Summary parliamentary round table CMRD-HD

Brussels, Chamber of Representatives, 25 March 2022

AGENDA

Introduction
- Gitta Vanpeborgh (Federal Representative, Forward)
- Hanne Sanders (Advisor Minister Dermagne)

Overview of the need for prevention
- France Duvivier (BOPP)
- Daniel Schuermans (AUVB-UGIB-AKVB)

Session 1: summary of legislative changes
- Emilie Marquis-Samari (Social Affairs Inspector, French EU Representative)
- Ian Lindsley (Secretary, EBN)

Session 2: current situation
- Eline Verscheure (KU Leuven)
- Marijke Quaghebeur (UZ Ghent)
- France Duvivier (BOPP)
- Birgit Tans (UZ Leuven)

Conclusion and conclusion
- Gitta Vanpeborgh (Federal representative, Vooruit)

REPORT

Overview of new insights and additional recommendations to the experts' consensus and recommendations document on preventing exposure to hazardous drugs (HD):

GENERAL
- **Cancer is still the main work-related cause of death in the EU**: in Europe, approximately 106,500 people have died from cancer as a result of occupational exposure to carcinogens
- Annually also **25,000 calls to the Antigifcentrum in Belgium** (not only from health workers) about the harmful effects of working with carcinogenic, mutagenic and reprotoxic substances
- The Carcinogens, Mutagens and Reprotoxic Substances Directive - CMRD (4th revision) was recently published and previously amended at the instigation of Belgium. The guidelines on handling hazardous drugs (HMPs) are expected by the end of 2022. A list of toxic hazardous drugs will follow. Work also needs to be done on training requirements
- Important to work on **clear labelling**

TRAINING AND INFORMATION
- Concerns about (**independent) home care** - and by extension the patient who is treated in home care or day hospital: training and knowledge of staff in this context must be improved. There is a need for a framework for this sector that also includes oral medication. Pharmacists can also play a role here

- **Extra hands** and resources are needed in the services to absorb the time investment for training: there is a **clinical need for well-trained staff**
- Training should be **as broad as possible**
    - To all healthcare staff: awareness must be raised among staff working on wards where patients are treated with cytostatics or other hazardous medicinal products
    - Additional efforts for cleaning staff, transport, ...
    - Specialised nursing staff (level 7) and nursing staff in medical imaging => competence profile of specialised nursing staff (banaba)
    - Doctors and doctors in training are still often forgotten in training today
    - The risk for employees who want to have children or are pregnant is higher and therefore extra attention is needed in training
    - Attention to information flow to patients (and family and informal carers)
    - Educate and inform without creating fear
    - Practical focus & attention for incidents
- **Cooperation with schools, with professional associations, with healthcare institutions and with social interlocutors,** as well as recognition of this competence through IFIC, portfolio composition and nomenclature are important
- **Cancer plan**: there are gaps in the education of the patient's care pathway and hospitals must finance costs, e.g. to provide training or monitoring themselves to primary care, home care, informal care, etc.
- **Closed systems should be the norm in all areas of manufacturing, preparation, administration, transport and disposal**, but must be used properly

MONITORING

- Need for clear technical and administrative **procedures**, **monitoring** and **controls** in all centres (use of closed systems, decontamination, PMB, testing, etc.)
- Attention to **safety and decontamination protocols** throughout the chain (transport, cleaning, but also at the patient's home, etc.)
- However, monitoring costs money: **contamination tests / wipe samples are expensive**
    - Who pays for this?
    - Prevention is better than cure
- Do not forget day clinics and specialised doctors outside the hospitals (e.g. dermatologists) in monitoring.
- In case of introduction of new instruments or treatments, additional monitoring is recommended
- **Incentive** for good monitoring: hospitals and other medical centres that perform well on monitoring, can benefit from a **transparent system** (awards, certification, ...). Patients, staff, ... can then make an informed decisions in selecting a hospital for their care

INDUSTRY

- **Labelling**: Problem that the yellow label has not yet been sufficiently integrated or rolled out by the industry: is proving difficult and is therefore currently being introduced mainly at hospital level. The responsibility of producers for labelling should be clarified/provided at EU level. A "*Yellow Hand Award*" could, for example, help to stimulate the uptake of the responsibility, as a low-threshold initiative to raise awareness in the industry
- **Contaminated flacons** are a real problem: attention to **safety in production**
- In addition to labelling, require the industry to provide **monographs of incidents**
- *Javel* is forbidden as a cleaning product in hospitals, but sometimes necessary to clean some surfaces properly (again, exception provided)

- **Lack of stock and supply problems** of closed systems are today's reality and must be considered when drafting the directives
- Attention to the **compatibility of closed systems** with products that have been on the market for years: this is not always the case / not always clear
- **Medicinal products in a clinical study**: in the development of new medicinal products, studies usually involve the use of needles, whereas here it is particularly important to proceed with caution. The compatibility of the products with closed systems therefore must be tested first

LEGISLATION

- Broadening the focus for the **list of medicines**:
    - For now, we are working with an American list but we need a European list for all hazardous medicinal products, including cytotoxics
    - A list should also include GMOs and ATMPs. These are new generations of medicines, but certainly important to include as they are gaining ground
- The European definition and list of hazardous medicinal should be in the **guidance document which is currently being developed by the European Commission**, which is not statutory
- **Total cost of use** can be reviewed (price of monitoring, training, education, protective equipment, ...)
- According to the legislation, the worker has no responsibility, this lies entirely with the employer. However, **employers must be monitored by government agencies** to ensure they are carrying out their responsibilities effectively
- Translation into practice is important: **advocate good cooperation for exchange of data and control**