



European Federation of Public Service Unions (EPSU)
Rue Joseph II, 40
B-1000 Brussels, Belgium
+32 2 2501080
epsu@epsu.org
www.epsu.org

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Contact person: Mathias Maucher, Policy Officer Health and Social Services, mmaucher@epsu.org

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EPSU letter on revisions of the Carcinogens and Mutagens Directive (2004/37/EC) (CMD) in the third batch of amendments (CMD3)

EPSU shares the view of ETUC concerning the different elements needed for a global EU strategy against work related cancer. As the European trade union federation representing the interests of workers in the health care (and social services) sector, we want to insist on the need to provide better prevention for more than 12.7 million healthcare workers in Europe, including millions of nurses, who are exposed to carcinogenic, mutagenic and reprotoxic hazardous drugs. According to EU-OSHA, these drugs represent the most dangerous chemical risk factors in healthcare and some of the most hazardous chemicals ever developed. Studies show that hospital workers who handle cytotoxic drugs are three times more likely to develop malignancy. It is estimated that in Europe each year occupational exposure to hazardous drugs produces 2,220 new cases of leukaemia alone which results in 1,467 additional deaths of healthcare workers each year.

Hazardous drugs (also referred to as cytotoxic, cytostatic or antineoplastic drugs) describe a group of medicines designed to destroy cells that grow in a rapid and uncontrolled manner, preventing their replication or growth. Worldwide, these medicines are increasingly being used in a variety of healthcare settings, prominently in the treatment of cancer. They also play an important role in haematology and rheumatology and are used to treat non-cancerous diseases such as multiple sclerosis, psoriasis and systemic lupus erythematosus, leading to a growing use of these drugs.

The hazardous drugs available for current use are generally non-selective, meaning that they do not differentiate between malignant cells and normal healthy tissue and are therefore likely to damage normal (non-tumour) cells, resulting in adverse health effects. Threshold levels of exposure to hazardous drugs cannot be predicted and therefore contact with genotoxic (gene destroying) carcinogens should be avoided at all levels. That is why they need to be included as "substances or mixtures or processes" in Annex I of the Carcinogens and Mutagens Directive without occupational exposure levels (OELs).

Sold in powder or as a concentrated solution, a form where a drug is more stable, hazardous drugs require individual manipulation for each patient prior to being administered as infusions or bolus injections. This may lead to errors, spillages, needle stick injuries and (spread of) contamination, which pose clear health risks to healthcare workers. Moreover, hazardous drugs may evaporate and form a gas during normal handling which may result in inhalation of the drugs.

EPSU Secretariat 40 rue Joseph II, box 5 - 1000 Brussels, Belgium
Phone: +32 2 250 10 80 Fax: +32 2 520 10 99 Mail: epsu@epsu.org www.epsu.org

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Surveys, conducted primarily with nurses, have associated workplace exposures to hazardous drugs with acute health effects and/or chronic effects. Indeed, increased genetic damage has been demonstrated in nurses, particularly in day hospital nurses, the group handling the highest amount of drugs during the administration process.

Importantly, the effects of exposure may be subclinical and not be evident for years or generations of continuous exposure. For example, as cancer often takes decades to emerge, a case of leukaemia diagnosed in a nurse or in a pharmacist today might be the product of workplace exposures in the 1970s or the 1980s. Unfortunately, in many instances, the connection between work and disease is never made.

While patients receive concentrated doses of a limited number of cytotoxic drugs for a defined period of time, healthcare workers may be exposed to small doses of a broad range of hazardous drugs over decades, with some workers being exposed every workday, year after year. In recent years several of EPSU's members have done targeted work to better prevent exposure to and/or to reduce risks linked to the manipulation or use of hazardous drugs, including EPSU's Spanish member CC.OO, with a hospital based awareness-raising and training campaign and legal action against non-compliant employers. More information is contained in the article "EPSU Reply Social Partner Consultation Revisions Carcinogens and Mutagens Directive" of 20 December 2017 (cf. <https://www.epsu.org/article/epsu-reply-social-partner-consultation-revisions-carcinogens-and-mutagens-directive>)

The Carcinogens and Mutagens Directive sets out steps to be taken to eliminate or limit exposure to carcinogenic and mutagenic chemical agents to help prevent occupational cancers and related diseases. However, the elimination of the cytotoxic drug or replacement with a less hazardous chemical is not practical or feasible in healthcare as they are used to treat cancer for tens of millions of patients across Europe. Amendments tabled by the rapporteur in CMD3 on 29 June 2018 state that any legislative changes to include hazardous drugs should not prejudice patients' health or decrease the efficiency of their treatment.

As replacement is not technically possible for hazardous drugs, the hierarchy of controls in the Carcinogens and Mutagens Directive requires that employers must use a closed technological system and the amendments reflect that hazardous drugs must be manufactured and used in a closed system. Closed technological systems in healthcare, include the engineering controls of biological safety cabinets, isolators and closed system transfer devices are highly effective in isolating the hazard and preventing occupational exposure in the preparation, administration and disposal of hazardous drugs, alongside the next levels of administrative controls and the use of personal protective equipment.

For all the reasons set out above, EPSU supports the amendments on hazardous drugs to CMD3 published by the rapporteur Laura Agea MEP on 29 June 2018.

Yours sincerely,



Jan Willem GOUDRIAAN
EPSU General Secretary