 <p> GIG CYMRU NHS WALES </p> <p> Iechyd Cyhoeddus Cymru Public Health Wales </p>	<p> Name of Meeting Quality, Safety and Improvement Committee Date of Meeting 24 February 2026 Agenda item: 3.2 </p>
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Policy / Procedure Approval Report

Section 1 - Policy / Procedure Information


Policy / Procedure Title	Medicines Management Policy
Policy Lead	Deputy Medical Director, Clinical Governance
Lead Executive	Prof, Fu Meng Khaw, Executive Medical Director
PHW / All Wales?	PHW
Date of last Review	December 2023
Is the current policy / procedure within review date?	Yes
Approving Body /Group	Quality, Safety and Improvement Committee
Version Number	V5

Section 2: Recommendation

The Committee is asked to:

- **Consider** the revised policy and the Equalities Impact Assessment
- **Note** that the Leadership Team endorsed the policy at its meeting on 22 January 2026
- Endorse the policy for submission and final approval by the Quality, Safety and Improvement Committee.



Section 3 – Details of the Review:	
Background:	
Reason for review	Update of policy required following the transition of responsibility for medicines management to the Office of the Medical Director.
Description/Assessment	<p>The Medicines Management Policy is a document required by PHW who has responsibility for administering a number of medicines in its service provision. Under the legislation, such a policy is required.</p> <p>The policy has had a complete and robust review and revision following the transition of responsibility for medicines management clinical governance to the Office of the Medical Director.</p> <p>To ensure effectiveness a task and finish group was established to review the policy involving a member of the Wales Medicines Advisory Service to ensure effectiveness and relevance.</p>
Consultation	
Has this Policy / Procedure been through the appropriate 28 day consultation process?	Yes
Date range of consultation:	20 November to 10 December 2025
Please provide details of any feedback received and outline what changes if any were made to the document as a result:	<p>Feedback received:</p> <p>Page 7 – MSO. Expand: organisationally responsible for the overall management of MHRA Safety Alerts and Notices including reviewing, actioning, distribution and oversight to the relevant groups within the organisation – to make it clear that it will be their responsibility to review and action anything that comes in to the organisation and this will align with the new Alerts procedure once it’s been developed.</p> <p>Page 8 – Programme Lead Professional. Add Timely – they will need to ensure they order in a timely way to maintain/ manage suitable stock levels.</p> <p>Pg 8 - Amend reference to Datix Cloud (in case this ever changes) would suggest using Concerns Management System e.g. Datix Cloud.</p> <p>Pg 13 – Storage and Administration of Medicines. Consider adding  PSN030 Add Patient Safety Notice Details in full ie PSN030 Patient Safety Notice – The Storage of Medicines: Cupboards</p>



	<p>Pg 13 – Medicines Refrigeration. Add Patient Safety Notice Details in full ie PSN055 – Cupboards for the storage of medicines in health care premises</p> <p>Add Patient Safety Notice details in full. ie PSN 015 – The storage of medicines – refrigerators. Add in some details around the requirements for recording of fridge temperatures. Maximum and minimum temperatures to be recorded twice daily and an audit log kept – aware that this is unable to happen over weekends and must be within the policy.</p> <p>Add that Refrigerators should be locked when not in use. (as people don't want to be searching for the PSN to find the detail).</p> <p>Pg 14 - Standards of Practice for the Administration of Medicines Add to the checklist: Check the medicine for any defects e.g. box/ vial/ etc has not been tampered with. If it is a liquid, check that it is clear with no deposits/ cloudy.</p> <p>Pg 16 – Incident Reporting. Amend reference to Datix Cloud (in case this ever changes) would suggest using Concerns Management System e.g. Datix Cloud.</p> <p>Pg 17 – Audit and Information Governance. Is there an expectation that these audits should be added the PHW Annual Quality and Clinical Audit plan? This should be referenced within the policy – and that the CG manager will be responsible for the oversight, including action plans for this.</p>
<p>Detail of updates:</p>	<p>Pg 7 – paragraph now reads: Acting as the organisational link with the Medicines and Healthcare Products Regulatory Agency (MHRA) to receive essential communications, review, distribute as appropriate and escalate concerns related to the safe use of medications.</p> <p>Pg 8 – Timely has been added.</p> <p>Pg 8 – DATIX Cloud added.</p> <p>Pg 13 – information added on where to find Patient Safety Notices which are held centrally.</p> <p>Pg 14 – Medicines defects added to checklist.</p> <p>Pg 16 – DATIX Cloud added.</p> <p>Pg 17 – additional paragraph added: The Clinical Audit Programme will provide assurance that relevant medication management audits are undertaken. These</p>



	audits will be added to the PHW Annual Quality and Clinical Audit plan, for which the CGM will have oversight.
Had this policy / procedure been considered by any other groups?	Yes
If so, please provide detail of any comments / feedback or amendments made to the documents as a result of this	HPSS DMT – no comments

Section 4: Impact Assessments	
Equality and Health Impact Assessment	Equality and Health Impact Assessment attached; no issues identified.
Welsh Language Impact	The Policy will be translated to Welsh and available on the internet bilingually.
Risk and Assurance	This policy provides assurance that PHW has an appropriate policy in place relating to the applicable medicines used within the services.
Health and Social Care (Quality and Engagement) (Wales) Act	This Policy supports compliance with the Health and Social Care (Quality and Engagement) (Wales) Act by promoting safe, effective and person-centred medicines use, embedding continuous quality improvement, and ensuring openness, transparency and learning when medicine-related incidents occur, in line with the Duties of Quality and Candour.
Financial implications	There are no additional financial implications. The Service Level Agreement is still in place with the Wales Medicines Advisory Service with 6 monthly reviews scheduled.
People implications	No impacts on staff.
Socio Economic Duty	No implications.

Section 5 - Implementation

Implementation plan (with timescales)		
Next steps	Timescale	Responsible officer(s)
Leadership Team	15 January	DMD
QSIC	24 February	DMD
Publish in English and Welsh on policy webpages	TBC	BBU



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Reference Number: PHW26

Version Number: V3

Date of next review:

February 2029

Medicines Management Policy

Policy Statement

Public Health Wales (PHW) does not routinely have responsibility for administering medicines directly and, thus, has only limited involvement in direct medicines management. Consequently, PHW does not require the wider range of clinical governance infrastructures for medicines management established within other NHS healthcare organisations. However, there are some clinical care situations that require or potentially require PHW staff to supply or administer medicines to members of the public and to staff.

Policy Commitment

The aim of this policy is to ensure that there is a clinical and corporate governance framework to support safe and secure systems for the controlling and handling of all medicines supplied or administered by PHW staff. It aims to protect service users by ensuring the control of medicines through safe administration, storage, and disposal and through the reporting, monitoring and review of any medication incidents.

Objectives

The objectives of the policy are for all PHW employees administering, ordering, transporting, storing, and disposing of medicines to act in compliance with legislation, professional guidance and PHW procedures and requirements.

Linked Policies and Procedures

[All corporate policies and procedures are available on the Public Health Wales website](#)

[Diabetic Eye Screening Wales \(DESW\) Minims® Tropicamide 1% Eye Drops Administration Protocol](#)

[Records Management Procedure](#)

[Public Health Wales Vaccines \(Handling and Storage\) Cold Chain Management Procedure Chain Management Procedure 2022](#)

[Putting Things Right Incident Reporting and Management Procedure](#)

[Waste Management Policy](#)

Related Documents

[All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal \(MARRS 2015\)](#)

[BNF \(British National Formulary\) | NICE](#)

[Duthie Report: Guidelines for the Safe and Secure Handling of Medicines published by the Royal Pharmaceutical Society \(2005\)](#)

[Eye Drops instillation by unregistered health care professionals for use within NHS Ophthalmic Services](#)

[Information | Making medicines and medical devices safer \(mhra.gov.uk\)](#)

[Patient Group Directions: who can use them MHRA](#)

[Professional guidance on the safe and secure handling of medicines](#)

[SmPC](#)

[Standards for Health Services in Wales: Standard 15 – Medicines Management](#)

[The Green Book: Immunisations against Infectious Disease](#)

[Tools and resources | Patient group directions | Guidance | NICE](#)

Scope

This policy applies to all staff who are involved in ordering, transporting, storing, administering and disposing of medicines.

Equality and Health Impact Assessment

An Equality, Welsh Language and Health Impact Assessment has been completed and can be viewed on the policy webpages.

Approved by

Quality, Safety and Improvement Committee

Approval Date

Tbc

Review Date

Tbc

Date of Publication:

tbc

Accountable Executive Director

Professor Fu-Meng Khaw, Executive Medical Director

Authors	Assistant Medical Director, OMD Business and Workforce Manager, OMD Clinical Governance Manager, OMD
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Disclaimer

If the review date of this document has passed, please ensure that the version you are using is the most up to date by contacting the document author or the [Board Business Unit](#)

Summary of reviews/amendments				
Version number	Date of Review	Date of Approval	Date published	Summary of Amendments
1	2013	31.01.13	04.03.13	First Policy (Medicines Management policy and code of practice)
02	2023	13.12.23	04.01.24	Updated the content and clarified roles and responsibilities
03	2024-26			<p>Updated the content to reflect changes within the PHW structures</p> <p>Updated with roles and responsibilities, amendments made to reflect current PHW requirements around medicines management</p> <p>Added links and updated information related to actions required if defects in medicines are identified.</p>

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DRAFT

1. Introduction

Public Health Wales (PHW) is required to establish, document and maintain an effective system for the safe handling, storage and administration of medicines in line with legislation and best practice. This Medicines Management Policy describes the responsibilities of ordering, storage, dispensing and administration of medicines and aims to ensure the highest standards of medicines management and minimise risks associated with use of medicines¹.

This policy is not a detailed procedure for any aspect of Medicines Management. Divisional procedures must be drawn up where necessary to supplement this policy, providing specific detail on medicines management relevant to each service provided. The PHW governance structures relating to Medicines Management are outlined in Appendix 1.

2. Roles and Responsibilities (Appendix 2)

2.1 Chief Executive

The Chief Executive has overall responsibility for Medicines Management in PHW. The provision of resources to ensure the safe ordering, transport, administering and disposal of medicines is the responsibility of the Chief Executive and Board. It is their responsibility to ensure that guidance is consistent with the legal requirements. The leadership of the organisation should put mechanisms in place to monitor adherence to this policy. Where there is non-compliance, the Board is responsible for ensuring that there are appropriate actions in place to mitigate any risks identified.

2.2 Executive Medical Director

The above is delegated to the Executive Medical Director (the Board lead for Medicines Management), who is responsible for ensuring the implementation and review of this policy in consultation with other Health Care Professionals.

The Executive Medical Director is responsible for ensuring systems are in place within the clinical area/departments in their directorates to facilitate the processes within this policy and that the information and guidance is available to staff and adhered to.

2.3 Medicines Safety Officer

The Medicines Safety Officer (MSO) provides a leadership role within the organisation to set and deliver the medication safety agenda. The MSO will be

¹ [Duthie Report: Guidelines for the Safe and Secure Handling of Medicines published by the Royal Pharmaceutical Society \(2005\)](#)

involved in organisational discussions regarding medicines. MSO role is held by the Clinical Governance Manager within the Office of the Medical Director (OMD).

The MSO is responsible for², but not limited to,

- Planning, improving and sustaining medicines safety.
- Acting as the organisational link with the Medicines and Healthcare Products Regulatory Agency (MHRA) to receive essential communications, review, distribute as appropriate and escalate concerns related to the safe use of medications.
- Implementing local actions to improve medication safety which align with national safety initiatives and national patient safety alerts.
- Overseeing medication incident reporting in the organisation, improving reporting and learning.
- Being an active member of the Medicines Management Group (MMG) within PHW.

2.4 Clinical Governance Manager

The Clinical Governance Manager (CGM) will provide assurance that there is compliance with this policy and associated Standard Operating Procedures (SOPs) and that there are adequate mechanisms in place to monitor and report on the usage on medicines throughout PHW. The CGM will focus providing organisational oversight for assurance purposes.

The CGM will have oversight of medication incidents and undertake trend and root cause analysis where necessary.

The CGM is responsible for collating the divisional audits and reporting to the Quality, Safety and Improvement Committee as appropriate. The CGM will ensure that the quality standards are regularly audited as part of PHW's audit cycle.

2.5 Medicines Management Group

The purpose of the MMG is to ensure that there is compliance with legislation, regulatory and professional and local guidance for all aspects of medicines management.

The MMG is responsible for ensuring key issues such as, but not limited to, providing and seeking expert advice and leadership on untoward incidents. The MMG will co-ordinate actions required in the event of national safety alerts and produce and issue any local safety alerts deemed appropriate for areas. The MMG has the authority to initiate action, which may involve system redesign and

² [Collaboration opportunities to improve medication safety – NHS SPS - Specialist Pharmacy Service – The first stop for professional medicines advice](#)

improvement and/or education, training and competency assessment of healthcare professionals on any aspect of medicines use.

New medicines for use within PHW must be conveyed to the MMG.

The MMG will receive assurance reports from the Professional Programme lead that audits have taken place and be a forum for sharing of learning.

2.6 Programme Lead Professional

Each programme must have a named person with professional responsibility to ensure that there are appropriate systems in place for providing a timely, safe, effective, efficient and secure system for medicine stocks and distribution held within PHW sites. The Programme Lead Professional is responsible for:

- Providing a system for monitoring medicine usage and advising on appropriate stock range, expiry dates and stock holding levels in a timely manner.
- Ensuring appropriate environmental storage conditions.
- Ensuring safe and proper means of disposal of unused/unwanted medicines.
- Ensuring risk assessment forms are completed and updated accordingly and escalated where appropriate to MMG.
- Ensuring safe and effective systems and arrangements for medicine administration. This includes reviewing and managing medicine near misses and errors reported via a Concerns Management System e.g. Datix Cloud and identifying recommendations and lesson learnt.
- Ensuring transport of medicines and other pharmaceuticals in line with this policy.
- Recording the administration including dosage and batch numbers.
- Ensuring the supply of medicines to participants/staff is carried out in accordance with Patient Group Directions (PGDs)/local policy.
- The induction of appropriate staff with respect to this policy, code of practice and any local supporting procedures.
- Monitoring and reviewing competence and ensuring all training and competence assessments are documented.
- Auditing annually the compliance with this policy and the implementation of remedial action.
- Being a member of MMG.

2.7 Healthcare Professionals Involved in the Medicines Management Process

Healthcare Professionals involved in the medicines management process should:

- Read and understand this policy.

- Comply with this policy and their professional Code of Practice (e.g. GMC/NMC/HCPC guidance).
- Ensure that they have the required qualifications, competence and or authority to complete the tasks.
- Not undertake tasks beyond their qualifications, competency, or authorisation.
- Maintain the security of medicines within their practice area.
- Report any incidents where this policy is not adhered to.

3. Medicines Management Service Level Agreement- Pharmacy Advice

Through a Service Level Agreement (SLA) with Cardiff and Vale University Health Board (CAV UHB), the Director of Pharmacy Welsh Medicines Advisory Service (WMAS), is responsible for advising on effective medicines management, its systems and procedures.

4. Prescribing

PHW does not have responsibility for prescribing. PHW employees who prescribe within Health Boards and Trusts are covered under honorary contracts. They will need to refer to the local medicines management policy.

5. Patient Group Directions

A PGD is a specific written instruction for the supply and/or administration, of a named medicine in an identified clinical situation. It applies to groups of service users who may not be individually identified before presenting for treatment.

The use of a PGD does not constitute a form of prescribing. A PGD must not be confused with a Patient-Specific Direction (PSD). The template for a PGD is available at NICE³.

5.1 Healthcare Professions Able to Operate Under a PGD

The MHRA⁴ advise on who may use a PGD.

Practitioners may only operate under a PGD as named individuals.

A senior person in each profession should be designated with the responsibility to ensure that only fully competent, qualified, and trained professionals are authorised to operate within the PGDs.

³ [Tools and resources | Patient group directions | Guidance | NICE](#)

⁴ [Patient Group Directions: who can use them MHRA](#)

5.2 Circumstances Under Which PGDs are Permissible Within PHW

To authorise the supply or administration of medicines by PHW employed staff where PHW is directly responsible for the care of patients or group of individuals, e.g. Breast Test Wales.

Unlicensed medicines or licensed medicines for an unlicensed indication are not covered under the PGD.

5.3 Criteria Required to Ensure Valid PGD Within PHW

Within PHW the following criteria must apply when developing and authorising a PGD:

- It should be drawn up by a multi-disciplinary group involving a doctor, a pharmacist and a representative of any professional group expected to supply and/or administer medicines under the PGD.
- It must be signed by the relevant healthcare professionals involved in the preparation of the PGD.
- It must be signed by the Director of Pharmacy WMAS
- It must be signed by the individual(s) that may supply administer medicines under the PGD, who must belong to one of the classes of person specified above.
- Be in effect (and in date) at the time of administration or supply.
- The PGDs are reviewed as documented and according to guidance.

5.4 National PGD Support Advisory Functions

It should be noted that PHW has an advisory role in the development of national immunisation PGDs working with the Welsh Medicines Advisory Service. This activity is not covered by this policy.

6. Protocol

A protocol has been developed, in line with guidance from the Royal College of Ophthalmologists⁵, to provide direction for the users of the policy allowing the safe administration of Minims® Tropicamide 1% eye drops to participants attending for diabetic eye screening⁶.

The MHRA have confirmed that the administration of eyedrops for diabetic eye screening is not in breach of the Medicines Act. No prescription, PGD, PSD or other order is required.

The protocol is reviewed every 2 years and this is covered in the SLA.

⁵ [Eye-Drops-Instillation-by-Unregistered-Health-Care-Professionals-for-use-within-NHS-Ophthalmic-Services.pdf \(rcophth.ac.uk\)](#)

⁶ [Tropicamide Protocol 2024.docx](#)

7. Medicines Requiring Special Consideration

7.1 Administration for the Purpose of Saving Life in an Emergency

Regulation 238 of the Human Medicines Regulations 2012 allows for certain prescription only medicines to be administered by anyone for the purpose of saving life in an emergency without a prescription. Adrenaline 1 in 1000 (1mg/mL) by intramuscular injection can be administered for the emergency treatment of anaphylaxis⁷. Current clinical guidelines should be followed. The full list of exemptions can be found in The Human Medicines Regulations.⁸

7.2 Controlled Drugs

PHW does not hold any controlled drugs.

8. Ordering Stock Drugs and Pharmaceuticals

8.1 Responsibility

The Programme Lead Professional of each department is responsible for all aspects of the control and security of medicines within their area and must ensure that this policy is followed. Duties may be delegated but accountability remains with the Programme Lead Professional.

Medicines may only be supplied or administered in accordance with this policy. PHW employees must not take medicines supplied to departments for their personal use, or another employee's use, unless the product has been supplied in a first-aid kit for employee first aid.

8.2 Stock Drugs and Ordering

The process of ordering and receiving medication from a pharmacy as stock medication must ensure that certain controls are in place to cover the safety and security of the medicines (to include a proper audit trail) prevent overstocking of the area, ensure safety of staff and service users, and clearly show who has the direct responsibility for each stage of the process.

The Programme Lead Professional in each department and the supplying pharmacy department will agree a list of medicines which are either used regularly or are required in case of an emergency to be kept in stock by the department and the stock level. The department and the regional supplying pharmacy department must each keep a copy of this list. This will be reviewed at regular intervals (minimum annually) by the Programme Lead Professional. A

⁷ [Adrenaline BNF](#)

⁸ [The Human Medicines Regulations \(2012\)](#)

named pharmacist within the supplying pharmacy will be provided as a point of contact to discuss and address any ongoing issues or concerns.

The Programme Lead Professional has responsibility for all the medicines in that department. Duties can be delegated but the responsibility cannot be transferred to anyone else since it covers the strategic elements of medication handling in the department which ensures that day to day practice is in line with current legislation, local and national policies/guidance.

Adequate stocks should be ordered and kept for the day to day running of the department/clinics. Medicines with the earliest expiry date must be used first.

9. Delivery and Transport

Drugs may be carried for delivery by authorised PHW staff. Medicines must never be given to patients to deliver.

9.1 Transport of Medicines from the Supplying Pharmacy Department by Authorised Transport

Once order received, assembly and transfer to the department will be the responsibility of the supplying pharmacy. The pharmacy will highlight medicines needing special storage or temperature conditions, to ensure the security and stability of the medicines until they are delivered to the location.

All medicines will be transported securely and safely to the designated Trust location. The authorised person accepting the delivery must sign the documentation on receipt. Once delivered to the department/clinic, the responsibility for the security of the medicine rests with an appropriate registered healthcare practitioner, who will arrange that the contents be unpacked, checked against the delivery note and put away securely as soon as possible.

9.2 Storage Conditions in Transport

Whenever medication is to be transported from one area to another, the recommended storage conditions, temperature and humidity must be considered, and the method of transfer must take these storage conditions into account and consider the cold chain described in the National Patient Safety Agency Rapid Response directive⁹.

9.3 Packaging for Transportation

When transporting any medicine, due regard must be taken of the fragility of the item being dispatched. Those items known to be fragile, e.g. items already packed in a glass container, or items which are known to have a COSHH hazard must be packed carefully (these may require additional packaging around the

⁹ [NPSA Rapid Response directive \(RRR008 Cold Storage\)](#)

container) in order to remain intact and present no external hazard throughout the transport process.

9.4 Transport Documentation

For any transfer, the person carrying out the delivery must sign on collection. Carriers sign for the outer transport bag or box and not the individual contents. A transport log will be maintained and held locally.

10. Storage and Administration of Medicines

Medicines received by departments must immediately be placed in the appropriate locked cupboard or locked refrigerator (with the exception of emergency drug boxes) and should comply with guidance and legislation including patient safety notices which are contained on AMaT (Audit Management and Tracking) system.

If it is found that the storage conditions are inappropriate, the Programme Lead Professional must be informed.

10.1 Medicine Refrigerators

Medicines labelled 'Store in a refrigerator' shall be stored between 2°C and 8°C in a dedicated locked medicines refrigerator per PHW Vaccines (Handling and Storage) Cold Chain Management Procedure 2022¹⁰.

Non-medicines, e.g. milk or food, must not be stored in a dedicated medicines refrigerator.

Fridge excursions can be referred to Welsh Medicines Advice Service to assess whether the breach is significant

10.2 Safe Custody

The responsibility for safe custody (continuing responsibility) is that of the programme lead professional. The person with continuing responsibility can delegate such responsibility for the possession and custody of the keys to the medicine storage. All medicines storage keys must be stored in a locked key box out of hours or when left unattended. Unauthorised persons must not be permitted access to medicines. Risk assessments must be completed and the Risk recorded on the Risk Register where usual practice is not achievable.

¹⁰ [Public Health Wales Vaccines \(Handling and Storage\) Cold Chain Management Procedure Chain Management Procedure 2022](#)

11. Administration

The purpose of this section is to establish the principles for safe practice in the management and administration of medicines by registered nurses, midwives and other healthcare professionals^{11,12}.

Administer is 'to give a medicine either by introduction into the body, whether by direct contact with the body (e.g. orally or by injection) or by external application (e.g. application of an impregnated dressing); overseeing the self-administration of medication by a patient or assisting the patient with administration of a medicine.'

11.1 Standards of Practice for the Administration of Medicines

Medicines may only be administered by persons who are qualified to do so. They must be employed and authorised by PHW to administer and have the appropriate knowledge and experience to administer e.g. a doctor, a dentist, or an appropriately accredited healthcare practitioner e.g. a nurse. All employees administering medicines will be held individually accountable for their actions. In administering any medication, the healthcare professional must exercise their professional judgement and apply their knowledge and skills in a given situation.

When administering medicines, healthcare professionals must act within the framework of the current PGD and protocol and in accordance with their Code of Professional Conduct, the current standards of administration of medicines and the relevant policies of PHW.

Medicines may only be administered to a patient by a person working under a PGD or protocol.

In order to administer medicines, the person administering must take the following actions:

- Establish the identity of the service user in accordance with local requirements and the three point ID check.
- Be guided by the 5Rs principles- the widely adopted safety framework in healthcare (RIGHT patient, medication, time, route, dose; NO allergy).
- Check the expiry date of the medicine to be administered.
- Use the opportunity to emphasise the importance and implications of the prescribed treatment and enhance their understanding of the effects and side effects and provide additional relevant information when requested or required (PIL).
- Check the medicine for any defects e.g. box/vial has not been tampered with. If it is a liquid, check that it is clear with no deposits/cloudy (refer to para 14.1).

¹¹ [All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal \(MARRS 2015\)](#)

¹² [Professional guidance on the safe and secure handling of medicines](#)

- Make a clear and accurate recording of initials on medicines administration chart once you are sure all medicines administered have been taken/applied
- Monitor and evaluate and record the effects of the medicines administered and report to the appropriate prescribing medical practitioner or pharmacist immediately if any adverse reactions to the prescribed medication are identified.
- Medicines must never be left unattended and must be securely stored when not in use.

11.2 Patient Information Leaflets (PIL) and Labelling

Service users must receive sufficient information about the medicines to allow them to make an informed decision. It is a legal requirement that the manufacturer's PIL is provided each time a medicine is supplied. All service users must have an opportunity to discuss and agree to receiving medication. Specific labelling requirements apply equally to medicines supplied under PGDs.

11.3 Safe Administration of Medicines

It is the responsibility of the healthcare professional to ensure that standards of medicines practice are adhered to and ensure they have received the relevant training and education to enable them to safely administer medicines.

11.4 Training and/or Communication with Staff

PHW will ensure that all healthcare professionals directly involved in medicines use have the appropriate levels of training to comply with the medicines management policy. Training is delivered in various ways (group sessions, self-learning via Intranet, etc).

This policy may be communicated to all staff via Staff Induction and the intranet.

12. Disposal

All waste must be disposed of in line with the PHW (and/or local clinical waste disposal procedures) policy on waste.

Medicines that are no longer needed retain their legal status as medicines until such time as they are assessed and destroyed when their legal status becomes controlled under Waste Regulations. It follows that the management and handling of excess or unwanted medicines requires equal diligence to the management and handling of other medicines in current use.

13. Additional PHW Requirements

13.1 Master Copies

The PGDs and medicines protocols are held within the relevant programmes. A copy of all PHW PGDs and medicines protocols will be held by the OMD.

13.2 Staff's Own Medication

There are situations where staff will need to bring in, or keep, their own medication in the work environment. The medication must be stored securely in a location that does not permit service user access. PHW takes no responsibility for the use or quality of such medication and in all except life threatening conditions, it should be administered by the staff member themselves.

14. Incident Reporting

When an incident is discovered or suspected, the first duty of the person discovering it is to ensure the service user or member of staff receive prompt care and then instigate any remedial action¹³.

If at any time, during or following the administration, or supply of medication, it is suspected that an incident has occurred which could result in incorrect administration of a drug to a service user, it must be immediately reported to the most senior healthcare professional in charge of the department or division. This individual should inform the service user and it should be recorded in the clinical notes¹⁴.

If a medicine is administered in error, the person administering the medicine must report the incident to their line manager so that the situation can be assessed and determine that any appropriate medical action is taken. The appropriate person will inform the service user/staff member of the incident. The person administering the medicine must report the incident to their line manager.

Both 'near misses' and 'incidents' must be reported using a Concerns Management System e.g. Datix Cloud as soon as possible once the incident has been made safe and any required remedial action has been taken.

In the event of an adverse reaction to a medicine, the participant's GP must be informed by the responsible clinician for the service.

¹³ [Putting Things Right Incident Reporting and Management Procedure](#)

¹⁴ [PSA003](#)

Adverse Drug Reactions can be reported to the MHRA by the Yellow Card scheme¹⁵. The purpose of the Yellow Card scheme¹⁶ is to provide an early warning that a product may require further investigation.

14.1 Defects in a Medicine

On receipt, if a defect in a medicine is discovered or suspected, medical, nursing or other healthcare professional staff must immediately report the defect to a senior pharmacist at the supplying pharmacy department and the Lead Healthcare Professional. At the point of use, if a defect in a medicine is discovered or suspected, staff must contact the WMAS immediately. All suspect material must be identified and quarantined in a safe place for analysis. Instructions will be issued to all concerned regarding further use of the medicine. A Datix entry must be submitted. On completion of the investigation the pharmacy department will report back to the staff concerned at departmental level.

14.2 Loss/Discrepancy of Medication

Loss or suspected loss or misuse of medicines should be reported to the Programme Lead Professional and to the named Director of WMAS or deputy. A Datix entry must be submitted.

15. Pharmaceutical Public Health Links (Hazard Warning)

Each division must ensure a robust mechanism exists for receipt and action of pharmaceutical public health links (hazard warnings) from the Welsh Government.

16. Audit and Information Governance

A proper audit trail must be in place for any medicines, supplied or administered by PHW staff. All medicines to be supplied in accordance with a PGD or protocol authorised by PHW must be supplied in original packs or pre-packs made up by a licensed manufacturing unit. A proper audit trail must be in place. This requires a secure system for the recording of medicine used under the PGD. This will include the reconciliation of receipts and supplies of medicines on an individual service user basis. It must be possible to identify what service user has had which medicine. The names of the health professionals administering medication must also be recorded.

¹⁵ [Yellow Card | Making medicines and medical devices safer \(mhra.gov.uk\)](https://www.mhra.gov.uk/yellowcard)

¹⁶ [Information | Making medicines and medical devices safer \(mhra.gov.uk\)](https://www.mhra.gov.uk/yellowcard)

The Clinical Audit Programme will provide assurance that relevant medication management audits are undertaken. These audits will be added to the PHW Annual Quality and Clinical Audit plan, for which the CGM will have oversight.

The same rules apply to PGD records as to all other participant records as outlined in the Records Management Procedure for PHW¹⁷. For adults, all documentation must be kept for eight years; and for children until the child is 25 years, or for eight years after a child's death.

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¹⁷ [Records Management Procedure](#)

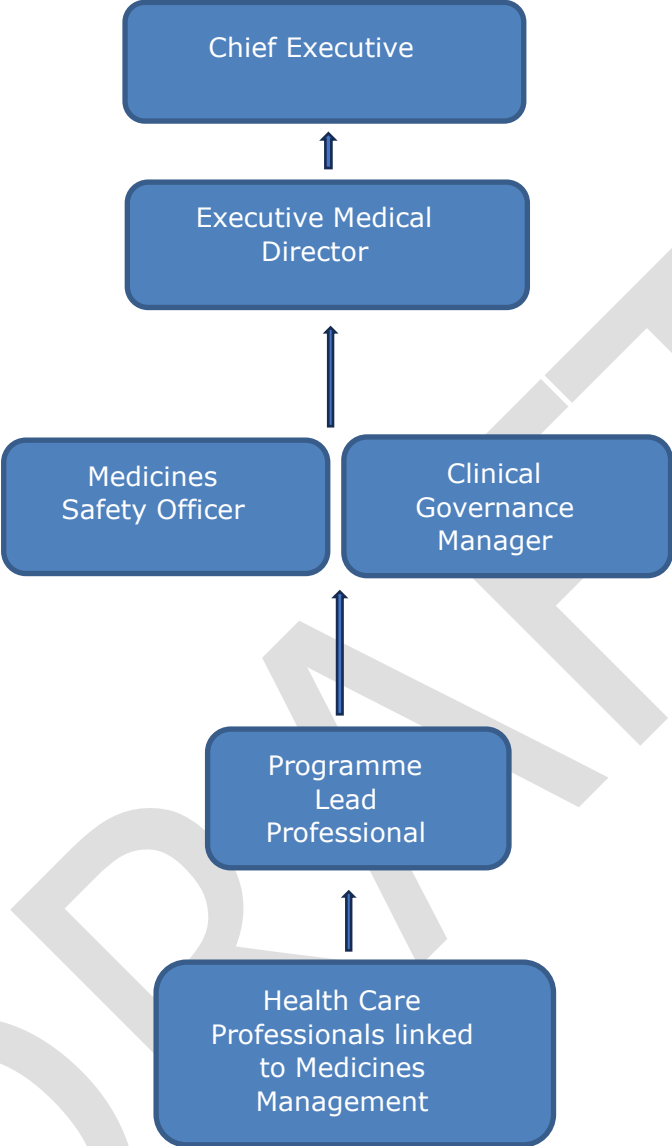
17. Appendices

Appendix 1- Flow chart: Medicines Management Governance Structures



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Appendix 2- Flow chart: Medicines Management Roles and Responsibilities



Equality & Health Impact Assessment for (*Medicine Management Policy*)

Part 1

Please answer all questions:-

1.	For service change, provide the title of the Project Outline Document or Business Case and Reference Number	
2.	Name of Clinical Board / Corporate Directorate and title of lead member of staff, including contact details	Health Protection and Screening Services Fu-Meng Khaw, Executive Medical Director Meng.khaw@wales.nhs.uk
3.	Objectives of strategy/ policy/ plan/ procedure/ service	The aim of this policy is to ensure that there is a clinical and corporate governance framework to support safe and secure systems for the controlling and handling of all medicines supplied or administered by Public Health Wales staff.
4.	Evidence and background information considered. For example <ul style="list-style-type: none"> • population data • staff and service users data, as applicable • needs assessment • engagement and involvement findings • research • good practice guidelines • participant knowledge 	Duthie Report: Guidelines for the Safe and Secure Handling of Medicines published by the Royal Pharmaceutical Society (2005) http://www.legislation.gov.uk/ukxi/2012/1916/schedule/19/made Tools and resources Patient group directions Guidance NICE Patient group directions: who can use them - GOV.UK www.gov.uk

	<ul style="list-style-type: none"> • list of stakeholders and how stakeholders have engaged in the development stages • comments from those involved in the designing and development stages <p>Population pyramids are available from Public Health Wales Observatory and the 'Shaping Our Future Wellbeing' Strategy provides an overview of health need.</p>	
<p>5.</p>	<p>Who will be affected by the strategy/ policy/ plan/ procedure/ service</p> <p>Consider staff as well as the population that the project/change may affect to different degrees.</p>	<p>All staff who order, transport and administer medicines across Public Health Wales NHS Trust.</p>

Part 2- Equality and Welsh language

6. EQIA / How will the strategy, policy, plan, procedure and/or service impact on people?

Questions in this section relate to the impact on people on the basis of their 'protected characteristics'.

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
6.1 Age For most purposes, the main categories are: <ul style="list-style-type: none"> • under 18; • between 18 and 65; and • over 65 	There is no identifiable impact.		
6.2 Persons with a disability as defined in the Equality Act 2010 Those with physical impairments, learning disability, sensory loss or impairment, mental health conditions, long-term	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
medical conditions such as diabetes			
6.3 People of different genders: Consider men, women, people undergoing gender reassignment NB Gender-reassignment is anyone who proposes to, starts, is going through or who has completed a process to change his or her gender with or without going through any medical procedures. Sometimes referred to as Trans or Transgender	There is no identifiable impact.		
6.4 People who are married or who have a civil partner.	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
6.5 Women who are expecting a baby, who are on a break from work after having a baby, or who are breastfeeding.	Medicine administering needs to take into account the medical status of the recipient of medicines in particular if they are pregnant / breastfeeding.	Training of administers addresses the issues of particular considerations related to the administering of medicines for those with medical or physiological conditions including pregnancy / breast feeding that require modifications.	
6.6 People of a different race, nationality, colour, culture or ethnic origin including non-English speakers, gypsies/travellers, migrant workers	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
6.7 People with a religion or belief or with no religion or belief. The term 'religion' includes a religious or philosophical belief	There is no identifiable impact.		
6.8 People who are attracted to other people of: <ul style="list-style-type: none"> • the opposite sex (heterosexual); • the same sex (lesbian or gay); • both sexes (bisexual) 	There is no identifiable impact.		
6.9 People according to their income related group: Consider people on low income, economically inactive, unemployed/workless,	There is no identifiable impact.		

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
people who are unable to work due to ill-health			
6.10 People according to where they live: Consider people living in areas known to exhibit poor economic and/or health indicators, people unable to access services and facilities	There is no identifiable impact.		
6.11 Consider any other groups and risk factors relevant to this strategy, policy, plan, procedure and/or service	There is no identifiable impact.		
6.12 Welsh Language			
There are 2 key considerations to be made during the development of a policy, project, programme, service to ensure there are no adverse effects and/or a positive or increased positive effect on: (please note these will continue to be reviewed to ensure Public Health Wales fulfils their duties to comply with one or more standards outlined within the Welsh Language Standards (No 7) Regulations 2018)			

How will the strategy, policy, plan, procedure and/or service impact on:-	Potential positive and/or negative impacts (unintended consequences) Opportunities or gaps	Action taken by Directorate. Make reference to where the mitigation is included in the document, as appropriate This column is to be updated in future reviews	Recommendations for improvement/ mitigation/ identified gaps or opportunities
Opportunities for persons to use the Welsh language	There is no identifiable impact.		
Treating the Welsh language no less favourably than the English language	There is no identifiable impact.		

Part 3 – Health

Questions in this section relate to the impact on the health and wellbeing outcomes of the population **and** specific population groups who could be more impacted than others by a policy/project/proposal.

The part of the assessment identifies;

- which specific groups in the population could be impacted more (inequalities)
- what those potential impacts could be across the wider determinants of health framework?
- Potential gaps, opportunities to maximise positive H&WB outcomes
- Recommendations/mitigation to be considered by the decision makers

7. Identification of specific population groups

Use the WHIASU Population Groups checklist as a reference to identify the population groups who could be more impacted than others by a policy/project/proposal. The check list can be found on the PHW Integrated EqHIA guidance pages (requires link to PHW Intranet pages for additional information and resources)

The groups listed have been identified as more susceptible to poorer health and wellbeing outcomes (health inequalities) and therefore it is important to consider them in a HIA assessment. In a HIA, the groups identified, as more sensitive to potential impacts will depend on the characteristics of the local population, the context, and the nature of the proposal itself.

7.1 Groups identified	Rational/explanation
None in addition to those in previous section.	

Assessment

Complete the wider determinants framework table below providing rational/evidence where appropriate:

1. Consider how the proposal could impact on the population and specific population groups identified above (positive/negative) for each of the wider determinants (the bullets under each determinant are there as a guide)
2. Record any unintended consequences (negative impacts) and/or gaps identified
3. Record any positive impacts or missed opportunities to maximise positive health and wellbeing outcomes
4. identify and record mitigation/recommendations where appropriate

Please note you may find that not all determinants are relevant to the project/plan however recording N/A is not acceptable a rational or evidence should be explained/referenced

Wider determinant for consideration	Positive impacts or additional opportunities	Unintended consequences or gaps	Population groups affected	Mitigation/recommendations
7.2 Lifestyles <ul style="list-style-type: none"> • Diet/nutrition/breastfeeding • Physical activity 	There is no identifiable impact.			

<ul style="list-style-type: none"> • Use of alcohol, cigarettes, e-cigarettes • Use of substances, non-prescribed drugs, abuse of prescription medication • Social media use • Sexual activity • Risk-taking activity i.e. gambling, addictive behaviour 				
<p>7.3 Social and community influences on health</p> <ul style="list-style-type: none"> • Adverse childhood experiences • Citizen power and influence • Community cohesion, identity, local pride • Community resilience • Domestic violence • Family relationships • Language, cultural and spirituality • Neighbourliness • Social exclusion i.e. homelessness • Parenting and infant attachment • Peer pressure • Racism • Sense of belonging • Social isolation/loneliness • Social capital/support/networks • Third sector & volunteering 	<p>There is no identifiable impact.</p>			
<p>7.4 Mental Wellbeing</p> <ul style="list-style-type: none"> • Does this proposal support sense of control? • Does it enable participation in community and economic life? • Does it impact on emotional wellbeing and resilience? 	<p>There is no identifiable impact.</p>			
<p>7.5 Living/ environmental conditions affecting health</p> <ul style="list-style-type: none"> • Air quality 	<p>There is no identifiable impact</p>			

<ul style="list-style-type: none"> • Attractiveness/access/availability/quality of area, green and blue space, natural space. • Health & safety, community, individual, public/private space • Housing, quality/tenure/indoor environment • Light/noise/odours, pollution • Quality & safety of play areas (formal/informal) • Road safety • Urban/rural built & natural environment • Waste and recycling • Water quality 				
<p>7.6 Economic conditions affecting health</p> <ul style="list-style-type: none"> • Unemployment • Income, poverty (incl. food and fuel) • Economic inactivity • Personal and household debt • Type of employment i.e. permanent/temp, full/part time • Workplace conditions i.e. environment culture, H&S 	There is no identifiable impact.			
<p>7.7 Access and quality of services</p> <ul style="list-style-type: none"> • Careers advice • Education and training • Information technology, internet access, digital services • Leisure services • Medical and health services • Other caring services i.e. social care; Third Sector, youth services, child care • Public amenities i.e. village halls, libraries, community hub • Shops and commercial services • Transport including parking, public transport, active travel 	There is no identifiable impact.			

<p>7.8 Macro-economic, environmental and sustainability factors</p> <ul style="list-style-type: none"> • Biodiversity • Climate change/carbon reduction/flooding/heatwave • Cost of living i.e. food, rent, transport and house prices • Economic development including trade • Government policies i.e. Sustainable Development principle (integration; collaboration; involvement; long term thinking; and prevention) • Gross Domestic Product • Regeneration 				<p>Adherence to Medicines Management Policy</p>
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Stage 3

Summary of key findings and actions Please answer question 8.1 following the completion of the EHIA and complete the action plan

Key findings: Impacts/gaps/opportunities	Actions (what is needed and who needs to do) to address the identified mitigation and recommendations	Lead		
<p>The aim of this policy is to ensure that there is a clinical and corporate governance framework to support safe and secure systems for the controlling and handling of all medicines supplied or administered by Public Health Wales staff. It aims to protect service users by ensuring the control of</p>	<p>Ensure that the policy is effectively cascaded and interpreted.</p>	<p>Directorate / Department Managers Prescribers.</p>		

medicines through safe prescribing, administration, storage, and disposal and through the reporting, monitoring and review of any medication incidents.				
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Alternatively, if appropriate, please explain the steps taken to consult with and consider the differential impact of the changes on the various protected characteristic groups (part 2) or any specific identified population groups (part 3).