Adopted by EAHP's General Assembly in June 2022

EAHP Position Paper on Hazardous Medicinal Products

Further increasing safety for healthcare professionals

Hazardous medicinal products are vital for the treatment of both cancerous and other non-cancerous diseases. Hospital pharmacists are responsible for the preparation of these medicinal products and like all healthcare professionals that handle and administer hazardous medicinal products are exposed to certain risks.[1] At European and national levels, several guidelines and regulations have been put in place for the protection of healthcare workers.[2] The latest addition to these regulations is the fourth amendment of the Carcinogens and Mutagens Directive (CMD) that was published in March 2022.[3] The amendment to the CMD requires the European Commission to develop a definition for hazardous medicinal products, establish an indicative list of them and prepare guidelines for handling these substances, particularly in hospitals, by the end of 2022. The handling of hazardous medicinal products includes activities such as proper storage, preparation, dispensing, administration, cleaning, waste management and transportation.

Hospital pharmacists are key stakeholders to be involved when creating definitions and guidelines for the products which they manage on behalf of the hospital or institution. Consequently, the European Association of Hospital Pharmacists (EAHP) established at the end of 2020 a Special Interest Group on Hazardous Medicinal Products to better understand the classification landscape for hazardous medicinal products in Europe. EAHP's Special Interest Group has put together comprehensive information and guidance for consideration by the European Commission and other interested parties such as national governments when developing a comprehensive approach to hazardous medicinal products.

EAHP calls on the European Commission and national governments across Europe to actively engage with hospital pharmacist representatives in the review of relevant Directives for the management of hazardous medicinal products in the healthcare environment.

EAHP asks national governments and health system managers to immediately engage with the European Statements of Hospital Pharmacy and implement best practices relating to hazardous medicinal products.

EAHP recommends an EU wide standard approach to the classification and management of hazardous medicinal products.

EAHP advises the European Commission and national governments across Europe to initiate best practice sharing on the classification and handling of hazardous medicinal products among its Member States.

EAHP advocates for the revision of pharmacy curricula and the expansion of training opportunities for the pharmacy workforce to account for the growing demand for the management of hazardous medicinal products and related health and safety issues.

[1] Kaestli L, Fonzo-Christe C, Bonfillon C, et al Development of a standardised method to recommend protective measures to handle hazardous drugs in hospitals European Journal of Hospital Pharmacy: Science and Practice 2013;20:100-105.

[2] EU OSHA guidance. Available at: https://osha.europa.eu/en/safety-and-health-legislation/european- guidelines (last visited on 2 February 2022). EU Strategic Framework on Health and Safety at Work 2021-2027, Occupational safety and health in a changing world of work. Available at: https://eu-osh-framework-2021.osha.europa.eu/upload_ftp/nirestream/euoshahybrid/pdf/eu-strategic-framework-on-safety-and-health-2021-27-pdf.pdf?updated=1624886105 (last visited on 2 February 2022). Valero-García S, González-Haba E, Gorgas-Torner MQ, Alonso-Herreros JM, Cercós Lletí AC, Poveda-Andrés JL, Calleja-Hernandez MÁ, Delgado-Sánchez O. Monitoring contamination of hazardous drug compounding surfaces at hospital pharmacy departments. A consensus Statement. Practice guidelines of the Spanish Society of Hospital Pharmacists (SEFH). Farm Hosp. 2021 Mar 11;45(2):96-107. English. doi: 10.7399/fh.11655. PMID: 33709894. Information about the Risk Instrument for Pharmaceutical Substances (RiFaS), available at: https://www.knmp.nl/over-de-knmp/producten-en-diensten/productzorg-en-bereiding/risico-instrument-farmaceutische (last visited on 1 April 2022).

[3] Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work OJ L 88/1, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2022.088.01.0001.01.ENG&toc=OJ%3AL%3A2022%3A088%3ATOC (last visited on 1 April 2022).

The role of hospital pharmacists in handling hazardous medicinal products and the protection of healthcare workers

To ensure the safety of patients and staff in the handling of hazardous medicinal products hospital pharmacists contribute to and promote their safe handling in institutions in Europe. To improve the current position and to support the work of hospital pharmacists proactive steps need to be taken to minimise the risks of hazardous medicinal products for healthcare workers and patients.

The European Statements of Hospital Pharmacy expresses commonly agreed objectives for the delivery of hospital pharmacy services that should be applied uniformly across Europe.[4] Section 3.5 specifically touches on the subject outlines *that 'Hazardous medicines should be prepared under appropriate conditions to minimise the risk of contaminating the product and exposing hospital personnel, patients and the environment to harm.'* The preparation under appropriate conditions includes the preparation of hazardous medicinal products under the responsibility of the hospital pharmacist in a dedicated room or area while observing the relevant safety procedures. Also, hospital pharmacists must provide leadership in reducing the environmental impact caused by the use of medicinal products in the hospital setting.[5] Section 3.5 as well as all other sections of the European Statements are crucial for enhancing patient outcomes and hospital pharmacy services. **Consequently, EAHP asks national governments and health system managers to immediately engage with the European Statements of Hospital Pharmacy and implement best practices relating to hazardous medicinal products.**

Additional guidance at the European level to promote healthcare workers' well-being is crucial. The involvement of hospital pharmacy expertise alongside those of other healthcare professionals is paramount as evidenced by research projects across Europe.[6] Based on the findings from the Survey on Hazardous Medicinal Products for Individual Chief Pharmacists conducted by EAHP in September and October 2021, guidance for healthcare professionals should promote the implementation of best practice, recognise and support training and education of the workforce, permit all available processes to reduce exposure to hazardous medicinal products in the workplace and allow for adaptability as new products or new evidence become available.[7] **EAHP calls on the European Commission and national governments across Europe to actively engage with hospital pharmacist representatives in the review of relevant Directives for the management of hazardous medicinal products in the healthcare environment.**

The classification of hazardous medicinal products

Hospital pharmacists play a distinctive role in the multidisciplinary care team. Their medication-related contributions are essential for optimising patient outcomes.[8] Hazardous medicinal products are part of the day-to-day work of pharmacists and members of the multidisciplinary team, such as nurses, pharmacy technicians and others. Their safe handling is of uttermost importance for the safety of healthcare workers

[4] The European Statements of Hospital Pharmacy European Journal of Hospital Pharmacy 2014;21:256-258.

[5] Sykehusinnkjøp HF, Experience Report – Environment, Environmental Requirements for Pharmaceutical Procurements 2020-2022, available at: https://sykehusinnkjop.no/Documents/Legemidler/Milj%C3%B8rapport/Erfaringsrapport%20Milj%C3%B8_EN.pdf (last visited 11 June 2022).

[6] Burch A, et al. (2021). "NP-020 Antineoplastic and other hazardous drugs: risk potential and exposure – less is more!" European Journal of Hospital Pharmacy. Science and Practice 28(Suppl 1): A176. Herrera CM, et al. (2020). "4CPS-201 Identification of hazardous drugs and process in a university hospital." European Journal of Hospital Pharmacy. Science and Practice 27(Suppl 1). Prado PT, et al. (2020). "5PSQ-116 Safer handling of oral hazardous drugs in hospital units." European Journal of Hospital Pharmacy. Science and Practice 27(Suppl 1). Buendía-Bravo S, et al. (2020). "3PC-043 Hazardous drugs: impact of measures for safe handling." European Journal of Hospital Pharmacy. Science and Practice 27(Suppl 1). Gerding J, et al. (2019). "Assessing the risk to health care workers from exposure to hazardous drugs: Classification and labelling of antineoplastic and immunomodulatory drugs." Naunyn-Schmiedeberg's Archives of Pharmacology 392 (Supplement 1): S67. Korczowska E, Crul M, Tuerk J, Meier K (2020). Environmental contamination with cyto-toxic drugs in 15 hospitals from 11 European countries – results of the MASHA project. Eur J Oncol Pharm 2020; 3(2): 1-9.

[7] European Association of Hospital Pharmacists (EAHP), SIG – final report, Special Interest Group on Hazardous Medicinal Products, March 2022, available at: https://www.eahp.eu/hp-practice/hospital-pharmacy/SIGs/HazardousMedicinalProducts (last visited on 1 April 2022).

[8] LeBrun PPH, Bauters T, Hug MJ, Tamés MJ, Carollo A, Daouphars M and Scott M, The role of the pharmacist in a multidisciplinary team, Hospital Pharmacy Europe, available at: https://hospitalpharmacyeurope.com/news/editors-pick/the-role-of-the-pharmacist-in-a-multidisciplinary-team/ (last visited 1 April 2022).

and patients treated with these medicines. Their classification plays an indispensable role in determining suitable handling procedures.[9] However, unlike the United States, Europe does not have one single body similar to the National Institute for Occupational Safety and Health (NIOSH) that addresses all questions linked to the classification of hazardous medicinal products.

When looking at different classification approaches in Europe, EAHP's Special Interest Group concluded that no overarching European approach exists and identified several approaches for further consideration. Examples from Austria, Spain, the United Kingdom, Ireland and the Netherlands outline how different the situation is in Europe. In Austria, no standardized classification system exists but normally hospital pharmacies take into account information from different databases and resources (for example the European Chemicals Agency (ECHA), the European Directorate for the Quality of Medicines & HealthCare (EDQM), the Food and Drug Administration FDA, the International Agency for Research on Cancer (IARC), NIOSH, the Employer's Liability Insurance Association for Health Services and Welfare Care (BGW) and prescription information/information from the European Public Assessment Report (EPAR)).[10]

In Spain, the National Institute for Safety and Health at Work (INSST) published in 2016 in collaboration with the Spanish Society of Hospital Pharmacists (SEFH) the document "Hazardous drugs: Prevention measures for their preparation and administration".[11] As a continuation and update to this document INSST and SEFH developed the INFOMEP database. Both resources are not binding but rather used as a guideline and plans are in place to regularly update them. The United Kingdom does not have a classification system for hazardous medicinal products. Handling of carcinogens and mutagens are covered by the Control of Substances Hazardous to Health (COSHH regulations 2002 (as amended), but for classification, like in Ireland the NIOSH list is used. The Risk Instrument for Pharmaceutical Substances (RiFaS) is the national approach to the management of hazardous medicinal products in the Netherlands[12]. RiFaS adopts the approach that actual risk equals intrinsic hazard multiplied by exposure opportunities[13]. RiFaS provides individual advice on request on the safe handling of products via Rifas.nl. The advice is tailored to the equipment available in the requesting pharmacy, such as a dust extractor or a safety bench. It also takes into account how long the healthcare worker will be working with the substance. EAHP's SIG on Hazardous Medicinal Products considers the Dutch model to be an exemplar and that this model should be used as a reference for future development. **Given that no uniform classification approach exists, EAHP advises the European Commission and national governments across Europe to initiate best practice sharing on the classification and handling of hazardous medicinal products among its Member States.**

Based on its research, EAHP's Special Interest Group considers that while there is evidence of much ongoing work and activity on the topic of hazardous medicinal products there is an absence of a coherent approach to the management of hazardous medicinal products in Europe. Much of the risk assessment activity takes place at the institutional level with guidance from the national levels but little further oversight of implementation.[14] The exposure of healthcare workers to hazardous medicinal products is a serious issue that in the view of EAHP needs to be addressed uniformly across the European Union and its Member States to ensure the protection of patients and healthcare personnel. Consequently, **EAHP recommends an EU wide standard approach to the classification and management of hazardous medicinal products**.

[9] Mari ABM, et al. (2018). "Guidelines for safe handling of hazardous drugs: A systematic review." Plos One 13(5): e0197172-e0197172.
[10] European Association of Hospital Pharmacists (EAHP), SIG – final report, Special Interest Group on Hazardous Medicinal Products, March 2022, available at: https://www.eahp.eu/hp-practice/hospital-pharmacy/SIGs/HazardousMedicinalProducts (last visited on 1 April 2022).
[11] Instituto Nacional de Seguridad e Higiene en el Trabajo (INSHT), Medicamentos peligrosos. Medidas de prevención para su preparación y administración. 2016, available at: https://www.insst.es/documentacion/catalogo-de-publicaciones/medicamentos-peligrosos.-medidas-de-prevencion-para-su-preparacion-y-administracion (last visited on 1 April 2022).
[12] Information about the Risk Instrument for Pharmaceutical Substances (RiFaS), available at: https://www.knmp.nl/producten/producten-diversen/risico-instrument-farmaceutische-stoffen-rifas (last visited on 19 January 2022).
[13] Presentation on file. Please contact EAHP (info@eahp.eu) for further information.
[14] European Association of Hospital Pharmacists (EAHP), SIG – final report, Special Interest Group on Hazardous Medicinal Products, March 2022, available at: https://www.eahp.eu/hp-practice/hospital-pharmacy/SIGs/HazardousMedicinalProducts (last visited on 1 April 2022).

Education and training in relation to hazardous medicinal products

The complex nature of handling hazardous medicinal products requires training that is tailored to the conditions of the working environment which differ depending on the settings in the hospital or community as well as from country to country.[15] Consequently, **EAHP advocates for the revision of pharmacy curricula and the expansion of training opportunities for the pharmacy workforce to account for the growing demand for the management of hazardous medicinal products and related health and safety issues.**

[15] European Commission, Directorate-General for Employment, Social Affairs and Inclusion, Directorate B – Employment, Unit B.3 — Health and Safety, Study supporting the assessment of different options concerning the protection of workers from exposure to hazardous medicinal products, including cytotoxic medicinal products, 2021, available at: https://op.europa.eu/en/publication-detail/-/publication/f43015ec-a24f-11eb-b85c-01aa75ed71a1 (last visited on 1 April 2022).