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Open letter on revisions of the Carcinogens and Mutagens Directive (2004/37/EC) (CMD) in the fourth batch of amendments (CMD4)

The European Oncology Nursing Society (EONS), the European Federation of Public Service Unions (EPSU) and the European Trade Union Confederation (ETUC) who are joining forces in supporting this call, welcomes the proposal from the European Commission on a fourth revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. In the legislative process, we call on the European Parliament and the Council to include hazardous medicinal products and substances toxic for reproduction in the CMD.

Nurse led research has associated workplace exposures to hazardous drugs with both acute and chronic health. [EONS Cancer Nursing Index 2020](#)[©] found major risks related to both patient and occupational safety. Among the most serious risks reported by cancer nurses across Europe were lack of training and guidelines for handling cytotoxic drugs and even worse, nurses in many countries reporting exposure to these drugs during pregnancy and breast feeding. In addition, nurses reporting risks of negative consequences if asking for alternative duty during pregnancy/breast feeding.¹

Cancer is the second leading cause of mortality in the EU countries after cardiovascular diseases, accounting for about a quarter of all deaths¹. It is also the first cause of work-related deaths in the EU²: 52% of annual occupational deaths are currently attributed to work-related cancers.

The simplest definition of Occupational and Patient Safety is the prevention of errors and adverse effects experienced by healthcare workers and patients. While healthcare has become more effective it has also become more complex, with greater use of new technologies, medicines and treatments³. According to the WHO (2018) – out of hospitalised patients, approximately 1 in 10 experience harm and around half of those incidents could have been prevented⁴. Unsafe handling of medication is both costly and causes harm to our patients; around 15% of health care spending is wasted on adverse events in hospitals.

Healthcare workers often have to make difficult decisions such as prioritising their patients' needs over their personal safety and wellbeing⁵. While the economic crisis of 2008 and the following austerity measures led many governments to cut health and education budgets, the COVID-19 pandemic highlighted the importance of investing in health and safety in workplaces, especially for those who are in the front line of our healthcare systems. Society has applauded and recognized their hard work in keeping our healthcare

¹ [EONS Safety Survey](#)



systems efficient, ongoing, and safe. Now is the moment for the European Union to invest in occupational safety and health with clear legislative actions.

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 which are particularly used in cancer treatments. These drugs are defined by their association with genotoxicity, carcinogenicity, teratogenicity, fertility impairment or reproductive toxicity, and/or serious organ toxicity at low doses⁶. Every year more than 12.7 million health professionals in Europe, including 7.3 million nurses, are exposed to carcinogenic, mutagenic and reprotoxic hazardous drugs⁷.

Hazardous drugs require individual preparation for each patient prior to being administered in tablet form and administered via many different routes other than infusion and 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.⁸

In many EU Member States either safety guidelines do not exist, are not followed or the management within the hospitals and clinics put pressure on their staff to continue delivering chemotherapy even during pregnancy². Many healthcare workers (among them cancer nurses) fear losing their jobs if they report this malpractice or it is up to the individual nurse whether or not to continue administer chemotherapy during pregnancy. Cancer nurses play a pivotal role within the multi-professional team in ensuring the safe delivery and management of cancer therapies. Nurses and other professionals who come in to contact with cytotoxic agents during preparation, administration, nursing care and cleaning are at risk of exposure. Current practice and guidelines for occupational safety and access to PPE vary between countries and organisations as well.

The [EONS Safety Manifesto](#) calls for cancer nurses to:

1. Provide information to patients & their significant others and encourage them to take an active part in their care
2. Avoid direct contact with cytotoxic and radiation drugs when planning pregnancy or during pregnancy
3. Always follow safety precautions; use personal protective equipment
4. Always speak up and question if something is, or appears to be wrong

As it is not always possible to research the impacts of cytotoxic materials on healthcare worker health and reproductive functions, **we call for the Carcinogens and Mutagens Directive to utilise the Precautionary Principle and adopt the following amendments in CMD4:**

Inclusion of Hazardous Medicinal Products in CMD Annex I and Substances toxic for reproduction in the CMD scope in order to ensure;

1. Protection of cancer nurses and other workers who are exposed at work;



2. Mandatory training on safe handling of Hazardous Medicinal Products for all cancer nurses and other workers at risk involved in the delivery and care of patients who are receiving/have received these products;
3. Better implementation of the Pregnant workers Directive (92/85/EEC) by giving to workers who are pregnant/breast feeding or trying to conceive legal grounds to request alternative duties if they are involved with caring for patients receiving Hazardous Medicinal Products;
4. Subsequent adoption of non-legislative instruments at EU level to help employers comply with these new legal requirements and improve the occupational safety and health of workers exposed to Hazardous Medicinal Products.

For all the reasons set out above, we call on the EU institutions to ensure that these concerns are included in CMD4.

Yours Sincerely,

Lena Sharp

EONS Board and Advocacy Working Group

Jan Willem Goudriaan

General Secretary

European Federation of Public Services

Per Hilmersson

Deputy General Secretary

European Trade Union Confederation



Personal quotes from Cancer Nurses from
EONS Safety Survey on Patient and Occupational Safety.

More information: <https://cancernurse.eu/advocacy/eons-work-on-safety/>

"There are no guidelines for safe handling of cytotoxic drugs for pregnant and breast-feeding staff in my hospital"

Cancer nurse from Ireland

"There need to be a strict legislation/rules and inspections from the MOH to check on the safety of the cancer nurses and cancer patients"

Cancer nurse from Georgia

"Nursing shortages are a big problem"

Cancer nurse from Croatia

"In Germany 1 nurse cares for 10-15 patients, out of which 8-10 receive cytotoxic drugs. Shortages together with time pressure can lead to errors"

Cancer nurse from Germany

"When nurses are working a long time in the same unit, they forget risk exposure and don't really concern themselves with it"

Cancer nurse from Ireland

"There is a need for better training and more awareness of the health risks"

Cancer nurse from Spain

"There are more nurses needed in 24-hour assessment areas, because now calls are being missed on a daily basis"

Cancer nurse from UK

"I would like to be offered continued online training in how to handle hazardous drugs"

Cancer nurse from Austria

"Hospital managers, policy makers and political leaders need to be engaged to provide the necessary Personal Protective Equipment in the oncology units and to encourage nurses to protect themselves while handle hazardous drugs"

Cancer nurse from Sweden

"There is a need for development of mandatory guidelines (from EONS) for prevention of exposure and adverse effects among nurses and patients"

Cancer nurse from Ireland

"In Croatia 1 nurse needs to: administer nursing care, do blood sampling, write directions, divide meals, assist surgery, administer all forms of Giving Therapy, make transfusion preparations and keeping records. There is a need for proper work distribution"

Cancer nurse from Croatia

"There is a need for continuing (on the job) training for oncology nurses"

Cancer nurse from Ireland



¹ https://ec.europa.eu/eurostat/statistics-explained/index.php?title=Cancer_statistics#Deaths_from_cancer

² <https://osha.europa.eu/en/publications/international-comparison-cost-work-related-accidents-and-illnesses/view>

³ <http://www.euro.who.int/en/health-topics/Health-systems/patient-safety>

⁴ https://www.who.int/features/factfiles/patient_safety/en/

⁵ <https://www.ncbi.nlm.nih.gov/pubmed/28134008>

⁶ <https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf>

⁷ <https://www.theparliamentmagazine.eu/news/article/preventing-the-exposure-of-nurses-and-health-professionals-to-hazardous-drugs>