

# EDQM Webinar: 'Resolution on good reconstitution practices' – the hospital pharmacy perspective

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## European Association of Hospital Pharmacists

EAHP represents and develops the hospital pharmacy profession within Europe in order to ensure the continuous improvement of care and outcomes for patients in the hospital setting.

Engagement areas:

- (1) Education
- (2) Professional / scientific projects
- (3) Policy

*35 member organisations  
Representing 23,000 hospital pharmacists*



## Reconstitution Resolution – considerations (I)

- Hospital pharmacists are responsible for the medication workflow and the therapeutic aspects of compounding/reconstitution
- Many European countries have put in place guidelines in relation to reconstitution practice (either at national or hospital level) → development by (hospital) pharmacists in cooperation with other healthcare professionals

## Reconstitution Resolution – considerations (II)

- Resolution Res/CM(2016)2 → Minimising risks & increasing patient safety
- Hospital pharmacy engagement is key for the successful implementation of the Resolution (setting procedures & training personnel)

**EAHP's Position Paper on Pharmacy preparations and compounding**

[www.eahp.eu](http://www.eahp.eu)

## Implementation in Europe (I)

### Austria

- There is no law that transposes the Resolution
- Guidelines covering reconstitution on wards and hygiene measures are usually in place in every hospital, provided in a cooperation by the quality department, the hospital pharmacy (if available) and the hospital hygiene department.
- Reconstitution of cytotoxic medicines has to take place in (hospital) pharmacies only. A law covering this exists.

### Croatia

- No specific law was adopted.
- The Resolution's provisions are implemented in a few hospitals, but this applies only to reconstitution and preparation of antineoplastic medicines.

## Implementation in Europe (II)

### France

- There is no law in France that transposes the Resolution

### Germany

- Integration of Resolution into the 'Interpretation aid for the supervision of the manufacture of sterile medicinal products, in particular parenterals, by physicians or other persons authorised to practice medicine under the Medicinal Products Act' created by the Working Group on Medicinal Products, Pharmacies, Transfusions and Narcotics
- The interpretation aid is used by monitoring authorities as a common basis for assessing the situation during audits

## Implementation in Europe (III)

### Hungary

- No law transposing the Resolution
- Law regulating pharmacies refers to guidance of the national competent authority → making it mandatory to follow
- Regularly updated guidance for compounded pharmaceuticals and IV preparations, incl. their reconstitution, mixtures of infusions and cytotoxics

### Italy

- There is no specific law. But there are two Health Minister recommendations on the handling of antineoplastic drugs and on the manipulation of drugs for oral administration.
- If the pharmacist is involved in the preparation then the Italian Pharmacopoeia is applied, otherwise the SmPC is the only tool for drug reconstitution.

## Implementation in Europe (IV)

### Latvia

- There is no law transposing the Resolution.
- It's partly implemented in one hospital and implementation started in another hospital. COVID is currently the main priority of Latvia due to this there is no wider implementation at the moment.

### Luxembourg

- Reconstitution of chemotherapy, biotherapy, parenteral nutrition and all the hazardous drug centralised in the pharmacy.
- Hospital pharmacists are involved in the assessment of nurses practices and give all the information for a good and a safe reconstitution.

## Implementation in Europe (V)

### Norway

- The resolution's provisions are implemented in Norwegian law ("The drug handling regulation")

### Netherlands

- The implementation has triggered a total review of the reconstitution guidelines. Several items from the Resolution were already standard practice.
- In a multidisciplinary team (including representatives from hospital pharmacies, community pharmacists, nurses etc) the current guidelines are reviewed and the resolution is integrated in the new guidelines.
- A concept of the guideline is available, implementation is foreseen for 2022.

## Implementation in Europe (VI)

### Poland

- There is no legislation that transposes the Resolution.
- The Polish Hospital Pharmacy Associations is spreading knowledge about the Resolution.
- Some pharmacies are following the recommendations and solutions proposed by the Resolution are partially adopted in the National Pharmacopoeia Monograph "Pharmacy prepared medicines". The ward drug preparation risk management system is not implemented.

### Portugal

- No specific legislation exists.
- Effort to ensure that the entire production of cytotoxics (incl. immunotherapy) is internalised by hospital pharmacies
- There is no formal "National Parental Manual" but there are 2 books written by 2 Portuguese hospitals, which are used by pharmacists and by other professionals in an informal way.

## Implementation in Europe (VII)

### Serbia

- The Resolution was used in the process of drafting the "Good Pharmacy Practice" document, which has been successfully adopted after many years.
- It helped to raise the standards of hospital pharmacy and increase patient safety.
- Parts of the Resolution may help hospital pharmacists to perform some risk assessment at an individual hospital level and this will be conducted as well in the future on a regular basis.

### Slovenia

- The Resolution was not incorporated into the Slovenian Pharmacy Act
- To some extent the resolution is applied in several Slovenian hospitals

## Implementation in Europe (VIII)

### Slovakia

- The Slovak Pharmaceutical Chamber decided to initiate the preparation of a national guideline as an implementation of the Resolution.
- There are several hospitals where local hospital guidelines/manuals for the reconstitution and dilution of parenteral drugs that have been developed by hospital pharmacists in cooperation with the medical team (nurses, physicians, pharmacist assistants). These guidelines contain some or all of information included in the Resolution.

### Spain

- The resolution's provisions are implemented in daily practice even without any transposition into national legislation.

## Implementation in Europe (IX)

### Sweden

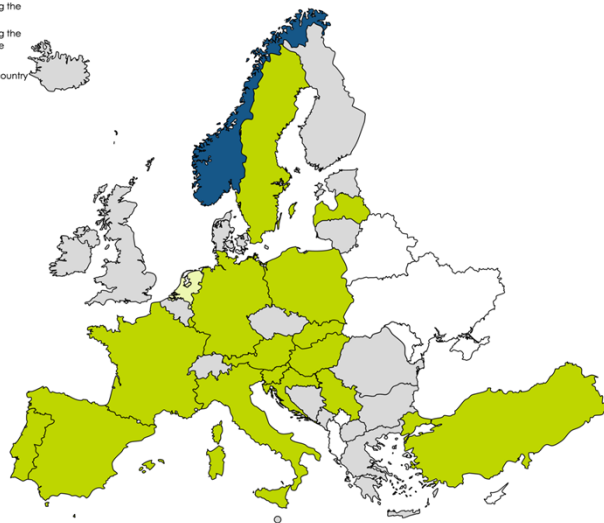
- ePed (paediatric national drug service) includes guidance on risk assessment and drug monographs with dosing, indication, reconstitution information ,etc. for drugs used in children
- For adults, no national initiative similar to ePed exists, instead responsibility and work in this area is local on a hospital, or more often, department within the hospital level.
- Some of the provisions of the EDQM resolution are implemented in local guidelines to varying degrees

### Turkey

- The Annexes of the Directive on On-Site Evaluation of Health Facilities Affiliated to the Public Hospitals Institution of Turkey have been amended to include 'Instructions on the management of the drug preparation process in aseptic condition'
- According to the relevant instruction, the preparation of drugs in aseptic environments is subject to various standards and is still applied in many hospitals in our country.

## Implementation Overview

- Low implementing the Resolution
- Guidance implementing the Resolution
- Guidance implementing the Resolution being update
- No feedback provided
- Not an EAHP member country



## Implementation barriers and needs (I)

- Hospital pharmacy workforce – better anticipation of needs (incl. staff increases in certain places to aide the implementation of the Resolution)
- For the implementation, different starting conditions in Europe – some countries are more advanced than others
- Priorities of governments, health authorities & hospital directors – strong focus on COVID at the moment

## Implementation barriers and needs (II)

### How could EDQM help?

- Share best practices collected by EAHP and other (European) organisations
- Conduct a study looking into the obstacles encountered during the implementation and the barriers that prevent countries from implementing the Resolution



**Thank you for your attention!**



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