European Commission

Questionnaire on health and safety preventive and protective measures for workers handling cytotoxic pharmaceuticals

81th Pharmaceutical Committee
23 October 2018

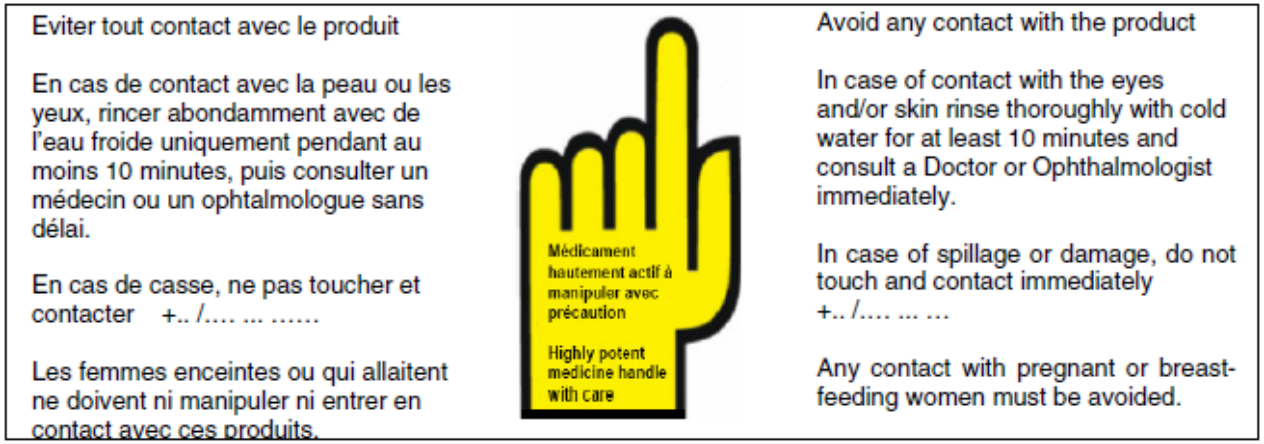
Health and Food Safety

European Commission

The request for "Yellow Hand" symbol

European Society of Oncology Pharmacy - ESOP

" a symbol with additional information on packaging of pharmaceuticals for humans to **raise the awareness of danger** that might occur when **handling of cytotoxic/hazardous pharmaceuticals** amongst **workers** (e.g. transport workers, pharmaceutical staff, medical staff, doctors, etc.) at their **working place** (e.g. pharmacies or hospitals)"



European Commission

Regulatory Framework

- Framework Directive 89/391/EEC
  - **Chemical Agents Directive (CAD, 98/24/EC)**
  - **Carcinogens and Mutagens Directive (CMD, 2004/37/EC)***
  - **Biological Agents Directive (2000/54/EC)**

- EU pharmaceutical legislation - Directive 2001/83/EC
  - regulates the particulars that appear on the **outer and/or immediate packaging (labelling)** and on the **package leaflet** of the medicinal product
  - the outer packaging and the package leaflet **may include symbols or pictograms** designed to clarify certain information which is **useful to the patient** and where **requested by the marketing authorisation holder**
  - **"blue box"** on the outer packaging of medicinal products **may include some additional pictograms or information** whether is **required by Member States legislation**

European Commission

Questionnaire

ACTION: To acquire information on measures put in place by the Member States on safety of workers handling cytotoxic pharmaceuticals

Member States contributed: **CZ, DE, DK, EE, GR, HU, LV, NL, PT, SE**

QUESTIONS: Does your country have any measures in place to address the safety of and health of employees/workers in regard to handling cytotoxic pharmaceuticals?

1. specific **measures at national level**
2. any **legal** measures in place
3. any **administrative** measures in place
4. any **mandatory** measures (e.g. list of specific pharmaceuticals, symbols, pictograms, text, other visualisations, additional leaflets, labels etc.)
5. any **voluntary** measures
6. any **examples**

European Commission

Answer 1. Does your country have **any specific measures** in place to address the safety of and health of employees/workers in regard to handling cytotoxic pharmaceuticals?

- The **CZ** has transposed **Carcinogens and Mutagens Directive** 2004/37/EC into **Government Decree** No. 361/2007 Coll. § 16 a 18

- In **HU** preparation, control, transport and use of cytostatic infusions are specifically regulated by the **particular guideline** (OGYÉI-P-64 – 2007/2012/2015) issued by the National Institute of Pharmacy and Nutrition.

  This guideline regulates: conditions of personnel, facility and equipment; quality system; clothes and other equipment's; labelling; storage and transportation; rules of administration; cleaning, procedure of elimination of contamination etc.

- In **DE** is regulated by the Ordinance on Hazardous Substances and applicable **Technical Rules** (Technical Rule No. 525), set by the Committee on Hazardous Substances

European Commission

Answer 2. Does your country have any **specific legal measures** in place?

- In **HU** the legal framework of regulating the safety and health of employees/workers in regard to handling cytotoxic pharmaceuticals:
  - several governmental Acts and Decrees - define dangerous materials on the occupational health;
  - protection from the occupational carcinogens and prevention the health damage;
  - reconstitution and preparation of cytostatic infusions is a specific task of the **hospital pharmacies and regulated by the particular guideline**

- In **DE** Technical Rules regulate the handling of and dealing with hazardous substances in health-care-institutions. The specific classification of the hazardous substance in question dictates the appropriate safety-measures to be taken.
  - **there are no general rules** with regard to the group of cytotoxic pharmaceuticals as a whole

European Commission

Answer 3. Does your country have any **specific administrative measures** in place?

- In **HU** adherence to law and mandatory guidelines is supervised by the environmental and health authorities:
  - Hospitals (by public health authorities)
  - Pharmacies, hospital pharmacies, hospital wards, clinics (by pharmacy inspectors "pharmaceutical officers")

European Commission

Answer 4. Does your country have **any mandatory measures** (e.g. list of specific pharmaceuticals, symbols, pictograms, text, other visualisations, additional leaflets, labels etc.), please explain?

- **DK** in Executive order no. 869 of 21 July 2011, as amended, on labelling the specific warning should be indicated **"Cytostatics"**
- **EE** the requirement of the QRD template published by EMA (QRD product-information template): special warning on labelling **"Cytotoxic"**
- **HU** the measures described in particular **guideline (mandatory)**: provides a **definition** and **lists** of cytotoxic pharmaceuticals; regulates the **labelling requirements**
    - of the **primary packaging** of and the use of specific **colour coding**;
    - of the **working/preparatory room "Caution! Dangerous working room! Do not enter!"**
    - of the **secondary containers** for transferring "**Caution! Cytotoxic!**"
    - of the **containers** used for the collection of **waste materials** "**Dangerous, cytotoxic waste!"**
- **SE** in national regulation LVFS 2005:11 2 § 8 and guidance to LVFS 2005:11 requirement for specific warnings for certain pharmaceuticals "**Cytostatikum**" on primary and (if applicable) secondary packaging

European Commission

Answer 5. Does your country have **any voluntary measures** (e.g. list of specific pharmaceuticals, symbols, pictograms, text, other visualisations, additional leaflets, labels etc.), please explain?

- In **HU** the measures described in particular guideline are **mandatory** for **all hospital pharmacies and other sites**;
  - **additional safety measures** may be applied by the **pharmacies and hospitals** in line with the local quality systems.

- In **EE** wholesale distributors **label shipment boxes/containers** with "**yellow hand**"; Hospital pharmacies have dedicated areas for storage, labelled with "yellow hand"

European Commission

Answer 6. Please provide **examples of these measures** (e.g. list of specific pharmaceuticals; full text of additional information, leaflets or other labels; mock of symbols, pictograms or other visualisations, etc.)

- In **HU** scope of regulation is defined in particular guideline:
  - **List** of cytostatic infusion (ATC code) based on USA and WHO practices
  - Regulation **requirements on labelling** (primary and secondary)
  - Colour coding locally determined not defined in the guideline

- In **EE** wholesale distributors **use labelling with** "**yellow hand**" symbol

European Commission

Next steps:

- Any other Member States to respond?
- Finalise the questionnaire
- Share with ESOP

European Commission

Thank you!

European Commission

Public Health information:

http://ec.europa.eu/health/index_en.htm

Health and Food Safety