

Highlights of the Resolution on Good Reconstitution Practices in European health care establishments

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High risk medication and patient safety

The aseptic preparation or reconstitution of parenteral medicinal products in health care establishments is crucial for patient safety. Errors in the preparation of these high risk medicines may lead to a product that can cause immediate harm to patients. Errors have been shown to be associated with additional morbidity and mortality in an already critically ill population. The preparation of parenteral medicines in health care establishments is a process that carries high risks of microbiological contamination and incorrect product composition. Parenteral medication errors are a serious safety problem and are recognised as a high-priority topic in health care establishments.

High risk medication and health care establishments

Aseptic preparation is carried out in hospital pharmacies as well as in clinical areas in health care establishments such as wards and operation theatres. In these different locations the risk profile may be different, depending on the conditions that exist in the location such as, for example, the premises, the personnel and the equipment.

In many cases parenteral medicines with a marketing authorisation cannot be administered directly to patients, i.e. they are not presented in a form which is ready to administer. Before administration to patients, these medicines have to be reconstituted. Reconstitution is defined as the manipulation to enable the use or application of a medicinal product with a marketing authorisation in accordance with the instructions given in the summary of product characteristics (SmPC) or the patient information leaflet. Reconstitution has a special position; it can neither be seen as industrial manufacture nor as a routine pharmacy preparation.

Resolution of the Council of Europe concerning high risk medication

At present, legislation and/or guidance concerning reconstitution of high risk medication are missing or insufficient in most of the countries of the Council of Europe. The draft Resolution concerning Good Reconstitution Practices was set up by the Committee of Experts CD-P-PH/PC, coordinated by the European Directorate for the Quality of Medicines and HealthCare (EDQM) [1] (Council of Europe), and the resulting Resolution was adopted by the Council of Europe's Committee of Ministers on June 1st, 2016 (in its composition restricted to the representatives of the States Parties to the Convention on the Elaboration of a European Pharmacopoeia, i.e. 37 Member States) [2].

Different roles for authorities and health care establishments in improving patient safety with high risk medication (according to Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use)

National authorities

National authorities are encouraged to develop specific legislation and guidance on reconstitution based on the recommendations of the Resolution.

Health care establishments

The management is expected to ensure that the conditions for aseptic preparation of high risk medication in the different locations within their health care establishments are adequate, i.e. systems are in place for reconstitution; resources are provided for safe reconstitution; the decision is taken where to reconstitute safely; regular risk reviews are performed and the parenteral manual is authorised.

Designated person

The nomination of a specific person in the health care establishment with appropriate qualifications with overall responsibility for the reconstitution process of high risk medication is recommended. The designated person should have a clear mandate and direct access to the health care establishment management. Responsibilities of the designated person include:

- the quality management system (standard operating procedures and practices; documentation);
- ensuring appropriate training of personnel;
- approval of decision where to reconstitute which products (based on risk assessment);
- preparation of parenteral manual (contents), which provides technical information on how to handle high risk medication.

Challenging new role of the hospital pharmacist

The designated person should preferably be a pharmacist; if this is not the case, the person should be of suitable training and have appropriate experience to perform this role. The position of the designated person offers a challenging opportunity for hospital pharmacists in Europe to contribute to patient safety in their health care establishments. Provided that they have a clear mandate, hospital pharmacists can have a leading role in the health care establishment to ensure patient safety.

Minimum requirements (standards) for reconstitution

The designated person and the management of the health care establishment should ensure that there are minimum requirements for high risk medication. These requirements include for example:

- Quality system in the clinical area to encompass reconstitution.
- Overall standard operating procedure for reconstitution practices.
- Detailed instructions for safe reconstitution of each product (parenteral manual).
- Procedures for labelling of each product (check on prescription, product and patient).
- Documentation of individual reconstitutions (incl. calculations).
- List of medicinal products which can be reconstituted safely in the clinical area.
- Documented evidence of personnel's competency.

Risk assessment

A risk assessment for the reconstitution of each medicinal product should be performed in the health care establishment taking into account the most relevant risk factors. Prospective and retrospective risk analysis and auditing are useful methods that may yield divergent views on

risks in hospitals. Since all these methods may have their bias, their combined use provides managers with a more complete and balanced picture of risks. A checklist is included in the Resolution.

The main purpose of the risk assessment performed in the health care establishment for all medicinal products (e.g. group-wise assessment) is to make a hierarchy of all medicinal products, ranked in order of their reconstitution risk. The risk review is documented and signed by the designated person and manager of clinical area. Based on this risk assessment the managing board of the health care establishment should decide and document which medicinal products should be reconstituted in a pharmacy and which medicinal products can be safely reconstituted in clinical areas. This hierarchy should be regularly reviewed and risks reassessed. When reconstitution takes place in clinical areas, the designated person and manager of clinical area should approve standard operating procedures and ensure that the personnel involved in reconstitution are appropriately trained.

Application of the rules for high risk medication is necessary

Application of the rules for quality and safety for high risk medication, adopted by the Council of Europe, is necessary for the benefit of the patient. The rules are set up in cooperation with the European Association for Hospital Pharmacy (EAHP).

At the 23rd EAHP congress in Gothenburg (Sweden) (21-23 March 2018) [3] a seminar will be held to discuss the topic of safe reconstitution of high risk medication in health care establishments: Seminar PC5 (22 March 2018; 12h00-13h30): Presentation and workshop dedicated to the implementation of the Resolution [CM/Res(2016)2] on good reconstitution practices in European hospitals. Speakers: Dr. H. Scheepers; Dr. P. Le Brun.

References

1. Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Pharmaceutical Care (CD-P-PH/PC) – EDQM (Council of Europe) (link: <https://go.edqm.eu/PC>)
2. Resolution CM/Res(2016)2 on good reconstitution practices in health care establishments for medicinal products for parenteral use (*Adopted by the Committee of Ministers on 1 June 2016 at the 1258th meeting of the Ministers' Deputies*) (link: <https://go.edqm.eu/Res20162>)
3. 23rd Congress of the EAHP, 21-23 March 2018, Gothenburg (Sweden) (link: <http://www.eahp.eu/congresses>)