulin products, addendum to the good practice guide on risk minimisation and prevention of medication errors (Addendum available here)

Table 3 - The table should include a focus on the long term storage (cold) of insulin products at patients´ home

Line 99 - The guide should consider the eventual use of (high strength) insulin in hypo kaliemia. Use of insulin without additional glucose has caused deaths in EU.

Line 99 - The guide should take into consideration that patients in hospitals and nursing homes have name labels on their pen devices – hiding part of the colour coding.

Line 99 - The MAHs should agree on suffixes and colour codes to indicate mix/long term, etc.