Joint Summit

Preventing occupational exposure to Hazardous Medicinal Products (HMPs)

30th January 2024, 9.30am to 3pm, at Fórsa, Dublin

FÓRSA

European Biosafety Network

hpai Hospital Pharmacists Association of Ireland

N.A.H.P.T.

Introduction and Summary

A joint Summit on preventing occupational exposure to Hazardous Medicinal Products (HMPs) was held at Fórsa's office in Dublin on 30th January 2024, hosted by Fórsa, the European Biosafety Network (EBN), the Hospital Pharmacists Association of Ireland (HPAI) and the National Association of Hospital Pharmacy Technicians (NAHPT).

The Summit looked at the practical aspects of preventing occupational exposure of healthcare workers and professionals to HMPs. Exposure to HMPs, often used to treat cancer and other life-threatening conditions, can happen anywhere from manufacture to preparation, administration and disposal, and can cause health impacts from headaches and hair loss to miscarriages, reproductive problems and different types of cancer.

New EU legislation, which comes into force on 5 April 2024 in Ireland, together with new EU guidance on safe handling of HMPs, requires greater protection for workers and, in particular, as part of the hierarchy of control for employers to provide closed systems in the manufacture and use of HMPs and for training of workers who handle HMPs. This is needed to protect workers from long term exposure to HMPs, which can cause cancer, leukaemia and miscarriages in healthcare workers including pharmacists, technicians, nurses and other workers in health and social care.

The EU Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD) was amended in 2022 to include HMPs (as well as reprotoxic substances) within its scope for the first time as well as a new and clear definition of HMPs as substances which include carcinogens, mutagens or reprotoxins, classified as category 1A or 1B under the EU Classification, Labelling and Packaging Regulation. In April 2023, the EU published new practical and holistic guidance for the safe management of HMPs at work throughout their lifecycle from manufacture to disposal. The guidance includes the same broader legal definition of HMPs, not just focusing on cytotoxic or cytostatic drugs, but also antivirals, hormones, antibiotics and immunosuppressants.

The event was attended by a wide range of representatives, professionals and members of the Irish healthcare and social care community, frontline staff, government agencies and regulators, trades unions, policy makers and academics. Attendees had the chance to hear presentations from Darren Arkins of the Health and Safety Authority, Dr Tony Musu of the European Trade Union Institute, Dr Paul Sessink, EU expert on HMPs, and Ian Lindsley, Secretary of the European Biosafety Network. Lively and engaged discussions took place throughout the day between panellists, including hospital pharmacists, pharmacy technicians, oncology nurses and occupational health specialists and the audience from across the Irish healthcare and social care sector.

Calls to action

Fórsa, the EBN, HPAI and NAHPT called upon the Health Service Executive (HSE) to urgently update their 'Guideline on the Safe Handling of Cytotoxic Drugs', which was last published in February 2022, to include updates made to the new EU Directive and new EU guidance on handling HMPs. The Health and Safety Authority (HSA) must also play a role by increasing inspections of healthcare and manufacturing sites which handle and produce HMPs. Following the Summit, Fórsa will also write, in coordination with other Irish healthcare trade unions, to the HSE to request immediate and nationwide adoption of the ETUI's list of HMPs in Ireland to protect healthcare and social care workers.

Linda Kelly, National Secretary of Fórsa said: "With the issue of exposure to hazardous medicinal products (HMPs) directly and indirectly impacting so many of our members, it is

imperative that awareness by employers and workers of the risks is improved and we act now to prevent the damaging health effects that exposure to HMPs can have on the workforce. We are calling for preventive measures to be put in place to protect all workers potentially exposed to contamination. We must work holistically to ensure that all workers in health and social care are sufficiently protected when doing their jobs.

“The new EU Directive that includes HMPs for the first time must be transposed into Irish law by 5 April 2024. But the real work does not stop with changes to legislation or the implementation of new EU guidance; employers in Irish health and social care need to understand the risks of exposure to HMPs, implement controls and take immediate action to protect workers.”

Ian Lindsley, Secretary, European Biosafety Network said: “The European Biosafety Network conducted a survey to determine the level of awareness and protection of workers in Ireland of the risk of exposure to HMPs and what safe handling measures were in place to prevent exposure. Worryingly the results presented at the Summit show a lack of awareness about the issue and low levels of risk assessments undertaken, coupled with insufficient training and a lack of preventive measures and surveillance of contamination.

“New EU legislation and guidance must be disseminated and implemented in Ireland now to protect healthcare workers from potentially devastating health impacts due to exposure at work. Further progress needs to be made. And fast.”

Opening Remarks

Clodagh Kavanagh, Chairperson of the Health & Welfare Division of Fórsa gave a warm welcome to attendees, followed by opening remarks from Darren Arkins, Senior Inspector in the Occupational Health Division of the Health and Safety Authority (HSA).

Darren Arkins outlined the HSA’s work to transpose the new EU law into Irish law with a new Statutory Instrument, the **Safety, Health and Welfare at Work (Carcinogens, Mutagens and Reprotoxic substances) Regulations 2024**. The HSA intends to publish a consolidated set of regulations with an update to the 2021 Code of Practice as well to provide clearer requirements for employers handling HMPs.

In 2022, the HSA set up an Occupational Health Division, which comprises the Occupational Health and Hygiene teams, the health and social care sector team, the psychosocial hazards team along with other teams addressing employer/ employee supports and the agriculture sector. Darren Arkins said that the Authority is recognising the importance of an enhanced focus on Occupational Health, but also aligning the HSA with similar developments in other European countries.

In terms of stakeholder engagement in the healthcare space, there will be a newly established Health and Social Care Advisory Committee of the Board, and the Authority looks forward to the sectoral expertise that this Committee can provide to the HSA and to establishing strong networks through this group.

Darren Arkens highlighted the HSA’s full commitment to enforcing the EU’s new Directive (CMRD) and the new Irish legislation and regulations which flow from the Directive to safeguard the health of workers in healthcare and other relevant sectors where HMPs occur.

How changes in European law and guidance will help prevent exposure of Irish healthcare workers and professionals to HMPs

Panellists:

- Dr Tony Musu, Senior Researcher, European Trade Union Institute (ETUI)
- Dr Paul Sessink, EU expert on HMPs and chemist
- Frank Vaughan, OSH expert, Irish Congress of Trade Unions
- Ian Lindsley, Secretary, European Biosafety Network (EBN)

Chaired by Linda Kelly, National Secretary, Fórsa

The session started with a presentation from Dr Tony Musu, in which he provided an overview of new European legislation including HMPs for the first time and a new EU list of HMPs, which must be transposed in all EU member states by 5 April 2024. This was followed by a presentation on the new EU guidance published in 2023 for the safe management of HMPs at work from Dr Paul Sessink. Both speakers drew attention to the EU's new working definition of HMPs, which describes them as medicinal products that contain one or more substances that meet the criteria for classification as carcinogenic, mutagenic and toxic for reproduction (category 1A or 1B). This means that these substances are known or presumed to have carcinogenic, mutagenic or reprotoxic potential for humans.

In 2022, the ETUI formulated a report and a list of substances to identify which HMPs fall under the legislative scope of the new Carcinogens, Mutagens or Reprotoxic substances Directive (CMRD) in Europe. Users of the European 2022 guidelines on safe handling of HMPs would thus know which specific HMPs the guidelines now apply to, well ahead of the Commission's indicative list, to be published by 2025. In this report, the ETUI found 121 substances that fall under the new EU definition for HMPs.

Key takeaways:

- HMPs affect a wide range of people and settings, from workers in the pharmaceutical industry, transport, hospitals, waste and wastewater treatment and homecare.
- Healthcare professionals exposed to HMPs risk multiple issues, including cancers and reproductive disorders for both men and women.
- 12.7 million workers are potentially exposed to HMPs in the EU of which 7.3 million are nurses.
- Annex I of the ETUI list is the first and only list of HMPs publicly available identifying hazardous drugs used in the EU that strictly fall within the scope of the EU legislation (CMRD).
- Annex II contains hazardous drugs used in the EU which are not in the scope of the CMRD but which should be treated as those in Annex I to avoid exposure of workers in a precautionary approach.
- Risk assessments are crucial to evaluate the likelihood of adverse health effects at the assessed exposure levels and responsibility lies with Occupational Safety and Health employers to carry out such checks.
- The use of Closed System Transfer Devices (CSTDs), appropriate personal protective equipment (PPE) and surface wiping are recommended methods to manage HMP exposure.

Following the presentations, the panel identified that the Irish healthcare system lacks a harmonised system of labelling to fully prevent occupational exposure to HMPs which unfortunately Tony Musu said is not part of EU policy or practice either so there is reliance on manufacturers to label the products. Therefore, healthcare workers need to identify which substances are HMPs which is why the ETUI list of HMPs is so important now as it is the only list which uses the EU definition of HMPs in the new EU Directive (CMRD) from March 2022. Healthcare workers need to cross-reference the list of HMPs to confirm which of the drugs they are using are hazardous to human health based on their known or presumed carcinogenicity, mutagenicity and reprotoxicity which is the EU definition of HMPs.

The consensus of the Summit was that there is a need for greater collaboration and communication on this issue between different levels within the Irish healthcare system. Audience members also called for greater responsibility from the pharmaceutical industry to label products as HMPs, where necessary, to facilitate clearer identification of HMPs.

Darren Arkins from the HSA clarified that changes to include HMPs in EU law, which will be transposed into Irish law by 5 April 2024, mean that Irish employers are for the first time are required to apply the hierarchy of control of preventive measures in the new Carcinogens, Mutagens and Reprotoxic Substances Directive (CMRD) and the new Irish regulations. Employers in Ireland must therefore now ensure that HMPs are made and used in closed systems, including CSTDs, where technologically possible, and if not be able to justify why they are not doing so.

Are healthcare workers and professionals in Ireland aware and engaged in preventative measures to prevent exposure to HMPs?

Panellists:

- Ian Lindsley, Secretary, European Biosafety Network
- Darren Arkins, Senior Inspector, Occupational Health Division, Health and Safety Authority

Chaired by Clodagh Kavanagh, Fórsa

Ian Lindsley started the session with a presentation and an analysis of a survey launched in January 2023, which investigated the extent of contemporary awareness of HMPs exposure among healthcare workers in Ireland and preventative measures currently taken across the country. The survey was conducted by the EBN and targeted healthcare workers and professionals based in Ireland. The presentation was followed by a panel session, chaired by Clodagh Kavanagh, and included Ian Lindsley and Darren Arkins. Speakers identified that lack of resources in Irish healthcare will make effective implementation of closed systems and CSTDs difficult. Ian Lindsley said that employers cannot use cost as a reason not to implement closed and safe systems of work to prevent occupational exposure.

Key takeaways:

- The survey concluded a lack of understanding and awareness amongst healthcare workers and professionals regarding occupational exposure to HMPs, as evidenced by relatively poor identification of the HMPs, lack of written policies for risk assessment and handling of HMPs.
    - Less than half of respondents use a list of HMPs in their workplace. Where a list is not used to identify the hazard, it is more difficult to know which drugs are hazardous let alone to prevent exposure to them.
    - The majority of those that use a list, use the National Institute for Occupational Safety and Health (NOISH) list of hazardous drugs, which is the comprehensive list from the US, dating from 2020, and therefore may not reflect the HMPs used in Ireland.
    - The majority of respondents use safety data sheets or other labelling to identify HMPs, but these does not usually include the majority of HMPs in use and is therefore do not provide comprehensive identification.
    - Almost 40% of respondents do not have a written policy for risk assessment or handling of HMPS.
- Awareness of occupational exposure is higher in pharmacy and nursing but low in other areas of the life cycle of HMPs where exposure can occur, eg cleaning, transport, and waste disposal.

- Reporting of incidents of exposure is to a good standard but this likely only reflects major spills and does not consider long term low level exposure.
- Preventative measures and controls for the safe handling of HMPs are currently in widespread use across Ireland and where controls are in place they are regularly reviewed.
- Cleaning of potentially exposed surfaces is at a good level and policy is in place for most of those who are pregnant not to work in areas of potential exposure, but 20% of respondents did not have a policy on pregnancy in place. Furthermore, reproductive problems affect male workers, however this does not appear to be addressed appropriately, if at all.
- Training on HMPs for pharmacy, nursing and medical staff is available, but most other occupational groups do not have access to it.
    - Worryingly 40% respondents said there was no requirement to maintain a record of training on handling HMPs
- Environmental and surface monitoring is poor and health monitoring of staff working with HMPs is not widely available.
    - Less than a third of respondents said that they have an environmental monitoring programme to measure surface contamination, therefore this information is not available to staff and, more crucially, without monitoring it is impossible to measure whether staff are being exposed to HMPs.
    - Among the minority of those who do monitor, the majority said it is carried out daily or twice daily. However, this is mainly during preparation and administration, not during other areas of the life cycle of HMPs.
    - The majority of staff did not receive any baseline health monitoring before starting work with HMPs
- Healthcare workers are aware of the issues facing HMPs, however plans need to be implemented by national organisations to facilitate this process.

What should Irish healthcare workers and professionals be doing in practice to protect themselves from exposure to HMPs?

Panellists:

- Dr Paul Sessink, EU expert on HMPs and chemist
- Eamonn Henry, Hospital Pharmacists Association of Ireland
- Carol McCabe, National Association of Hospital Pharmacy Technicians
- Olivia Quigley, Irish Association of Nurses in Oncology
- Dr Martin Hogan, Faculty of Occupational Medicine Ireland at RCPI

Chaired by Linda Kelly, National Secretary, Fórsa

Dr Paul Sessink introduced the session with a presentation on a case study of best practice in handling HMPs, focusing on surface wipe testing, before panellists discussed what the upcoming revisions to Irish legislation and guidance mean in practice for healthcare workers and professionals.

Key takeaways:

- Occupational healthcare professionals can be exposed to hazardous medicinal drugs via inhalation, ingestion and absorption through the skin.
- Healthcare workers are likely to be exposed to HMPs during pharmaceutical preparation, due to external vial contamination and poor handling technique, as well as administration, due to poor handling, patient contamination, waste and laundry.
- Sessink advised thorough and regular exposure assessments, using environmental and/or biological monitoring, such as air sample testing and surface wipe testing, and the use of closed system transfer devices.
- A traffic light system was advocated following surface contamination testing. The system provides a framework for when and the level of action required to prevent further contamination.
- Closed system transfer devices (CSTDs) ensure minimal contamination for healthcare professionals. In a case studies using CSTDs, low levels of contamination were found, reducing the need for regular testing and further precautions.

Following the presentation, panellists highlighted the need for training and widespread awareness of the risks posed by HMPs. Further to the data that showed that 40% of healthcare workers do not have a risk assessment in place for HMPs there was a discussion about whether this responsibility should fall to OSH specialists or be undertaken by those most affected by contamination in preparation and administration. The lack of specialist training for OSH was identified as a problem that needed to be addressed but the only way that risk assessment and the hierarchy of control can be properly applied is for a multidisciplinary approach from all stakeholders in the life cycle of HMPs. Furthermore, many at the Summit agreed for a more collaborative multidisciplinary approach to prevent further harm to healthcare workers.

Paul Sessink was asked about the need for closed systems in healthcare in the hierarchy of control required by the EU and Irish law from April 2024 for HMPs, which includes Biological Safety Cabinets, Isolators and CSTDs. He replied that cabinets and isolators are mainly designed to protect the product from microbial and HMP contamination and less focus on the

healthcare worker from contamination from HMPs while CSTDs were primarily designed to protect the healthcare worker from HMP contamination but also protect the product from chemical contamination. He also said that in no circumstances should syringes and needles ever be used to manipulate HMPs in any of the processes of manufacture or use as it will always result in environmental contamination with HMPs.

Linda Kelly thanked all the speakers and all the attendees for coming and for their constructive contributions and attention and closed the Summit.