Llywodraeth Cymru
Welsh Government

PUBLICATION, DOCUMENT

Sterile preparation of medicine in NHS Wales (WHC/2024/004)

New guidance to support the sterile preparation of medicine in NHS Wales.

First published: 12 February 2024

Last updated: 12 February 2024

Contents

Details

Status:

Action.

Category:

Information.

Title:

Assurance of aseptic preparation of medicines in NHS Wales.

Date of expiry / review:

Non-applicable.

Action by:

- Chief Executives local health boards and Velindre University NHS Trust
- Managing Director, NHS Wales Shared Services Partnership
- Chief Pharmacists local health boards, Velindre University NHS Trust and NHS Wales Shared Services Partnership

Required by:

Immediate.

Sender:

Andrew Evans, Chief Pharmaceutical Officer, Welsh Government.

Welsh Government contacts:

Darren Ormond
Pharmacy and Prescribing
Welsh Government
Cathays Park
Contact Tel: 03000 255621

Enclosures:

Assurance of aseptic preparation of medicines in NHS Wales:
Governance and regulatory arrangements for aseptic preparation of medicines by health boards and NHS trusts in Wales.

Assurance of aseptic preparation of medicines in NHS Wales

Background

NHS hospital pharmacy aseptic services provide sterile, controlled environments in which highly qualified staff prepare a range of medicines including injectable Systemic Anti-Cancer Therapy (SACT), parenteral (intravenous) nutrition for people whose medical condition mean they are unable to absorb nutrients from the food they eat, and radiopharmaceuticals used in diagnosis and treatment of cancers. The use of these medicines enhances quality and safety, releases nursing time to be devoted to patient care, and facilitates care closer to people's homes.

In general, the aseptic (sterile) preparation of unlicensed medicines in hospitals takes place either under a Medicines and Healthcare products Regulatory Agency (MHRA) Manufacturer's 'Specials' (MS) authorisation or under the supervision of a pharmacist permitted under section 10(1) of the Medicines Act 1968 (the so called 'section 10 exemption').

The MHRA is responsible for the inspection and oversight of facilities operating under MS authorisations. NHS organisations are responsible for the oversight of facilities operating under the section 10 exemption.

To support NHS organisations and to ensure section 10 facilities operate under broadly the same conditions as MHRA authorised facilities, since 1997 NHS organisations in Wales have operated within an assurance process for the aseptic preparation of injectable medicines described in circular DGM(97)5.

The guidance 'Assurance of aseptic preparation of medicines in NHS Wales' (annex one) describes updated governance and regulatory arrangements for

aseptic preparation of medicines by health boards and NHS trusts in Wales. The updated guidance takes account of changes to NHS organisational structures, policies and governance frameworks since DGM(97)5 was published in 1997, and the recommendations of the Department of Health and Social Care's report Transforming NHS pharmacy aseptic services in England.

Purpose

Assurance of aseptic preparation of medicines in NHS Wales makes clear the accountability and responsibility of health boards and NHS trusts in relation to the unlicensed preparation of aseptic medicines and the important role of health board and trust chief pharmacists.

This guidance sets out the governance and regulatory arrangements for aseptic preparation of medicines for NHS patients in Wales and replaces NHS DGM(97)5 entitled Aseptic Dispensing in NHS Hospitals issued in 1997. It defines the roles and responsibilities of:

- NHS organisations in meeting quality standards, responding to audits and inspections, and reporting quality indicators when performing aseptic preparation activities; this includes the statutory responsibilities of chief pharmacists as established by The Pharmacy (Preparation and Dispensing Errors – Hospital and Other Pharmacy Services) Order 2022
- the NHS Wales National Lead Pharmacy, Quality Assurance (and nominated deputies) in providing regulatory oversight and inspection of aseptic preparation activity, and auditing services against quality standards
- the Welsh Government's Chief Pharmaceutical Officer who is responsible for commissioning the overarching governance and assurance process, providing oversight and supporting enforcement where necessary

The principles and processes described in this guidance apply to all aseptic preparation of medicinal products in NHS pharmacy aseptic facilities in Wales,

other than those products manufactured under an MHRA authorisation. The guidance therefore applies to all NHS pharmacy aseptic facilities undertaking preparation of sterile medicinal products under the Section 10 exemption, even when provided from facilities that concurrently hold an MHRA MS authorisation.

The guidance applies to:

- aseptic reconstitution of any medicinal products or Investigational Medicinal Products (IMPs), where this is performed in a pharmacy aseptic facility
- aseptic reconstitution of innovative therapies such as Advanced Therapy Medicinal Products (ATMPs) where this is performed in any NHS aseptic facility with pharmacy oversight
- all types of preparation made aseptically (for example it applies to formulations such as eye drop preparations under limited and defined circumstances, in addition to injections)
- all NHS radiopharmacy services in Wales, including those operating under an MHRA MS authorisation, whether within or outside pharmacy oversight, until specific national radiopharmacy guidance is produced

This guidance comes into effect on the date of publication of this Welsh Health Circular.