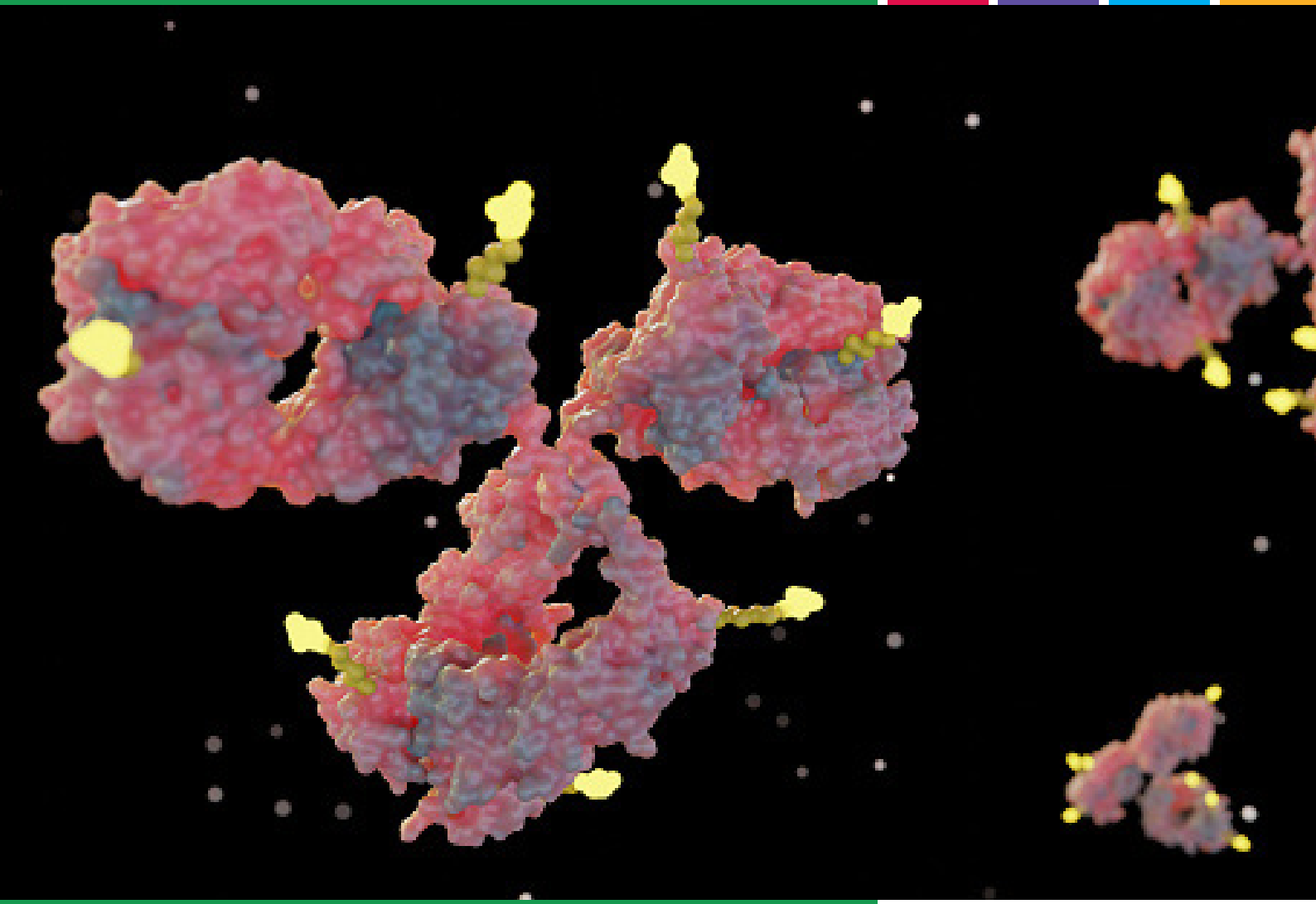
Royal College of Nursing

The use of Hazardous Medicinal Products

POLICY AND POSITION STATEMENTS



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Background

Hazardous medicinal products are pharmaceutical substances used predominantly for the treatment of cancer in the form of cytotoxic/cytostatic or antineoplastic drugs. Hazardous medicinal products are also used in the non-cancer setting, for treating non-cancerous diseases such as multiple sclerosis, HIV, psoriasis, rheumatoid arthritis, systemic lupus erythematosus and in organ transplantation, for example, as antivirals, vaccines and immunosuppressants. Hazardous medicinal products also extend to other therapeutic groups and some antibiotics.

Hazardous medicinal products have the potential to cause effects in people other than the patient being treated if they are unintentionally exposed to the substance. For example, nursing staff handling, administering and disposing of hazardous medicinal products. A recent European Commission study on hazardous medicinal products published in March 2021 stated there are almost 1.8 million workers exposed to relevant hazardous medicinal products in the EU (European Commission, 2021). When taking into account all those potentially exposed in the health care sector, that number may be as high as 12.7 million exposed workers in the EU, of which 7.3 million are nurses (ETUI, 2020).

Identifying and Labelling Hazardous Medicinal Products

There is not currently a consistent approach in identifying hazardous medicinal products to inform the risk assessment process in the UK. Employers need to use several methods to try and gather information which may result in a lack of detailed information on hazardous medicinal products some not being identified easily or at all.

Labelling

Product packaging labels are used as a way to identify hazardous medicinal products. The Retained Classification, Labelling and Packaging (CLP) Regulation (EU) No. 1272/2008 as amended for Great Britain (GB CLP) does not apply to finished medicinal products for the final user (European Commission, 2023). Many labels focus predominantly on cytotoxic medicines and may not identify other types of hazardous medicinal products.

Finished medicinal products for human use are exempt from the requirement to provide a safety data sheet (SDS) (European Commission, 2023) under UK Registration, Evaluation, Authorisation and Restriction of Chemical (REACH) for England, Scotland and Wales and EU REACH which applies to Northern Ireland. Many manufacturers prepare SDSs for finished medicinal products on a voluntary basis (European Commission, 2023). It is possible that SDSs or sufficient information supplied by manufacturers may not be available to help employers identify hazardous medicinal products and inform the risk assessment.

Existing lists and databases

Unlike the European Union and the US, the UK does not have an accepted definition or list of hazardous medicinal products. There is also no comprehensive UK developed list or an endorsed and recommended list of hazardous medicinal products for use by employers, based on the EU definition included in the revised 2022 EU Carcinogens, Mutagens or Reprotoxic substances Directive (CMRD) that hazardous medicinal products are substances classified as category 1A (known carcinogen mutagen or reprotoxin) or category 1B (presumed carcinogen, mutagen or reprotoxin) medicinal products. In 2022, the ETUI published a list of hazardous medicinal products (HMPs), including cytotoxics, based on the EU CLP classification system of Carcinogenic, Mutagenic and Reprotoxic (CMR) substances, in anticipation of the European Commission publishing an EU indicative list of hazardous medicinal products.

Following this the US National Institute for Occupational Safety and Health (NIOSH) published an updated list of hazardous drugs in health care settings in 2024.

The EU indicative list of hazardous medicinal products list was published in February 2025.

The US list and imminent publication of the EU list and definition of hazardous medicinal products will not have legal force in the UK. As there are a variety of methods currently adopted by employers in the UK to identify hazardous medicinal products and no current robust way of doing so, it is likely that nursing staff are being exposed to harm from handling, administering and disposing of hazardous medicinal products.

Risks to nursing staff

Hazardous medicinal products are received, prepared, administered and disposed of in hospitals as part of inpatient, day case and outpatient settings and in the community including nursing, care homes and peoples own place of residence.

The routes of exposure for nursing staff to hazardous medicinal products is varied and includes:

Ingestion: from poor hand hygiene and food or beverages being prepared, stored or consumed in areas at risk of contamination.

Absorption: as a result of spills contaminating a person and/or working environment, splashing eg during drug reconstitution or spiking bags, drug administration, waste disposal, changing bed linen, nursing patients and contact with bodily fluids (urine, faeces, vomit, blood) and during waste disposal. Inadequate PPE e.g. incompatible gloves, poor quality, surface contamination* (from difficulty in cleaning and removing contamination).

Inhalation: droplets/ vapours as a result of spillage or splashing during drug reconstitution, administration and disposal. Some antineoplastic drugs can vaporise e.g. carmustine, ifosfamide.

Injection: needlestick/ sharps injuries.

*Studies have found that most work surfaces where cytostatic drugs are handled are contaminated with the drugs (ISOPP, 2022).

Nursing staff exposed to hazardous medicinal products may suffer from a range of adverse health effects including skin rashes, dizziness, sore throat, headaches, cough, eye irritation, hair loss, nausea and vomiting, contact dermatitis and allergic reactions, risks to reproductive health of women, including increased risk of infertility, spontaneous abortion and congenital abnormality. Hazardous medicinal products may also cause other adverse effects including organ, respiratory, haematological toxicity.

The risk of exposure to hazardous medicinal products may be increased for nursing staff who are more vulnerable or have specific health issues including anyone who is pregnant, breastfeeding or planning to conceive, immunocompromised, a young worker, older worker and nursing staff who have a pre-existing condition, for example, respiratory or skin disorders, or who have allergies and hypersensitivity (European Biosafety Network, 2024).

Environmental monitoring

Environmental monitoring is critical in preventing the exposure of nursing staff exposure to hazardous medicinal products. Research has highlighted the most common route as dermal exposure. Regular surface decontamination and measuring surface contamination before and after use of closed systems is a key method of monitoring and preventing exposure (Viegas, Susana et al., 2018).

UK guidance and legislation

The Control of Substances Hazardous to Health Regs 2002 (COSHH)/ The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003 require exposure to substances that have been classified as carcinogens and mutagens to be controlled as low as is reasonably practicable (ALARP).

There is not any specific UK legislation or guidance for hazardous medicinal products, other than the current COSHH regulations. However, COSHH does not mandate the same level of control for reprotoxins as it does for carcinogens or mutagens. HSE guidance focuses mainly on cytotoxics.

Globally, since 2007 the gold standard for best practice in reducing occupational exposure to hazardous medicinal products in oncology pharmacy has been the International Society of Oncology Pharmacy Practitioners (ISOPP) Standards. The standards were updated in 2022 and published as ISOPP Standards for the Safe Handling of Cytotoxics (ISOPP, 2022). In 2023, NIOSH published guidance on Managing Hazardous Drug Exposures: Information for Healthcare Settings (NIOSH, 2023).

EU changes to legislation

Changes in EU legislation have strengthened the requirement for managing hazardous medicinal products within the EU.

In March 2022, the EU published Directive (EU) 2022/431 to amend Directive 2004/37/EC. The amendment stated “hazardous medicinal products which contain substances which meet the criteria for classification as carcinogenic (categories 1A or 1B), mutagenic (categories 1A or 1B) or reprotoxin (categories 1A or 1B) in accordance with Regulation (EC) No 1272/2008 fall under the scope of Directive 2004/37/EC. All requirements of Directive 2004/37/EC apply to hazardous medicinal products accordingly.”

The new definition of hazardous medicinal products in the directive provides a broader scope than previous legislation and guidance which focused mainly on cytotoxic drugs.

Specific requirements under the amended directive include:

- mandatory training for all workers likely to be exposed to hazardous medicinal products periodically in health care settings
- risk assessment and where use of a hazardous medicinal product cannot be eliminated, replace or substituted, use must be manufactured and used in a closed system and administered via closed system transfer device (CSTD)
- development of updated EU guidelines for the preparation, administration and disposal of hazardous medicinal products at the workplace – published April 2023
- a requirement to develop and update a register of workers who have been exposed or who are likely to be exposed to CMRs
- a requirement for the European Commission to draw up a definition and indicative list of dangerous drugs or substances in accordance with the criteria for classification as CMR Cat 1A and 1B by 2025

- stricter limit values for a number of widespread carcinogens, mutagens or reprotoxic substances.

In April 2023, the EU published new practical and holistic guidance (European Commission, 2023) for the safe management of hazardous medicinal products at work throughout their lifecycle from manufacture to disposal. The guidance includes the same broader legal definition of hazardous medicinal products, not just focusing on cytotoxic or cytostatic drugs, but also antivirals, hormones, antibiotics and immunosuppressants.

RCN Position

As nursing staff are at risk of exposure to hazardous medicinal products, the RCN wants to see positive action being taken to protect health care workers now and in the future.

We are making calls on the UK Government, the Health and Safety Executive, the Health and Safety Executive for Northern Ireland and other relevant enforcement authorities and employers to take preventative action.

UK Government

Recent changes, including a strengthening of the law in the European Union have resulted in the UK lagging behind in legislative requirements and without the necessary guidance about safe handling of hazardous medicinal products that European and US employers are provided with, via EU-OSHA and NIOSH, to support the robust management of hazardous medicinal products. The RCN is concerned that UK nursing staff are at risk of harm from exposure to hazardous medicinal products.

The RCN calls for the UK Government to:

- Update and strengthen UK legislation on the requirements to:
    a. control and prevent exposure to reprotoxins and give parity to this classification alongside the increased requirements for carcinogens and mutagens mirroring EU legislation and guidance on this point
    b. change the definition of control of CMRs, under COSHH from 'as low as reasonably practicable' which takes trouble, time and cost to control into consideration to 'lowest possible level' which suggest stronger controls and effort are required
    c. Develop and adopt a definition of hazardous medicinal products
    d. mandate the use of closed systems eg biological safety cabinet and closed system drug transfer devices (CSTDs) for preparation and administration of hazardous medicinal products and where this is not feasible mandate the need for a detailed risk assessment which must include use of exposure data and utilisation of plant and procedural interventions to reduce exposure to the lowest possible level, and at least below the limit value (where one exists).
    e. mandate the requirement and frequency of environmental monitoring for hazardous medicinal products to ensure controls are robust and exposure of nursing staff is maintained at the lowest possible level.
- Update and strengthen retained UK legislation 'Retained CLP Regulation (EU) No. 1272/2008 as amended for Great Britain' (GB CLP) to mandate the requirement to label finished medicinal products that are intended for the final user with appropriate warning symbols (in line with the Globally Harmonized System (GHS)).
- Update and strengthen the UK REACH legislation to mandate the provision of SDSs for finished medicinal products.
- Mandate the development and adoption of a detailed list of hazardous medicinal

products which fall under the scope of updated UK legislation to enable health and social care employers to identify hazardous medicinal products and control risks to nursing staff.

- Adopt and promote a currently available detailed database/ list of hazardous medicinal products to support health and social care employers to identify and assess the risks of hazardous medicinal products to their workers e.g. European Trade Union Institute (ETUI) 'The ETUI's list of hazardous medicinal products (HMPs)' (ETUI, 2022) and the NIOSH List of Hazardous Drugs in Healthcare Settings, 2024 (NIOSH, 2024)
- Mandate the development of guidance on preparation, administration and disposal of hazardous medicinal products as part of the whole lifecycle of hazardous medicinal products in the workplace. In addition to EU and ISOPP guidance, NIOSH Managing Hazardous Drug Exposures: Information for Healthcare Settings provides a blueprint for practice (NIOSH, 2023).
- Mandate the requirement for employers to maintain a register of staff who have been exposed or who are likely to be exposed to hazardous medicinal products.

Regulators

HSE Great Britain and HSE Northern Ireland

There is an inconsistent approach in identifying hazardous medicinal products to assess risks to nursing staff and implement robust controls. Health and social care employers cannot rely on safety data sheets and product packaging labels to identify hazardous medicinal products.

In addition, employers have limited access to UK produced guidance on the control of hazardous medicinal products in the workplace.

The RCN calls for the national regulators of health and safety in the workplace to:

- Produce detailed guidance on the preparation, administration and disposal of hazardous medicinal products as part of the whole lifecycle of hazardous medicinal products in the workplace. Current HSE guidance focuses on cytotoxins, however this guidance should be broadened to take into account all hazardous medicinal products, including but not limited to cytotoxins.
- Implement a programme of proactive themed inspections of a cross section of hospitals, care homes and clinics where the preparation, administering and disposal of hazardous medicinal products takes place.
- Publicise a currently available detailed database/ list of hazardous medicinal products to support employers to identify and assess the risks of hazardous medicinal products to their workers e.g. European Trade Union Institute (ETUI) 'The ETUI's list of hazardous medicinal products (HMPs)' (ETUI, 2022).
- Develop a detailed database/ list of hazardous medicinal products to support employers to identify and assess the risks of hazardous medicinal products to their workers.

Employers

Develop, implement, monitor and review a robust written policy and guidance on handling hazardous medicinal products in consultation with staff side RCN representatives and make this accessible to all groups of staff who may be involved in the life cycle of hazardous medicinal products. Policy and guidance should include:

- the appointment of a nominated person (people) for hazardous medicinal product queries.
- establishing a steering committee for hazardous medicinal product occupational safety and health
- identification and labelling of hazardous medicinal products early in the supply chain
- thorough risk assessment of the lifecycle of hazardous medicinal products and safe operating procedures for tasks and activities
- promotion of incident reporting related to hazardous medicinal products
- environmental monitoring of air and surfaces
- develop and maintain an up-to-date register of workers who have been exposed or who are likely to be exposed to hazardous medicinal products
- health surveillance for all staff working with or at risk of exposure to hazardous medicinal products
- ongoing education and training for nursing staff who handle or may come into contact with hazardous medicinal products.

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The RCN represents nurses and nursing, promotes excellence in practice and shapes health policies

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