Health Care Inspectorate
Ministry of Health, Welfare and Sport

CoE Resolution Good Reconstitution Practices (GRP)

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EAHP

Conflict of interest:
nothing to disclose

Question 1

The European Directorate for the Quality of Medicines (EDQM) is a directorate of the Council of Europe.

Yes is green

No is red

Question 2

The resolution on good reconstitution practices (Resolution CM/Res(2016)2 was prepared to improve safety of reconstitution in clinical areas

Yes is green

No is red

Question 3

The GRP resolution recommends that the designated person should preferably be a pharmacist.

Yes is green

No is red

Goals for the workshop

• To discuss the Council of Europe Resolution Good Reconstitution Practices (CM/Res(2016)2).

• To discuss its implementation in daily practice and potential suggestions.

• To familiarize with the checklist for identification, assessment and reduction of risks posed by reconstitution of medicinal products.

Workshop plan

- Headlines of the Council of Europe Resolution Good Reconstitution Practices (Resolution CM/Res(2016)2) (±20 minutes)

- Interactive discussions and case studies (group activities) (±40 minutes)

- Discussion and final thoughts (±20 minutes)

- Questionnaire to be answered (±10 minutes)

EDQM

- European Directorate for the Quality of Medicines & HealthCare.
- A Council of Europe's Directorate.
- Based on the Convention on the Elaboration of a European Pharmacopoeia (1964).
- Leading organisation that protects public health through the development and the implementation of quality and safety standards for medicines.

Committee of Experts on Quality and Safety Standards in Pharmaceutical Practices and Care (CD-P-PH/PC)

• Mission: improve pharmaceutical care and practices through specific programmes and policies.

• Composition: representatives from the relevant health authorities from member states parties to the Ph. Eur. Convention.

• Activities (examples):

- Resolution CM/Res(2016)1 on pharmacy preparation of medicinal products;
- Automated Dose Dispensing (ADD) guidelines;
- CoE Resolution ResAP(2007)2 on good practices for distributing medicines via mail order.

CoE Resolution Good Reconstitution Practices

- Resolution of the Council of Europe (Resolution CM/Res(2016)2).

- Adopted by the Committee of Ministers on June 1st, 2016 (37 Member States parties to the Ph. Eur. Convention).

- Draft Resolution set up by the Committee of Experts CD-P-PH/PC.

- Rapporteur: H. Scheepers (NL).

- Recommendation (soft law) to member states to adapt their regulations in accordance with the provisions in the Resolution, taking into account the national frameworks.

CoE Resolution Good Reconstitution Practices

- Draft text prepared in cooperation with EAHP.

- Draft Resolution working group:
  - Dr. V. Neerup Handlos, EAHP
  - Dr. A. Beaney, EAHP
  - Dr. P. Le Brun, EAHP
  - Dr. H. Scheepers, rapporteur Committee of Experts.
  - Delegations of the Committee of Experts CD-P-PH/PC.

CoE Resolution Good Reconstitution Practices (GRP)

Background and scope

- GRP in health care establishments.
- Not primarily aimed at hospital pharmacies but at clinical areas in health care establishments.
- Medicinal products for parenteral use (High Risk medication).

CoE Resolution Good Reconstitution Practices

- Definition reconstitution: manipulation to enable the use in line with SmPC or package leaflet.

- If it is not reconstitution, or not according the SmPC, then preparation (Resolution pharmacy preparations CM/Res(2016)1).

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Responsibilities

1. Authorities: development of specific legislation and guidance on reconstitution.

2. Management health care establishment:
- systems in place for reconstitution.
- nominate the designated person.
- provision of resources for safe reconstitution.
- decision where to reconstitute safely.
- regular risk review performed.
- authorisation of parenteral manual.

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3. Designated person health care establishment:

- Mandate.
- responsible for quality management system (SOPs / documentation).
- ensuring appropriate training of personnel.
- approval of decision (which products in which clinical areas).
- preparation of parenteral manual (contents).
- preferably a pharmacist.

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Risk assessment

- Overview of all GRP activities throughout the hospital.
- Hierarchy of medicinal products, ranked in order of reconstitution risk.
- Basis for decision of managing board which products should be reconstituted where (pharmacy, clinical area).
- Risk review documented and signed by designated person and manager of clinical area.
- Regular review of risks through a checklist.

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Minimum requirements (standards) clinical area

- Quality system that encompasses reconstitution.
- Overall SOP for reconstitution.
- Detailed instructions for safe reconstitution of each product (parenteral manual).
- Procedures for labelling of each product (prescription, product and patient).
- Documentation of individual reconstitutions (incl. calculations).
- Per clinical area a list of medicinal products which can be reconstituted safely.
- Documented evidence of personnel’s competency.

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Conclusions

- Resolution CM/Res(2016)2 implementation crucial for increasing safety for patients receiving high risk medication:
  - Designated person for GRP (preferably a pharmacist).
  - Minimum requirements for reconstitution in clinical areas.
  - Risk assessment as a tool (which products can be reconstituted where?).
- A major challenge for hospital pharmacists!

CoE Resolution Good Reconstitution Practices

Details and contact details to be found on the website of CoE/EDQM:
http://www.coe.int/cm.

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).

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Any questions?