# HAZARDOUS DRUGS

# UNION INTERVENTION REQUIRED

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federación de sanidad
y sectores sociosanitarios

# Agenda

- What are hazardous drugs?
- What effects do they have on patients and professionals?
- Which staff are exposed to cytostatic drugs?
- Regulations
- Regulations vs. workplace reality
- Need for research
- The precautionary principle
- What do we need to do?

# What are hazardous drugs? (1)

- Hazardous drugs are those that present one or more of the following characteristics, which can cause harm to humans (NIOSH criteria):
  - Carcinogenicity
  - Teratogenicity or other toxicity for development
  - Reproductive toxicity
  - Toxicity for organs in low doses
  - Genotoxicity

  - New drugs with similar structural profiles and toxicity to existing drugs that were identified as hazardous based on previous criteria

# What are hazardous drugs? (2)

The National Institute for Occupational Safety and Health (NIOSH) categorises these drugs into three groups:

- Group 1: antineoplastic drugs

- Group 2: non-antineoplastic drugs that present at least one of the previously mentioned characteristics

  These refer to drugs that are considered cytostatic, given that they work at the cell level. However, their treatment indication is not for treating cancer, but for immunosuppressive, anti-fungal, hormonal and anti-convulsive therapy, among others.

- Group 3: drugs that present risks for the reproductive process and may affect men and women who are actively trying to conceive, and pregnant or breastfeeding women, but that do not present risks to other staff

# What effects do they have? (1)

On patients:

- Expected treatment benefits outweigh the health risks that can be associated with their side effects. This is not the case for the professionals caring for these patients, who by handling these substances without adequate safety measures, are also exposed to these risks. In these cases, by taking precautions to prevent risks in the workplace, exposure should be avoided.

- However, it has been shown that cytostatic compounds can have harmful effects on patients' health in treatment doses.

# What effects do they have? (2)

On professionals:

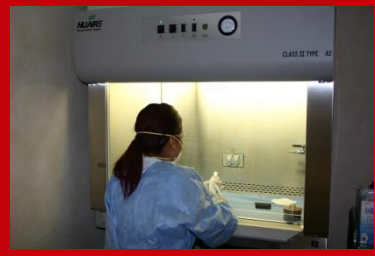
It is more complicated to establish a causal relation between chronic professional exposure to low-concentration levels of these compounds and possible adverse effects.


In this respect, it should be noted that exposure in the workplace involves exposure to multiple substances, meaning that possible adverse effects may be increased, despite the doses being low. It should also be noted that effects may be subclinical and may not be apparent over the years of ongoing exposure; they may even appear in subsequent generations.

# Which staff are exposed to cytostatic drugs?

Various staff in the healthcare environment are exposed to cytostatic drugs:

- Healthcare staff (cytostatic preparation areas i.e. pharmacies and treatment areas i.e. hospitals)
- Staff involved in supply, handling and storage
- Transportation staff
- Laboratory staff
- Auxiliary and cleaning staff, via contact with excreta from patients undergoing chemotherapy or in the event of accidents (spillages, splashes or punctures)
- Staff that dispose of waste



# Regulations

In Spain, there are state regulations and independent regulations. The main state regulation is:

- On the protection of workers against the risks associated with exposure to carcinogens in the workplace (Royal Decree 665/1997)

- Against chemical agents (Royal Decree 374/2001)

# Regulations vs. workplace reality

The adoption of preventive measures has been completely inadequate in the majority of healthcare centres due to:

- A lack of awareness about the issue
- Authorities underestimating the risks associated with handling these substances

One of the contributing factors has been that, from a healthcare usage perspective (not a manufacturing one), cytostatic drugs are not identified or labelled according to the criteria in the Regulation on notification of new substances and classification, packaging and labelling of hazardous substances (RD 363/1995).

Another factor is the lack of regulations specific to protection against hazardous drugs in the workplace.

# The precautionary principle

- Due to the toxicity of cytostatic agents, precautionary measures should be taken in keeping with the precautionary principle to systematically minimize exposure. As previously mentioned, the effects of exposure may only become apparent years after contact in the workplace, or even in subsequent generations.

- For the reasons discussed, we believe there are a series of measures that need to be taken.

# What do we need to do? (1)

- Develop a specific, compulsory European regulation that governs protection measures for workers exposed to hazardous drugs, using a model that classifies risk, taking into consideration that not all hazardous drugs have the same impact.

- Provide practical training on the subject throughout people's terms of employment, administered by either the government or by employers.

# What do we need to do? (2)

- Specific research: Scientific evidence on the effect of chronic exposure of staff to microdoses of drugs with possible carcinogenic, genotoxic and teratogenic effects, and those that are toxic in low doses or toxic for human reproduction, is scarce. Chronic exposure to multiple hazardous drugs in low doses, as is the reality for staff, may cause possible health effects to be multiplied.

# What do we need to do? (3)

- Develop “integrated guides” that outline these potential or verified negative aspects, both for patients and professionals.
- Keep a record of staff exposed to the substances and adequately monitor their health over the course of their employment and afterwards.
- Raise awareness: In order to avoid underestimating the risks to staff exposed, including by those in the political and judicial domain, efforts to raise awareness on the subject are required, similar to those that have been made regarding asbestos.

Thanks for your attention

Merci pour votre attention
Danke für lhre Aufmerksamkeit
Gracias por su atención
Bedankt voor je aandacht