Safe Management of Hazardous Medicinal Products in UK Healthcare Settings

A UK Multidisciplinary Consensus Document

Consultation and Endorsement
These recommendations have been developed through multidisciplinary consultation and are endorsed by the organisations listed in section 11 at the time of publication.
Consultation remains ongoing. Additional professional bodies and stakeholder organisations are reviewing the recommendations and may be added as endorsing organisations following publication or minor changes may be made to the document.
Publication of these initial recommendations represents the first stage of a wider programme of work. The subsequent development of detailed guidance and implementation arrangements will require broader multidisciplinary engagement, four-nation representation and further stakeholder consultation to ensure that the resulting approach is applicable and workable across healthcare settings and professional groups throughout the UK.

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Foreword

Hazardous medicinal products (HMPs) are used across many areas of healthcare and provide significant benefits to patients. However, they may also present occupational risks to healthcare workers if the risks are not managed appropriately. Whilst the UK has a well-established legislative framework, its interpretation and implementation varies between organisations and clinical settings. As new medicines and models of care continue to emerge, there is a need for nationally consistent, evidence-informed guidance that supports risk-based practice.

This multidisciplinary consensus document has been developed by representatives from pharmacy, nursing, pharmacy technical services, occupational health and safety, health and safety and other key stakeholders. It reflects the shared view that the safe management of HMPs cannot be addressed by any single profession in isolation. Instead, it requires collaboration across the entire medicines pathway and between all those involved in the design, manufacture, supply and use of medicines.

The document does not replace existing legislation or professional standards. Rather, it aims to support their consistent interpretation and implementation by bringing together current evidence, international experience and expert consensus within a UK healthcare context. It promotes a risk-based approach in which control measures are proportionate to the hazards presented by individual medicinal products, the tasks being undertaken and the environments in which they are used.

Although oncology has driven much of the development of safe handling practices over recent decades, the principles described in this document extend beyond cancer services. HMPs are used across many clinical specialties and healthcare settings, including acute hospitals, community services, primary care, homecare and patients' own homes. Consequently, the recommendations within this document are intended to be applicable across all healthcare sectors where HMPs are handled.

Our shared aim is to improve the protection of healthcare workers while ensuring patients continue to receive safe and effective treatment. We hope this document promotes greater consistency in practice across the UK and provides a foundation for future collaboration and continuous improvement in the safe management of HMPs.

We are grateful to all members of the multidisciplinary working group and the professional organisations that have contributed their expertise, experience and commitment to the development of this consensus document. We hope it serves as a valuable resource for all those involved in the safe management of HMPs and provides a foundation for continued collaboration and future improvements in practice.

Members, UK Multidisciplinary Working Group

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Executive Summary

Hazardous medicinal products (HMPs) are used increasingly across healthcare to treat cancer and a wide range of non-malignant conditions. Whilst these medicines provide significant clinical benefit, they also have the potential to present occupational risks to healthcare workers throughout the medicine's lifecycle, including procurement, preparation/manufacture, transport, administration, waste management and environmental decontamination. Protecting staff from occupational exposure is therefore an essential component of safe medicines governance, occupational health and safety (H&S) and patient care.

The United Kingdom already has a robust legislative framework governing occupational exposure to hazardous substances, principally through the Health and Safety at Work etc Act 1974, Health and Safety at Work (Northern Ireland) Order 1978, the Control of Substances Hazardous to Health (COSHH) Regulations 2002 and The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003. However, unlike some international approaches, UK legislation is intentionally risk-based rather than prescriptive. Employers are required to undertake suitable and sufficient occupational risk assessments and implement control measures that are proportionate to the level of occupational risk. Whilst this provides flexibility across different healthcare settings, it has also resulted in considerable variation in how HMPs are identified, risk assessed and managed.

Variation exists in the interpretation and implementation of legislation across healthcare organisations and professional groups, including pharmacy, nursing, medicine, community pharmacy and homecare services. Differences are evident in the classification of HMPs, occupational risk assessments, engineering controls personal protective equipment (PPE), health surveillance and the occupational H&S information used to support decision making. Consequently, healthcare workers undertaking similar activities may receive different levels of occupational H&S protection depending on where care is delivered.

International guidance, including that developed by the European Commission, the National Institute for Occupational Safety and Health (NIOSH), the United States Pharmacopeia (USP) and other organisations, provides valuable principles and examples of good practice. However, differences in legislation, healthcare delivery and regulatory systems mean these approaches are not currently adopted within the UK. There remains a need for nationally consistent guidance that supports the interpretation and implementation of existing UK legislation whilst remaining aligned with UK regulatory requirements and healthcare practice.

This multidisciplinary consensus document has been developed to support a more consistent, evidence-informed and proportionate approach to the safe management of HMPs across all UK healthcare settings. Although many examples relate to systemic anticancer therapy (SACT), the principles and recommendations apply to all HMPs where occupational exposure may occur. The document is intended for government officials, healthcare professionals, employers, regulators, trade unions, professional organisations, manufacturers and policy makers involved in the management of HMPs.

The document proposes five strategic recommendations:

1. **Establish a UK Framework for Hazardous Medicinal Products (HMPs)** through a nationally recognised approach to the identification and classification of HMPs, supported by transparent governance and occupational risk assessment principles.

2. **Prioritise Safer Product Design** by working with pharmaceutical manufacturers and regulators to promote pharmaceutical presentations that minimise handling and reduce occupational exposure, including ready-to-administer products and prefilled devices where appropriate.

3. **Develop National PPE Standards** to provide consistent, evidence-based recommendations for PPE across all healthcare settings.

4. **Improve Access to Occupational Health and Safety Risk Information** through a central, freely accessible resource bringing together Safety Data Sheets (SDSs), Summary of Product Characteristics (SmPCs) and other occupational H&S information, with consideration of dedicated occupational handling information within the SmPC.

5. **Improve Consistent Implementation Through Education and Collaboration** by supporting multidisciplinary education, competency frameworks and occupational health and safety expertise. National collaboration is imperative to promote consistent interpretation of UK legislation, strengthen the quality and consistency of occupational risk assessments, and support the consistent application of this guidance across all healthcare settings. Organisations should adopt a continuous quality improvement approach, including programmes of external audit, to evaluate implementation, identify unwarranted variation in practice, and support continual improvement.

In addition, the document identifies future work to evaluate the application of closed systems technologies as engineering controls throughout the medicines lifecycle, including the use of closed system transfer devices (CSTDs), closed-system bag spikes and other emerging technologies during aseptic preparation/manufacture, outsourced compounding, clinical area preparation, medicine administration and further work on the practical implementation regarding stability and microbial integrity. Published evidence has demonstrated that environmental contamination with HMPs may occur throughout the medicine's lifecycle, from preparation/manufacture through to administration, despite existing control measures (Sessink et al., 2026). The aim is to develop nationally consistent, evidence-informed recommendations that minimise occupational exposure whilst maintaining product quality, patient safety and operational efficiency as the evidence base continues to evolve.

Ultimately, this document concludes that the principal challenge within the UK is not the absence of legislation, but variation in its interpretation and implementation. A nationally coordinated, multidisciplinary approach has the potential to improve consistency, reduce unwarranted variation, strengthen occupational H&S protection for healthcare workers and support the safe management of HMPs across all healthcare settings.

1. Introduction

1.1 Background

1.1.1 Hazardous medicinal products (HMPs) are increasingly used across a wide range of healthcare settings to treat cancer and many non-malignant conditions. While these medicines provide substantial benefits for patients, they also have the potential to present occupational risks to healthcare workers and others who may be exposed during the receipt, preparation/manufacture, transportation, administration, storage, disposal or handling of contaminated waste and patient excreta. Exposure may occur through a variety of routes, including dermal contact, inhalation, accidental injection and ingestion, making appropriate risk assessment and implementation of effective control measures essential (Health and Safety Executive, nd, European Commission, 2023; Campbell et al., 2024; International Society of Oncology Pharmacy Practitioners (ISOPP), 2022; NIOSH, 2024).

1.1.2 The safe management of HMPs is therefore an essential component of both patient safety and occupational health and safety (H&S). UK employers have a legal duty to proactively assess and manage risks associated with hazardous substances under existing H&S legislation, including, but not limited to, Health and Safety at Work etc Act (1974), Health and Safety at Work (Northern Ireland) Order 1978, The Control of Substances Hazardous to Health (COSHH) Regulations (2002), The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003, Hazardous Waste Regulations (2005), The Hazardous Waste (Wales) Regulations 2005, Hazardous Waste Regulations (Northern Ireland) 2005 , Special Waste Amendment (Scotland) Regulations 2004, Management of Health and Safety at Work Regulations (1999), Management of Health and Safety at Work Regulations (Northern Ireland) 2000, Personal Protective Equipment at Work Regulations (1992) and Personal Protective Equipment at Work Regulations (Northern Ireland) 1993. Applying the hierarchy of controls and undertaking proportionate, evidence-informed occupational H&S risk assessments are fundamental to protecting healthcare workers from occupational exposure to HMPs.

1.1.3 HMPs encompass a broad range of medicines and dosage forms used across multiple therapeutic areas with individual medicines, dosage forms and handling activities. Despite the existing UK legislative framework, there is considerable variation across healthcare organisations in how HMPs are identified, risks are assessed and control measures implemented. This reflects the risk-based nature of UK legislation, which requires employers to undertake "suitable and sufficient" assessment of occupational risk and, in relation to substances hazardous to health, to prevent exposure where reasonably practicable or otherwise adequately control exposure (Management of Health and Safety at Work Regulations 1999, reg. 3; Management of Health and Safety at Work Regulations (Northern Ireland) 2000, reg. 3). Whilst this approach provides flexibility to accommodate different healthcare settings and models of care, it also requires local interpretation and professional judgement. Consequently, organisations may reach different conclusions regarding the management of similar HMPs, despite undertaking very similar tasks and activities. This has resulted in repeated local occupational risk assessments for similar medicines and activities, together with variation in the interpretation of legislation, application of the hierarchy of controls, engineering controls, PPE requirements, handling procedures and local policies. These variations are evident across pharmacy, nursing, medical, technical services, community healthcare, homecare and other care settings, and may result in inconsistent protection for staff, uncertainty in clinical practice and unnecessary variation in service delivery, duplication of local occupational risk assessments,

inefficient use of resources and barriers to implementing new models of care (European Commission, 2023; Campbell and Dicksit, 2025; Ryan et al., 2023; Specialist Pharmacy Service (SPS), 2025).

1.1.4 Internationally, several organisations have developed guidance and frameworks for HMPs. However, differences in legislation, healthcare systems and regulatory approaches mean that these are not currently adopted within UK practice. There remains a need for UK-specific multidisciplinary guidance that supports consistent interpretation and implementation of existing legislation while supporting the safe implementation of new and innovative ways of working, recognising the diversity of healthcare settings and evolving models of care (European Commission, 2023; NIOSH, 2024; USP, 2019).

1.1.5 The safe management of HMPs requires expert perspectives, and evidence-informed practices from pharmacy, nursing, medicine, occupational H&S, H&S, technical services, manufacturers and regulators. Each role has valuable insight into current service needs and the safe management of HMPS cannot therefore be addressed by any single profession alone. Developing nationally consistent approaches requires collaboration across disciplines to ensure occupational safety measures are evidence-informed and applicable across all healthcare settings and professional boundaries, ensuring that the full lifecycle of HMPs and associated occupational risks is considered (European Commission, 2023; ISOPP, 2022).

1.2 Scope of this document

1.2.1 This multidisciplinary consensus document examines the current management of HMPs within UK healthcare settings and considers the challenges associated with the interpretation and implementation of existing legislation and guidance.

1.2.2 The document reviews the available evidence, current UK practice and relevant international approaches to identify areas of variation and opportunities for improvement. It is intended to inform healthcare organisations, professional bodies, trade unions, regulators, policy makers and other stakeholders involved in the safe management of HMPs.

1.2.3 The recommendations are applicable across all healthcare settings where HMPs are handled, including, but not limited to, hospitals, aseptic services, community healthcare, primary care, homecare and patients' homes, and are intended to extend beyond oncology to encompass all HMPs.

1.2.4 For the purposes of this document, HMPs are medicines identified as presenting a potential occupational hazard based on their intrinsic hazardous properties, informed by available evidence including regulatory classifications, manufacturers' information and published literature. HMPs encompass a broad range of medicines across multiple therapeutic areas and dosage forms; however, the potential occupational risk varies considerably depending on the hazardous properties of the medicine, its formulation, the task being undertaken and the potential for occupational exposure.

1.2.5 This document primarily focuses on HMPs that require handling by healthcare workers during the medicine’s lifecycle, including receipt, storage, preparation/ manufacture, reconstitution, transport, administration, disposal and the management of contaminated waste and patient excreta. Although many examples relate to SACT, the principles are intended to apply across therapeutic areas where occupational exposure may occur. They are not intended to prescribe identical control measures for every HMP or dosage form, which should instead be determined through product-specific occupational risk assessment.

1.2.6 Some dosage forms (for example topical preparations, inhaled medicines, ophthalmic preparations and medicinal gases) may present different occupational exposure pathways and require additional product-specific risk assessments. These are outside the detailed scope of this consensus document.

1.3 Intended Audience

1.3.1 This document is intended for all healthcare professionals and organisations involved in the handling or management of HMPs, including but not limited to:

- UK Government
- Regulators and policy makers
- Commissioners
- Hospital pharmacy staff Registered nurses
- Medical staff
- Aseptic and technical services personnel
- Community pharmacy teams
- Homecare medicine administration service providers
- Health and social care providers e.g. care homes, nursing homes and community care
- Allied health professionals
- Healthcare support workers
- Occupational H&S
- H&S professionals
- Occupational hygienists
- Professional organisations
- Trade Unions
- Trade union H&S representatives
- Managers and organisational leaders responsible for medicines governance

1.4 Overview of the medicine's lifecycle

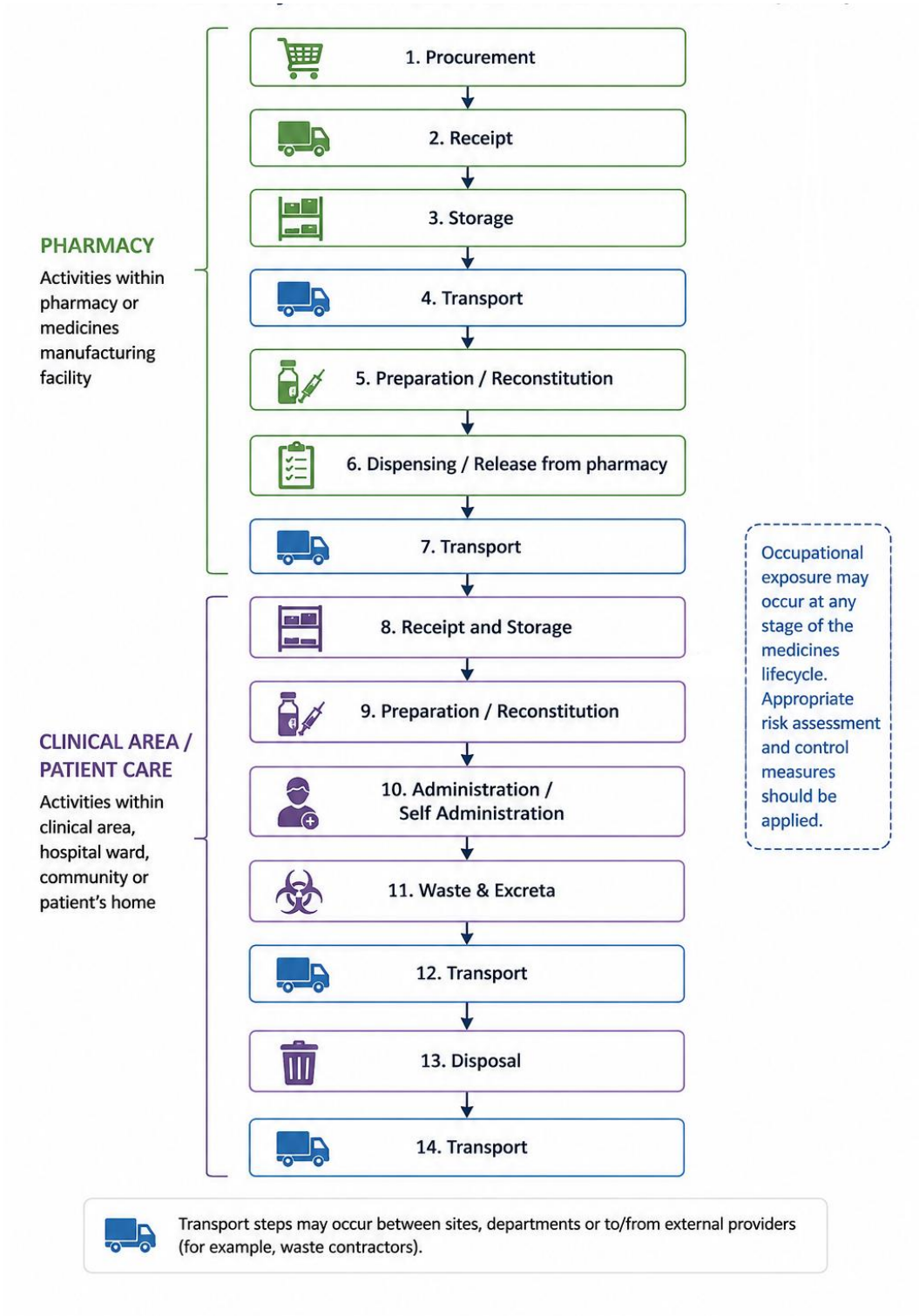
1.4.1 Healthcare workers may encounter HMPs at multiple stages throughout the medicine's lifecycle whilst in their working environment, each situation presenting different occupational risks, and requiring appropriate control measures (NIOSH, 2024; USP, 2019).

1.4.2 These stages include medicine procurement, receipt, storage, transport, preparation /manufacture or reconstitution, dispensing, administration, nurse/patient (self) administration, management of spills, handling of contaminated waste and excreta, cleaning of equipment and environments, and final disposal of all associated resources (European Commission,2023; NIOSH, 2024).

1.4.3 The nature and magnitude of occupational exposure may vary depending on factors such as the hazardous properties of the medicinal product, formulation, route of administration, packaging, frequency of handling, PPE worn and the clinical environment in which care is delivered. Consequently, risk assessments should consider both the intrinsic hazards of the medicinal product and the specific activities being undertaken, ensuring that control measures remain proportionate, evidence-informed and aligned with the hierarchy of controls. (COSHH Regulations, 2002; NIOSH, 2024; SPS, 2025).

1.4.4 A summary of the HMP pathway and key points at which occupational exposure may occur is provided in Figure 1.

Figure 1: HMP pathway *Developed by the UK Multidisciplinary Working Group for the Safe Management of HMPs in UK Healthcare Settings consensus document (2026).*



Source: Developed by the UK Multidisciplinary Working Group. Adapted from the medicine's lifecycle described within this consensus document.

2. Definitions

Term	Sub Term	Definition
Administration	**Administration**	The process of giving a medicinal product to a patient by an approved route, including associated handling immediately before and after administration and the safe disposal of equipment and waste generated during the procedure.
	Registered Nurse Administration	Administration of a medicinal product to a patient by a registered nurse. Where preparation is undertaken immediately prior to administration within a clinical area, this includes any associated reconstitution, dilution or manipulation required in accordance with the product licence, local policy or approved procedures.
	Self-Administration of medicines (SAM)	A structured process that enables a patient, or where appropriate their carer, to administer some or all of their prescribed medicines independently following an individual risk assessment, appropriate education and agreement by the healthcare team. Self-administration may occur in hospital, other healthcare settings or at home and should be subject to ongoing review.
Antibody-Drug Conjugates (ADCs)/ Conjugated monoclonal antibodies		Monoclonal antibodies that are chemically linked to another active component, such as a cytotoxic drug, radioactive substance or other therapeutic agent. The occupational hazard associated with a conjugated mAb should consider both the antibody and the properties of the conjugated component. Antibody–drug conjugates (ADCs) are a type of conjugated monoclonal antibody in which the antibody is linked to a pharmacologically active drug, often a potent cytotoxic agent.
Engineering Controls	**Closed System Transfer Device (CSTD)**	A drug transfer device that mechanically prevents environmental contaminants entering the system and hazardous drug or vapour escaping outside the system.
	Engineering Controls	Physical or mechanical measures used to minimise occupational exposure to HMPs, such as biological safety cabinets, isolators and containment devices.
	Partially enclosed system	An engineering control that provides containment of a HMP but may require limited manual intervention or open handling during part of the process.
	Totally enclosed system	An engineering control that completely contains the HMP, preventing occupational exposure during handling.
Hazardous Medicinal Product (HMP)		A medicinal product with one or more hazardous properties that may present an occupational risk to healthcare workers or others during handling, preparation /manufacture, administration, transport, storage or disposal.
Hazardous Properties		The intrinsic physical, chemical or toxicological characteristics of a medicinal product that may present a risk to health following occupational exposure. Examples include carcinogenicity, mutagenicity, reproductive toxicity, genotoxicity, sensitisation, organ toxicity and acute toxicity.
Hazardous Waste		Waste contaminated with HMPs that requires segregation and disposal in accordance with relevant legislation and local policy.
Healthcare Professionals (HCPs)		All healthcare workers who may handle HMPs, including pharmacy staff, nursing staff, medical staff, allied health professionals, healthcare support workers, technical services staff, homecare providers, housekeeping staff, transport staff, porters and waste management personnel.

Term	Sub Term	Definition
Key Legislative and Risk Management Terms	**Adequate control**	Control measures that prevent exposure where reasonably practicable and, where prevention is not possible, reduce occupational exposure so far as is reasonably practicable in accordance with COSHH and the hierarchy of controls.
	Evidence-informed	Decisions based on the best available information, including published literature, manufacturers' information (SmPCs and SDSs), environmental monitoring, incident reports, expert consensus and occupational risk assessment, recognising that high-quality evidence may not always be available.
	Hierarchy of controls	A structured approach to risk management that prioritises elimination, substitution, engineering controls and administrative controls before relying on personal protective equipment (PPE).
	Occupational risk assessment	A systematic assessment of the hazardous properties of the medicinal product, the task, the likelihood and route of exposure, the people at risk, the working environment and the effectiveness of existing control measures to determine appropriate risk controls.
	Precautionary approach	Applying appropriate control measures where uncertainty exists regarding occupational risk, whilst reviewing controls as further evidence becomes available.
	Proportionate	Control measures that are selected according to the assessed occupational risk and implemented using the hierarchy of controls. Proportionate does not mean accepting unnecessary occupational exposure.
	Reasonably practicable	A legal principle requiring employers to balance the level of occupational risk against the measures needed to control it, taking into account what is reasonably achievable. Where carcinogens, mutagens or reprotoxic substances are concerned, COSHH requires exposure to be prevented where reasonably practicable or otherwise reduced to the lowest level reasonably practicable.
	Suitable and sufficient	The standard required under COSHH for occupational risk assessments, meaning they adequately identify foreseeable hazards, persons at risk and appropriate control measures.
Occupational Exposure		Exposure of a worker to a HMP through inhalation, dermal contact, ingestion or accidental injection (or other routes) during work activities.
Personal protective equipment (PPE)		Equipment worn to minimise exposure to occupational hazards. PPE should be selected following an occupational risk assessment and used as part of the hierarchy of controls, after engineering and administrative controls have been considered.
Pins, Spikes and Transfer Devices		Devices used to access, transfer or administer medicinal products.
Preparation	**Manufacture**	The process of preparation in an aseptic unit under an MHRA Licence
	Preparation	This is a process of manipulation of a medicinal product before administration, which may include (some or all of the following): reconstitution, calculating the dose, drawing up the correct amount, dilution, withdrawal, transfer, labelling, checking compatibility and expiration, or assembly of administration systems.

Term	Sub Term	Definition
	Reconstitution	One step in the preparation of a medicinal product involving the addition of a liquid diluent or other constituent, into a dry ingredient, (in accordance with the manufacturer's instructions), to make a specific concentration, to prepare the product for administration
Professional Groups	**BOPA (British Oncology Pharmacy Association)**	A Specialist Pharmacy Group (SPG) for cancer pharmacy in the UK,, supporting pharmacists and pharmacy technicians through education, professional development, clinical guidance, research and national standards to improve cancer medicines optimisation and patient care.
	PASG (Pharmacy Aseptic Services Group)	The UK professional group representing pharmacists, pharmacy technicians and scientists working in aseptic services. PASG promotes safe, high-quality aseptic preparation through professional guidance, education, networking, research and the development of standards supporting NHS aseptic and technical service
	RCN (Royal College of Nursing)	The professional body and trade union for nursing staff in the UK, providing professional leadership, education, clinical guidance and representation to support high-quality nursing practice and improve patient care across all healthcare settings.
	UKONS (UK Oncology Nursing Society)	The UK professional organisation for cancer nurses, promoting excellence in oncology nursing through education, research, clinical guidance, networking and professional development to improve outcomes and experiences for people affected by cancer.
	UKSB (UK SACT Board)	A UK multidisciplinary advisory group comprising representatives from the Royal College of Radiologists (RCR), Royal College of Physicians (RCP), Association of Cancer Physicians (ACP), British Oncology Pharmacy Association (BOPA), UK Oncology Nursing Society (UKONS) and British Society for Haematology (BSH). The Board has representation from all four UK nations and from organisations involved in the delivery of SACT. It works collaboratively to develop national guidance, promote best practice and improve the quality, safety and consistency of SACT services across the UK.
UK REACH and Safety Data Sheets (SDSs)	**Safety Data Sheet**	A document produced by the manufacturer that provides information on the hazards of a substance or mixture and recommendations for its safe handling, storage, exposure control, emergency measures and disposal. A requirement of REACH regulation: Safety Data Sheets (SDSs) are the primary tool for communicating chemical hazards and safety measures. Suppliers must provide them for hazardous substances, mixtures, or non-hazardous chemicals containing specific dangerous components, ensuring workplace users can safely manage risks
	UK Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	UK legislation regulating the manufacture, import and use of chemicals to protect human health and the environment by ensuring that information on hazardous properties and safe handling is available.
Summary of Product Characteristics (SmPC)		A regulatory document approved as part of a medicinal product's marketing authorisation that provides healthcare professionals with information on the safe and effective use of the medicine, including indications, dosing, preparation, administration, storage and other product-specific information.

3. UK Legislative and Regulatory Framework

3.1 Introduction

3.1.1 The management of HMPs in the UK is governed by existing H&S legislation rather than legislation specific to hazardous medicines. Employers have a legal duty to protect the health, safety and welfare of employees and others who may be affected by work activities, including exposure to HMPs (Including but not limited to Health and Safety at Work etc Act(1974), Health and Safety at Work (Northern Ireland) Order 1978, The Control of Substances Hazardous to Health (COSHH) Regulations (2002), The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003, Hazardous Waste Regulations (2005), The Hazardous Waste (Wales) Regulations 2005, Hazardous Waste Regulations (Northern Ireland) 2005, Special Waste Amendment (Scotland) Regulations 2004, Management of Health and Safety at Work Regulations (1999), Management of Health and Safety at Work Regulations (Northern Ireland) 2000, Personal Protective Equipment at Work Regulations (1992) and Personal Protective Equipment at Work Regulations (Northern Ireland) 1993).

3.1.2 Throughout this document, terms such as *suitable and sufficient*, *adequate control*, *reasonably practicable*, *proportionate*, *evidence-informed* and *occupational risk assessment* are used in accordance with UK health and safety legislation and established occupational H&S risk management principles. These terms should be interpreted within the context of preventing or adequately controlling occupational exposure to HMPs through application of the hierarchy of controls rather than as justification for differing local standards of protection.

3.1.3 The Health and Safety at Work etc Act (1974) and Health and Safety at Work (Northern Ireland) Order 1978 are the primary pieces of legislation covering occupational H&S in Great Britain and NI. They place a duty on employers to ensure, so far as is reasonably practicable, the health, safety and welfare of employees and others who may be affected by their undertaking. Employees also have a responsibility to take reasonable care for their own H&S and that of others who may be affected by their actions (Health and Safety at Work etc Act 1974; Health and Safety at Work (Northern Ireland) Order 1978).

3.2 COSHH Regulations (2002), COSHH Regulations (Northern Ireland) 2003

3.2.1 The COSHH Regulations 2002 (as amended) and The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003 require employers to assess and adequately control the risks arising from exposure. The overriding duty is to prevent exposure. If prevention is not reasonably practicable the employer must control exposure adequately by all routes, (COSHH Regulations, 2002; The Control of Substances Hazardous to Health Regulations (Northern Ireland) (COSHH) 2003).

3.2.2 Under COSHH, employers are required to:

- Undertake a suitable and sufficient occupational risk assessment before work involving HMPs commences (Regulation 6).
- Prevent occupational exposure to HMPs. Where exposure cannot be prevented, employers must adequately control exposure by all routes (Regulation 7).
- Where an HMP meets the definition of a carcinogen or mutagen substance, implement the additional control measures required under COSHH, including reducing exposure to as low a level as is reasonably practicable (ALARP) and applying the specific provisions of Regulation 7.

- Ensure that risk assessments are undertaken by competent persons with appropriate knowledge of the hazardous properties of the medicinal product, occupational exposure risks and relevant control measures.
  Consideration could be given to:
  - The competencies required to perform occupational risk assessments for HMPs.
  - How individuals acquire and maintain these competencies through education, training, and continuing professional development.
  - Mechanisms for assessing and assuring competence over time.
  - Whether there is a professional body, regulatory body, or recognised framework responsible for overseeing or defining these competencies.
- Apply the hierarchy of control and where engineering controls are implemented, ensure they are appropriately designed, maintained, thoroughly examined and tested at the intervals specified by COSHH, including local exhaust ventilation where applicable (Regulation 9).
- Provide appropriate information, instruction and training to staff who may handle or come into contact with HMPs, including the hazardous properties of the medicines, routes of occupational exposure, control measures, emergency procedures and the correct use of personal protective equipment (Regulation 12).
- Monitor occupational exposure and implement health surveillance were indicated by the risk assessment and where an identifiable disease or adverse health effect may be related to the exposure there is a reasonable likelihood that the disease or effect may occur under the particular conditions of his work and there are valid techniques for detecting indications of the disease or effect as required by COSHH (Regulations 10 and 11).
- Review and update risk assessments whenever there is reason to believe they are no longer valid, or where changes to medicines, evidence, technology or working practices may affect occupational risk.

3.2.3 The occupational lifecycle of HMPs should be underpinned by the precautionary principle. Under the COSHH Regulations, where there is reasonable evidence that a medicinal product may present a risk to workers, particularly through carcinogenicity, mutagenicity, reproductive toxicity, sensitisation or other serious health effects, exposure should be prevented or reduced to the lowest level reasonably practicable. In the case of new and emerging medicines, where occupational exposure data may be limited or incomplete, employers should adopt a precautionary approach, undertaking robust risk assessments and implementing appropriate control measures until sufficient evidence demonstrates that lower levels of control are justified. Uncertainty should not be used as a reason to delay protective measures for workers potentially exposed to HMPs. The control measures implemented should be proportionate to the occupational risks associated with the HMP and the specific task being undertaken, rather than determined solely by therapeutic class or local custom.

3.3 Employer Responsibilities

3.3.1 Employers are responsible for implementing systems that protect staff from occupational exposure to HMPs. This includes ensuring that appropriate governance arrangements, standard operating procedures, hierarchy of control is properly applied (e.g. engineering controls, personal protective equipment) and training and competency assessment are in place (COSHH Regulations, 2002; COSHH Regulations (Northern Ireland) 2003). Where available, nationally recognised competency frameworks, such as the UKONS SACT Passport/BOPA verification SACT Passport for staff involved in SACT, should be used to support education, competency assessment and ongoing professional development.

3.3.2 Control measures should be proportionate to the level of occupational risk and based on the hazardous properties of the medicinal product, the task being undertaken, the likelihood of exposure and the healthcare setting in which the activity takes place (European Commission, 2023; ISOPP, 2022; National Institute for Occupational Safety and Health (NIOSH), 2024; SPS, 2025).

3.3.3 Employers should ensure that appropriate occupational H&S advice is available for staff handling HMPs, including following significant occupational exposure and for workers who are pregnant, planning pregnancy or breastfeeding (COSHH Regulations 2002; European Commission, 2023).

3.3.4 In line with HSG65's Plan-Do-Check-Act approach, organisations should systematically monitor (e.g. surface wipe testing), review and verify the effectiveness of their risk control measures, using performance data, audits, inspections and learning from incidents to adapt controls and management arrangements in response to emerging evidence, drive continual improvement, and ensure that H&S arrangements remain effective and proportionate.

3.4 Risk Assessment

3.4.1 Risk assessment forms the cornerstone of the UK approach to managing HMPs. COSHH requires employers to undertake a suitable and sufficient assessment of the risks associated with hazardous substances before work is undertaken (COSHH Regulations 2002; COSHH Regulations (Northern Ireland) 2003).

3.4.2 Risk assessments should consider:

- Information on health effects provided by the supplier, the nature and duration of the task (substances produced or emitted, e.g. as fumes, vapour dust, by a process or an activity, or as a result of an accident or incident)
- The level, type and duration of exposure
- The work activity and amount of substance used
- The potential routes of occupational exposure.
- The frequency of handling.
- The healthcare setting and environmental controls.
- The effectiveness of existing control measures.
- The results of health surveillance
- Risk assessments should be documented, regularly reviewed and updated when new evidence, medicines, technologies or working practices become available.

3.4.3 Occupational H&S risk assessment should consider the hazardous properties of the individual HMP, together with the formulation, task being undertaken, potential routes and likelihood of occupational exposure, and the environment in which the activity takes place. Not all HMPs present the same occupational risk, and control measures should therefore be proportionate to the level of demonstrated risk (SPS, 2025; NIOSH, 2024; ISOPP, 2022).

3.4.4 An example framework illustrating the key stages of occupational health and safety risk assessment for HMPs is provided in Figure 2.

3.5 Hierarchy of Controls

3.5.1 COSHH requires employers to apply the hierarchy of controls when determining how occupational exposure should be managed. Wherever reasonably practicable, exposure should be prevented. Where this is not possible, exposure should be reduced to ALARP using the most effective control measures available (COSHH Regulations, 2002; COSHH Regulations (Northern Ireland) 2003).

3.5.2 The hierarchy of controls comprises:

- Elimination of the hazard where possible.
- Substitution with a less hazardous alternative where appropriate.
- Engineering controls to isolate or contain the hazard.
- Administrative controls, including safe systems of work, procedures, training and competency.
- PPE as the final layer of protection and used in combination with other controls.

3.5.3 Personal protective equipment should not be relied upon as the sole method of exposure control where higher-order controls are reasonably practicable (ISOPP, 2022; NIOSH, 2024; USP, 2019).

3.5.4 The objective of occupational H&S risk management under the current UK legislative framework is to reduce occupational exposure to HMPs to ALARP through application of the hierarchy of controls and proportionate risk management measures (Health and Safety at Work etc Act, 1974; COSHH Regulations (Northern Ireland) 2003).

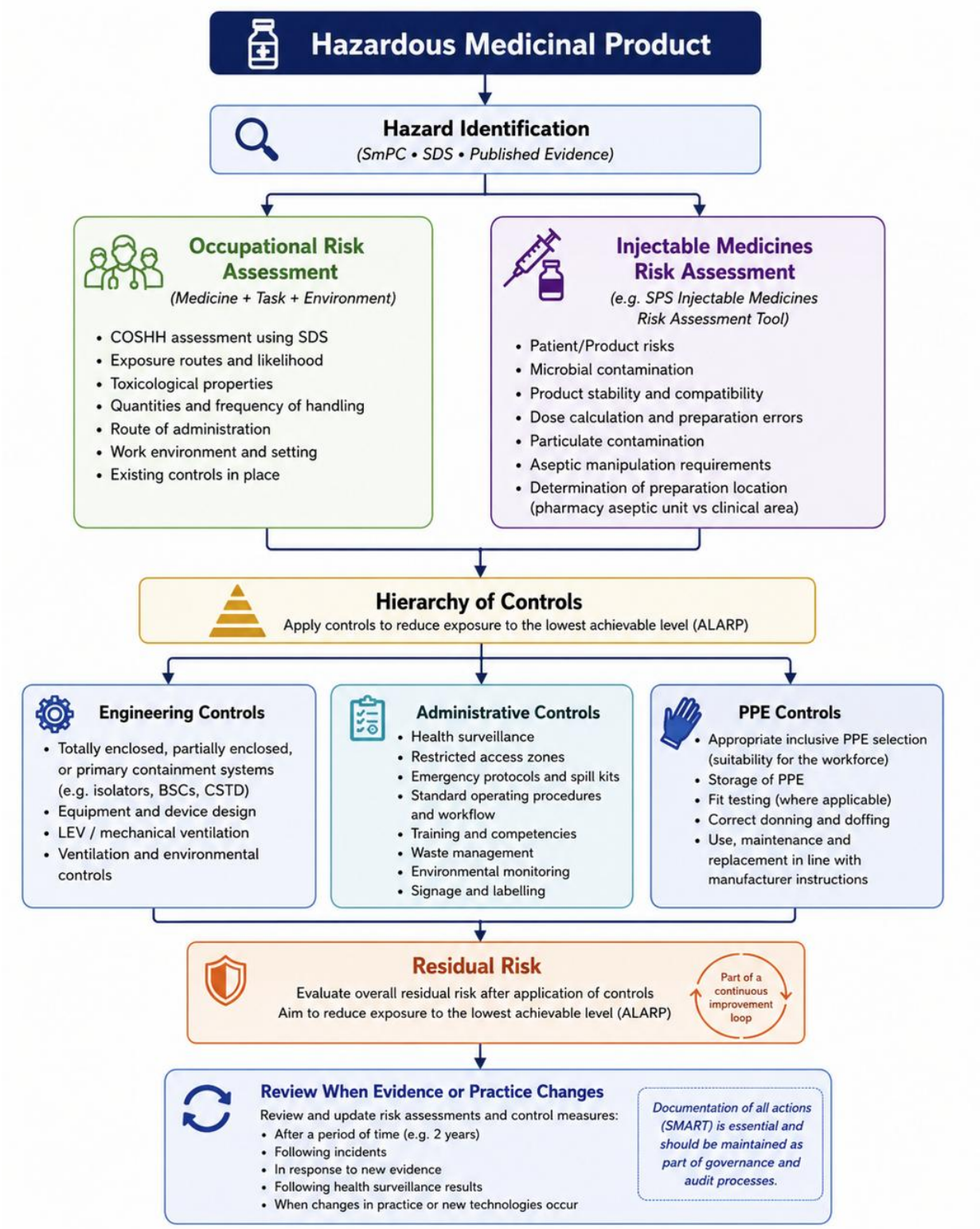
3.5.5 The Royal College of Nursing (RCN) has recommended that future UK legislation should strengthen the control of carcinogenic, mutagenic and reprotoxic (CMR) substances by replacing the current requirement to reduce exposure "as low as is reasonably practicable (ALARP)" with a requirement to reduce occupational exposure to the "lowest possible level." This recommendation is not a legal requirement of the current COSHH Regulations (Royal College of Nursing, 2025).

3.6 MHRA Requirements

3.6.1 The Medicines and Healthcare products Regulatory Agency (MHRA) regulates the quality, safety and efficacy of medicinal products placed on the UK market. Marketing Authorisations include information relevant to the safe use, preparation /manufacture, storage and disposal of medicines, as described within the Summary of Product Characteristics (SmPC) (Human Medicines Regulations 2012).

3.6.2 Whilst the SmPC provides important product-specific information, employers remain responsible under H&S legislation for adhering to COSHH regulations and undertaking occupational risk assessments and implementing appropriate control measures. The SmPC should therefore be considered alongside other relevant evidence and occupational H&S information when assessing the risks associated with handling HMPs (COSHH Regulations, 2002; MHRA, 2019; SPS, 2025).

Figure 2. Example Occupational H&S Risk Assessment Framework for Hazardous Medicinal Products *Developed by the UK Multidisciplinary Working Group for the Safe Management of Hazardous Medicinal Products in UK Healthcare Settings consensus document (2026).*



Source: Developed by the UK Multidisciplinary Working Group. Based on the principles of the Control of Substances Hazardous to Health (COSHH) Regulations, the hierarchy of controls and occupational risk assessment principles described within this consensus document.

4. International Context

4.1.1 A number of countries and organisations have developed guidance, standards and regulatory frameworks to support the safe management of HMPs. While these have informed international practice, they have been developed within different legislative, regulatory and healthcare systems and should therefore be considered within their respective contexts. They provide valuable examples that may inform future developments in UK practice and support consideration of whether existing international approaches could be adopted, adapted or endorsed within the context of UK service provision (European Commission, 2023; ISOPP, 2022; NIOSH, 2024; USP, 2019).

The following information is included for context and should be considered alongside the recommendations.

4.2 National Institute for Occupational Safety and Health (NIOSH)

4.2.1 The National Institute for Occupational Safety and Health (NIOSH), United States of America, publishes a list of hazardous drugs based on defined hazard criteria, including carcinogenicity, genotoxicity, reproductive toxicity, organ toxicity at low doses and other serious toxic effects. The NIOSH list is widely referenced internationally and provides a structured approach to identifying HMPs that may require additional precautions during handling (NIOSH, 2024).

4.3 United States Pharmacopeia Chapter <800> (USP <800>)

4.3.1 USP <800> establishes standards for the handling of hazardous drugs throughout the medication-use process, including receipt, storage, preparation /manufacture, transport, administration and disposal. The standard places particular emphasis on engineering controls, environmental requirements, PPE and staff training to minimise occupational exposure (USP, 2019).

4.4 European Approaches

4.4.1 Across Europe, approaches to HMPs vary between countries. The European Union has strengthened the protection of workers exposed to HMPs through updates to occupational H&S legislation, while implementation is undertaken at national level. Individual countries have developed their own guidance, risk assessment methodologies and recommendations, resulting in variation in practice across Europe (European Commission, 2023; European Parliament and Council, 2022).

4.5 Swedish Model

4.5.1 Sweden has developed a structured occupational risk assessment approach that considers both the hazardous properties of medicinal products and the specific tasks being undertaken. This allows control measures to be proportionate to the level of occupational exposure rather than applying identical precautions to all medicines and activities. The model has been used to support consistent decision-making across healthcare settings (European Commission, 2023).

4.6 Canadian Initiatives

4.6.1 Canada has developed several national and provincial initiatives to support the safe handling of hazardous drugs. In addition to national guidance, collaborative work is underway to develop internationally applicable approaches for the classification of HMPs, reflecting increasing recognition of the need for harmonisation across healthcare systems (National Association of Pharmacy Regulatory Authorities, 2015; ISOPP, 2022).

4.7 Relevance to UK Practice

4.7.1 Despite differences in legislation and healthcare delivery, several common principles are evident across international approaches:

- Identification of HMPs using defined criteria.
- Occupational risk assessment based on the hazardous properties of the medicine, the task being performed and environment.
- Application of the hierarchy of controls to minimise occupational exposure.
- Use of engineering controls, safe systems of work and appropriate personal protective equipment.
- Education, competency assessment and ongoing staff training.
- Regular review of emerging evidence and newly licensed medicines.

4.7.2 The principal differences relate to the legal frameworks, regulatory requirements and the degree of prescriptiveness within national guidance. Some countries specify minimum engineering controls or environmental standards, whereas the UK legislative framework is primarily risk-based and requires employers to determine appropriate control measures through suitable and sufficient risk assessment (COSHH Regulations, 2002; European Commission, 2023).

4.7.3 These international approaches provide valuable examples of how HMPs may be classified, assessed and managed. Consideration of their underlying principles may help inform future UK guidance, promote greater consistency in practice and support evidence informed occupational risk management, while recognising that any future UK approach follows aligned with UK legislation and healthcare practice (European Commission, 2023; ISOPP, 2022; NIOSH, 2024; USP, 2019).

5. Current Challenges in UK Practice

5.1.1 Although UK legislation provides a common framework for managing occupational exposure to HMPs, considerable variation exists in how this is interpreted and implemented across healthcare organisations. This variation extends across professional groups, healthcare settings and individual medicinal products, resulting in inconsistent approaches to risk assessment and the selection of control measures (European Commission, 2023; ISOPP, 2022; SPS, 2025).

5.2 Variation in Practice

5.2.1 Personal Protective Equipment (PPE)

5.2.1.1 The selection and use of PPE during the handling of HMPs varies between organisations and clinical settings. Current UK practice demonstrates broad consistency in the routine use of disposable plastic aprons during medicine administration; however, greater variation exists in glove selection, the use of long-sleeved impermeable gowns and the circumstances in which additional PPE is used (Campbell & Dicksit, 2025a; Campbell & Dicksit, 2025b). Differences exist in:

- the type of gloves used.
- the use of disposable plastic aprons compared with long-sleeved impermeable gowns.
- the activities for which PPE is required; and the circumstances in which additional PPE (for example, eye protection or respiratory protective equipment) is required following occupational risk assessment.

This variation is evident across both preparation /manufacture and administration activities and is often driven by local policy rather than a consistent national approach (NIOSH, 2024; USP, 2019;).

5.2.1.2 Although disposable plastic aprons are widely used in UK practice during medicine administration, international guidance generally recommends the use of impermeable, long-sleeved protective gowns for many HMP handling activities. This difference highlights variation between current UK practice and international recommendations (European Commission, 2023; ISOPP, 2022; NIOSH, 2024; United States Pharmacopeia <800>, 2019).

5.2.2 Engineering Controls

5.2.2.1 Differences are evident in the use of engineering controls, including biological safety cabinets, isolators, closed systems and environmental controls. Differences may reflect local infrastructure, service configuration, historical practice and organisational interpretation of occupational risk (Campbell and Dicksit (2025a); ISOPP, 2022; USP, 2019).

5.2.2.2 Variation also exists in environmental monitoring, with regards to assessing workplace contamination to verify the effectiveness of engineering controls and safe handling practices (European Commission, 2023; ISOPP, 2022; Sessink *et al.*, 2024).

5.2.3 Closed System Transfer Devices (CSTDs)

5.2.3.1 The use of CSTDs is inconsistent across the UK. Some organisations routinely use CSTDs during preparation /manufacture, administration or both, while others use them selectively or not at all.

5.2.3.2 Implementation is inconsistent in the indications for use, the types of devices employed, and the evidence considered when implementing local policies (Campbell and Dicksit (2025a); ISOPP, 2022; NIOSH, 2024; USP, 2019).

5.2.3.3 Current guidance recommends that closed-system transfer devices (CSTDs) are attached to prepared medicines as close as practicable to the time of administration, rather than during preparation within the pharmacy aseptic unit, due to potential concerns regarding product stability, compatibility and microbiological integrity when CSTDs remain attached for extended periods (Santillo et al., 2018).

5.2.4 Risk Assessment

5.2.4.1 Occupational H&S risk assessment forms the basis of the UK legislative approach; however, methodologies differ considerably between organisations. Some organisations undertake medicine-specific assessments, whereas others adopt broader approaches based on therapeutic class or local policy. This has resulted in differing conclusions regarding the level of risk associated with individual medicines and the control measures required (European Commission, 2023; NIOSH, 2024; SPS, 2025).

5.2.4.2 Occupational H&S risk assessments should consider the totality of available evidence, including toxicological data, occupational exposure studies, environmental monitoring, biomonitoring, regulatory information and published scientific literature. For injectable medicinal products requiring manipulation prior to administration, occupational risk assessment should be undertaken alongside assessment of product quality, microbiological safety and patient safety. Preparation/manufacture of injectable medicines introduces additional risks, including microbial contamination, dose calculation and preparation errors, chemical degradation, particulate contamination and occupational exposure. These risks should be considered collectively when determining the most appropriate location for preparation and the control measures required. (European Commission, 2023).

5.2.5 Occupational H&S Information

5.2.5.1 Healthcare professionals currently obtain occupational H&S information from multiple sources, including Safety Data Sheets (SDSs), Summary of Product Characteristics (SmPCs), manufacturer information and local guidance. These sources are not always readily accessible, consistent or sufficiently detailed to support occupational risk assessment. This contributes to variation in local policies and inconsistent implementation of control measures across organisations (MHRA, 2019; SPS, 2025).

5.2.6 Variation Between Healthcare Settings

5.2.6.1 The management of HMPs varies across healthcare settings because the medicines pathway, healthcare professionals involved, and potential routes of occupational exposure differ. As a result, the control measures required, and the interpretation of occupational risk may also vary.

5.2.6.2 **Pharmacy Services**

Differences are evident in pharmacy services with respect to the procurement, receipt, storage, transport, aseptic preparation/manufacture, dispensing and supply of HMPs. Differences are evident in the application of engineering controls, environmental monitoring, closed system transfer devices, product presentation and occupational risk assessment, reflecting local infrastructure, service configuration and interpretation of existing legislation (ISOPP, 2022).

5.2.6.3 Nursing Practice

Within nursing services, practice differs in the administration of HMPs, use of PPE, management of administration devices, handling of patient excreta, spill management, environmental decontamination and disposal of contaminated waste. Differences also exist in the occupational H&S risk assessments used to determine appropriate control measures during medicine administration. UK evidence demonstrates variation in safe-handling practices between organisations and clinical settings, despite similar nursing activities, reflecting differences in local policy, safety culture and implementation of occupational controls (Campbell and Dicksit, 2025).

5.2.6.4 Community Pharmacy

The expanding use of oral SACT and other HMPs has increased the involvement of community pharmacy in dispensing, patient counselling and medicines optimisation. Variation exists in advice provided to patients, storage arrangements, handling procedures and the management of returned or unwanted medicines, reflecting limited UK guidance specific to this setting (European Commission, 2023; SPS, 2025).

5.2.6.5 Homecare / Self-Administration Medication (SAMS)

The increasing delivery of HMPs in patients' homes has introduced additional occupational and household considerations. Organisations adopt different approaches in the information provided to patients and carers regarding storage, preparation where applicable, self-administration, disposal, management of accidental exposure and handling of contaminated waste and excreta. Approaches also differ between homecare providers and healthcare organisations, particularly for medicines that require preparation immediately before administration (European Commission, 2023; NIOSH, 2024).

5.2.7 Variation by Medicine

Approaches to risk management also differ according to the type of medicinal product.

Occupational controls should be determined through product-specific risk assessment rather than therapeutic class alone. Medicines within the same therapeutic class may differ substantially in their hazardous properties, exposure potential and occupational risk.

5.2.7.1 Cytotoxic Medicines

Cytotoxic medicines are well recognised as hazardous and are associated with well-established handling procedures. However, differences remain in the implementation of engineering controls, PPE and administration practices (Campbell and Dicksit (2025a); NIOSH, 2024; USP, 2019).

5.2.7.2 Monoclonal Antibodies (mAbs)

The preparation or reconstitution of mAbs within clinical areas, including wards, outpatient departments and patients' homes, has increased with the introduction of subcutaneous therapies and evolving models of care. Organisations vary in the products selected for preparation outside pharmacy aseptic facilities, the healthcare professionals undertaking these activities, the engineering controls available and the supporting occupational H&S risk assessments. Although many mAbs do not meet the criteria for classification as HMP, some conjugated mAbs (Antibody-Drug Conjugates – see 5.2.7.3) are classified as HMPs. Differences in how organisations assess and classify mAbs contribute to inconsistent use of engineering controls and

PPE. (Cracknell et al., 2026; European Commission, 2023; ISOPP, 2022; SPS, 2025).

5.2.7.3 Antibody-Drug Conjugates

Antibody-drug conjugates are HMPs that combine targeted mAbs with highly potent cytotoxic payloads and present unique occupational considerations. Current practice varies across organisations, reflecting the evolving evidence base and differing interpretations of occupational risk (SPS, 2025).

5.2.7.4 Immunotherapies

Most immune checkpoint inhibitors and other immunotherapies are not currently considered HMPs. However, organisations differ in their occupational risk assessments for these medicines, particularly with respect to preparation/ manufacture, administration and waste handling. These differences largely reflect variation in local risk assessments (SPS, 2025).

5.2.7.5 Oral Systemic Anticancer Therapy

The increasing use of oral SACT has shifted the handling of HMP beyond traditional chemotherapy units into outpatient clinics, community pharmacies and patients' homes. This has introduced new occupational considerations and greater variation in practice, particularly where medicines are crushed, split, opened, dispersed or otherwise manipulated prior to administration. Additional variation exists in patient counselling, handling, storage, disposal and the management of contaminated waste within community and homecare settings (European Commission, 2023).

5.2.7.6 Non-Oncology HMPs

HMPs are used across many therapeutic areas beyond oncology, including rheumatology, gastroenterology, neurology and dermatology. Current approaches to occupational risk management outside oncology are variable and may differ substantially between specialties (NIOSH, 2024).

5.3 Evidence of Variation

5.3.1 International studies have similarly highlighted substantial variation in HMP handling practices across healthcare systems, reinforcing the need for evidence- informed and proportionate approaches to occupational risk management (Campbell *et al.*, 2024; Campbell and Dicksit, 2025; European Commission, 2023).

5.3.2 Collectively, these findings suggest that while the legislative framework is common across the UK, there remains considerable variability in its interpretation and implementation. This contributes to inconsistent practice, uncertainty for healthcare professionals and potential inequity in occupational protection (European Commission, 2023; ISOPP, 2022; SPS, 2025).

6. Key Principles for Interpretation of UK legislation

6.1.1 The UK legislative framework establishes clear employer responsibilities for protecting workers from exposure to hazardous substances (Health and Safety at Work etc Act, 1974; COSHH Regulations, 2002). However, unlike some international frameworks, it does not prescribe how individual HMPs should be managed or specify the control measures that should be applied in every circumstance (European Commission, 2023). Instead, employers are required to undertake suitable and sufficient risk assessments and implement controls that are proportionate to the level of occupational risk (COSHH Regulations, 2002). This flexibility allows organisations to tailor controls to their local circumstances but has also contributed to variation in practice (European Commission, 2023). Although the development in patient specific drug formulations have increased the range of options available for drug reconstitution and administration, the clinical environment in which these activities take place has not been regulated. This included consideration of appropriate environmental controls such as ventilation to adequately manage potential risk

6.2 Why Interpretation Differs

6.2.1 Variation in interpretation arises from several factors, including differences in local governance, availability of evidence, service configuration, workforce, infrastructure, the availability of funding and the affordability of engineering controls and protective equipment, and organisational risk appetite. In the absence of nationally agreed guidance on the classification and management of HMPs, organisations have developed local policies based on their own interpretation of legislation, published evidence and professional guidance (European Commission, 2023; ISOPP, 2022; SPS, 2025).

6.3 Where Variation Exists

6.3.1 Variation is evident throughout the medicine's lifecycle and across healthcare settings. Differences exist in the classification of HMPs, the use of engineering controls and CSTDs, selection of PPE, management of waste and contaminated excreta, and advice provided to patients and carers. The introduction of new medicines and evolving models of care have further increased variation in practice (European Commission, 2023; SPS, 2025).

6.3.2 Occupational exposure to HMPs may occur throughout the medicine's lifecycle, including within pharmacy aseptic services, clinical areas and patients' homes. Within pharmacy, the preparation/manufacture of HMPs is generally undertaken within established quality management systems supported by national standards, Section 10 or licensed aseptic facilities, validated engineering controls and structured governance arrangements. However, greater variation exists where HMPs are prepared or handled within clinical environments, during medicine preparation, including reconstitution, administration, patient care, environmental cleaning, spill management and waste handling. Consistent interpretation and implementation of legislation is therefore required across all healthcare settings and professional groups involved in the medicine's lifecycle (ISOPP, 2022; European Commission, 2023).

6.4 Education and Competency

6.4.1 Consistent implementation of occupational H&S measures depends on appropriate education, competency and multidisciplinary collaboration. Differences in knowledge, training and experience between professional groups may contribute to variation in the interpretation of legislation and occupational risk. Nationally consistent H&S education

and competency frameworks would support more robust implementation across healthcare settings (ISOPP, 2022; NIOSH, 2024; USP, 2019).

6.4.2 Achieving greater consistency in practice will require continued collaboration between professional groups, healthcare organisations, regulators and industry to support shared learning and the development of nationally consistent approaches (European Commission, 2023; ISOPP, 2022).

6.5 Occupational H&S Risk Assessment

6.5.1 Occupational H&S risk assessment must be the cornerstone of the UK approach to managing HMPs. Risk assessments should consider both the intrinsic hazardous properties of the medicinal product and the specific task being undertaken, together with the likelihood, frequency and potential route of occupational exposure. This enables control measures to be proportionate to the actual risk rather than applying identical precautions to all medicines or activities (COSHH Regulations 2002; COSHH Regulations (Northern Ireland) 2003; European Commission, 2023; NIOSH, 2024; SPS, 2025).

6.6 Defining HMPs

6.6.1 One of the greatest challenges in achieving consistency is the absence of a nationally agreed framework for identifying and classifying HMPs. Whilst international lists and classification systems exist, there is currently no UK list that defines which medicines should be considered a HMP across the UK or how this should influence occupational risk management. Consequently, organisations may reach different conclusions for the same medicinal product despite applying the same legislative framework (European Commission, 2023; NIOSH, 2024; SPS,2025).

6.7 Balancing Evidence with Precaution

6.7.1 The management of HMPs should be informed by the best available scientific evidence while recognising that evidence relating to occupational exposure is often limited or unavailable. Randomised controlled studies are rarely feasible in occupational healthcare settings because of ethical, practical and methodological constraints. Consequently, occupational risk assessments should draw on multiple sources of evidence, including manufacturers' information (for example, Summary of Product Characteristics (SmPCs) and Safety Data Sheets (SDSs)), published scientific literature, environmental monitoring studies, case reports, incident reporting, observational studies, expert consensus and the known hazardous properties of the medicinal product. Where uncertainty exists, a precautionary approach should be adopted, with control measures selected using the hierarchy of controls and reviewed as new evidence becomes available (European Commission, 2023; ISOPP, 2022; SPS, 2025).

6.7.2 As healthcare continues to evolve, new medicines, technologies and models of care together with changes in workforce, service configuration and patient pathways, present additional considerations for occupational H&S. These include the increasing use of subcutaneous monoclonal antibodies, expanding roles for pharmacy staff, greater involvement of community pharmacy, increasing patient self-administration of medication (SAM) and homecare services, management of household exposure, and the availability of ready-to-administer and manufacturer-prepared products. These developments have the potential to alter both the nature and location of occupational exposure and should be considered within future risk assessments and guidance as practice continues to evolve (European Commission, 2023; SPS, 2025).

6.7.3 Collectively, the evidence presented demonstrates that the principal challenge within the UK is not the absence of legislation, but variation in its interpretation and implementation. Improving consistency will require collaboration between healthcare organisations, professional bodies, regulators, manufacturers and healthcare professionals, together with recognition of the practical challenges associated with implementing occupational risk controls across different healthcare settings, workforce models and resource constraints. The following recommendations are intended to support a nationally consistent, evidence-informed and proportionate approach to the safe management of HMPs across all healthcare settings and roles. By supporting consistent interpretation of existing legislation, these recommendations aim to improve occupational protection for healthcare workers whilst maintaining high-quality patient care and supporting future innovation in medicines delivery. (COSHH Regulations 2002; COSHH Regulations (Northern Ireland) 2003; European Commission, 2023; ISOPP, 2022).

7. Recommendations

7.1 Recommendation 1

Establish a UK Framework for Hazardous Medicinal Products (HMPs)

The MHRA, working collaboratively with the Health and Safety Executive and the Health and Safety Executive for Northern Ireland, professional bodies such as UK SACT Board (UKSB) and other stakeholders, should establish a nationally recognised UK framework for the identification and classification of HMPs.

The framework should consider adoption, endorsement or adaptation of an existing evidence-based international classification system, supported by UK governance arrangements, occupational risk assessment principles and a transparent process for reviewing existing and newly licensed medicines. The resulting UK HMP list should be freely and readily accessible to all healthcare organisations, healthcare professionals and other relevant stakeholders.

Occupational risk assessments should be informed by the Safety Data Sheets (SDSs), Summary of Product Characteristics (SmPC), and the best available scientific evidence. Where injectable medicines require manipulation before administration, occupational risk assessments should be considered alongside established injectable medicines risk assessment processes, including the Specialist Pharmacy Service (SPS) Risk Assessment Tool for the Preparation of Injectable Medicines where applicable.

The framework should include a transparent governance process for the ongoing review of newly licensed medicines, emerging evidence and changes in occupational risk to ensure classifications remain current and evidence based. The UK HMP list should be regularly maintained and updated through this process, with changes communicated transparently and made readily accessible to users.

7.2 Recommendation 2

Prioritise Safer Product Design

Pharmaceutical manufacturers should be encouraged by regulators and healthcare organisations to incorporate occupational H&S considerations into medicinal product design wherever feasible.

This should include development of ready-to-administer products, prefilled syringes, closed or simplified delivery systems and other presentations that minimise handling and reduce occupational exposure, while maintaining product quality, stability, shelf life, affordability and patient access. The development of licensed ready-to-administer products should also reduce the need for aseptic manipulation within clinical areas, thereby improving both patient safety and occupational H&S.

7.3 Recommendation 3

Develop National PPE Standards

The Health and Safety Executive, working with the relevant professional organisations such as UKSB, should develop evidence-based UK standards for personal protective equipment when handling HMPs.

These standards should reduce unwarranted variation in practice and provide consistent protection for healthcare workers across all healthcare settings.

7.4 Recommendation 4

Improve Access to Occupational H&S Information

The MHRA, in collaboration with the Health and Safety Executive and the Health and Safety Executive for Northern Ireland (HSENI), pharmaceutical manufacturers and professional organisations, should improve access to occupational H&S information by establishing a freely accessible central resource. The resource should be regularly maintained and updated to reflect newly licensed medicines, emerging scientific evidence and changes to regulatory information.

This resource should bring together product-specific occupational H&S information, including Safety Data Sheets (SDSs), Summary of Product Characteristics (SmPCs), and other relevant evidence and guidance.

Consideration should be given to the inclusion of a dedicated section on occupational handling and safety within the Summary of Product Characteristics (SmPC) to improve the consistency and accessibility of information for healthcare professionals.

7.5 Recommendation 5

Improve Consistent Implementation Through Education and Collaboration

National NHS organisations, professional bodies, trade unions, regulators and employers should work collaboratively to promote the consistent interpretation and implementation of UK legislation relating to HMPs across all healthcare settings. An overarching UK multidisciplinary HMP group, with an agreed lead organisation or appointed convenor, should be established to provide national oversight and coordinate implementation of these recommendations.

This should be supported through multidisciplinary education, competency frameworks, occupational H&S expertise and the sharing of best practice between healthcare organisations. Recommendations and supporting resources should be applicable across all healthcare settings and therapeutic areas where HMPs are handled, rather than being limited to oncology services.

Implementation of these recommendations will require collaboration between regulators, professional bodies, employers, manufacturers and healthcare organisations. National leadership should be supported by local occupational risk assessments, governance arrangements, education and competency frameworks to ensure recommendations are implemented proportionately across all healthcare settings. The national group should establish agreed standards, implementation priorities, timescales and measures against which progress can be evaluated.

Healthcare organisations should consider identifying a named multidisciplinary lead, or an appropriate governance group, to coordinate the local implementation of HMPs safety. This should include collaboration with pharmacy, nursing, medical, occupational health and health and safety professionals, recognising that responsibilities and governance arrangements may vary between organisations.
The multidisciplinary lead or governance group should support education and competency, facilitate audit and benchmarking, promote compliance with relevant legislation, act as a link with regional and national networks to share learning and best practice, and support a continuous quality improvement approach. Organisations should adopt programmes of external audit to evaluate implementation, identify unwarranted variation in practice and drive continual improvement.

8. Future Work and Conclusion

8.1 Closed Systems Throughout the Medicines Lifecycle

8.1.1 The overarching UK multidisciplinary HMP group (as stated in recommendation 5) should work collaboratively with professional bodies, pharmacy aseptic services, nursing representatives, regulators, pharmaceutical manufacturers and other stakeholders to review the application of closed technologies as engineering controls throughout the medicine's lifecycle. This will include evaluating the available evidence relating to closed-system technologies used during aseptic preparation, outsourced compounding, transport, clinical area preparation/ manufacture and intravenous administration, including the use of closed-system bag spikes and other emerging technologies.

8.1.2 Published studies have demonstrated that environmental contamination with HMPs may occur throughout the medicine's lifecycle, from compounding through to administration, despite existing control measures (Sessink et al. 2026). The aim should be to identify opportunities to develop nationally consistent, evidence-informed recommendations that minimise occupational exposure whilst maintaining product quality, patient safety and operational efficiency.

8.1.3 This group should also consider whether nationally consistent recommendations can be developed for the use of closed-system technologies during preparation/ manufacture, transport and administration based on the available evidence and occupational risk.

8.2 Conclusion

8.2.1 This document provides a foundation for a more nationally consistent, evidence-informed and proportionate approach to the management of HMPs.

8.2.2 Implementation of the recommendations will require coordinated action across multiple organisations. As an initial priority, stakeholders should work collaboratively to establish national governance arrangements. Many of these activities can commence immediately through existing multidisciplinary partnerships and professional networks.

8.2.3 This document should be regarded as the first step rather than the final position. As new medicines, technologies and models of care continue to emerge, the recommendations and supporting guidance should be reviewed and updated to reflect evolving scientific evidence, occupational H&S data and clinical practice. Continued collaboration between regulators, professional bodies, manufacturers, healthcare organisations and frontline healthcare professionals will be essential to ensure that occupational protection remains proportionate, evidence-informed and applicable across all healthcare settings.

8.2.4 The safe management of HMPs is a shared responsibility that extends across the entire medicines lifecycle and involves healthcare organisations, professional bodies, regulators, manufacturers, employers and healthcare professionals. Although the UK already has a comprehensive legislative framework, variation in its interpretation and implementation has resulted in inconsistent approaches to occupational risk assessment and the application of control measures across healthcare settings.

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10. Multidisciplinary Working Group

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11. Endorsing Organisations

Organisations	Version endorsed from
UK Oncology Nursing Society (UKONS)	1.0
Pharmacy Aseptic Services Group (PASG)	1.0
Association of Pharmacy Technicians UK (APTUK)	1.0
Royal College of Nursing (RCN)	1.0
British Oncology Pharmacy Association (BOPA*). Note: Approval by BOPA chair. Full approval pending a wider stakeholder engagement to follow.*	1.0

Additional organisations are currently reviewing to endorse and will be added as approved.

12. Acknowledgements

The multidisciplinary author group acknowledge the Safer Healthcare Biosafety Network (SHBN) for its leadership in initiating the multidisciplinary discussions that brought together representatives from professional bodies, occupational H&S, H&S, nursing and pharmacy. These discussions established the collaborative network from which this consensus document has emerged. This document represents the independent consensus of the multidisciplinary author group, developed through an evidence-informed consensus process.

13. Version History

Version	Date	Author(s)	Summary of Changes
0.1 to 0.8	July - Aug 2026	Multidisciplinary Working Group	Multidisciplinary consultation
1.0	Aug 2026	Multidisciplinary Working Group	Final consensus document

Appendix 1: Summary of Recommendations

Recommendation 1 - Establish a UK Framework for Hazardous Medicinal Products (HMPs)

The MHRA, working collaboratively with the Health and Safety Executive and the Health and Safety Executive for Northern Ireland, professional bodies such as UK SACT Board (UKSB) and other stakeholders, should establish a nationally recognised UK framework for the identification and classification of HMPs.

Recommendation 2 - Prioritise Safer Product Design

Pharmaceutical manufacturers should be encouraged by regulators and healthcare organisations to incorporate occupational H&S considerations into medicinal product design wherever feasible.

Recommendation 3 - Develop National PPE Standards

The Health and Safety Executive, working with the relevant professional organisations such as UKSB, should develop evidence-based UK standards for personal protective equipment when handling HMPs.

Recommendation 4 - Improve Access to Occupational H&S Information

The MHRA, in collaboration with the Health and Safety Executive and the Health and Safety Executive for Northern Ireland (HSENI), pharmaceutical manufacturers and professional organisations, should improve access to occupational H&S information by establishing a freely accessible central resource. The resource should be regularly maintained and updated to reflect newly licensed medicines, emerging scientific evidence and changes to regulatory information.

Recommendation 5 - Improve Consistent Implementation Through Education and Collaboration

National NHS organisations, professional bodies, trade unions, regulators and employers should work collaboratively to promote the consistent interpretation and implementation of UK legislation relating to HMPs across all healthcare settings. An overarching UK multidisciplinary HMP group, with an agreed lead organisation or appointed convenor, should be established to provide national oversight and coordinate implementation of these recommendations.