GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Reference Number:** PHW26 **Version Number:** V2 **Date of next review:** December 2026

Medicine Management Policy

Introduction

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 Public Health Wales staff to supply or administer medicines to members of the public and to staff.

Aim

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 medicines through safe prescribing, administration, storage, and disposal and through the reporting, monitoring and review of any medication incidents.

Objectives

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

Linked Policies, Procedures and Written Control Documents

All corporate policies and procedures are available on the Public Health Wales website

Standards for Health Services in Wales: Standard 15 – Medicines Management

Public Health Wales Vaccines (Handling and Storage) Cold Chain Management Procedure Chain Management Procedure 2022

Department of Health and Social Care 2020
https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book#the-green-book

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1034373/Greenbook-cover-Nov21.pdf

Scope

This medicines policy applies to all staff working within Public Health Wales who are involved in the prescribing, administering, ordering, transporting, storing, controlling 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.
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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**
02	2023	13.12.23	04.01.24	Updated the content and clarified roles and responsibilities

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This version of the PHW Medicines Policy is based on the Hywel Dda University Health Board Medicines Policy No 268-version 15 July 2021 whose help is gratefully acknowledged.

Any questions or enquiries relating to the Medicines Policy should be emailed to Caroline Whittaker Professional Lead Nursing, Midwifery and Standards Manager (caroline.whittaker@wales.nhs.uk) and to the Office of the Medical Director (OMD) – PHW.OMD@wales.nhs.uk or Dianne Burnett, National Lead Pharmacist for Medicines Advice (dianne.burnett@wales.nhs.uk) under the subject heading Medicines Policy

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 medicines[1].

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.

2. Role and Responsibilities

The Chief Executive has overall responsibility for Medicines Management in Public Health Wales. The provision of resources to ensure the safe prescribing, administration, ordering, transport, control 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.

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.

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

2.1 Chief Pharmacist

Through a Service Level Agreement with Cardiff and Vale Health Board, the Director of Pharmacy and Medicines Management for Cardiff and Vale UHB, is responsible for advising on effective medicines management, its systems and procedures.

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

3. Operational responsibilities

3.1 Lead Healthcare Professional

Each Directorate/Division must nominate a Lead Healthcare Professional with professional responsibility to ensure that there are appropriate systems in place for the following:

- Providing a safe, effective, efficient and secure system for medicine stocks and distribution held within Public Health Wales sites
- Providing a system for monitoring medicine usage and advising on appropriate stock range, expiry dates and stock holding levels
- Providing advice on appropriate environmental storage conditions
- Providing advice on safe and proper means of disposal of unused/unwanted medicines
- Providing advice on safe and effective systems and arrangements for medicine administration. This includes commenting and advising on medicine administration errors and near misses reported via the Incident Reporting system and appropriate retentions of documents in relation to these aspects
- Providing advice on transport of medicines and other pharmaceuticals.
- Ensuring that there are adequate mechanisms in place to monitor and report on the usage on medicines throughout Public Health Wales
- The recording of administration including dosage and batch numbers
- The supply of medicines to service users/staff in accordance with Patient Group Directions/local policy
- The induction of new staff with respect to this policy & code of practice and any local supporting procedures
- The auditing of compliance with this policy and the implementation of remedial action.

3.2 Health care professionals involved in the medicines management process should:

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

3.3 Medical and non-medical prescribers

It is the responsibility of medical and non-medical prescribers to practice in accordance with local procedures and guidance and to comply with their respective professional Codes of Practice.

3.4 Chief Pharmacist

The Chief Pharmacist will be asked to provide expert knowledge and advice on the following procedures:

- Lead on the adaptation of the national template PGD for flu vaccine administration for local use
- The safe, effective, efficient and secure system for medicine stocks held within Public Health Wales sites
- The safe, effective, efficient and secure systems for medicine distribution
- The appropriate monitoring of medicine usage and advising on appropriate stock range, expiry dates and stock holding levels
- The appropriate environmental storage conditions.
- The safe and proper means of disposal of unused/unwanted medicines
- The safe and effective systems and arrangements for medicine administration. This includes commenting and advising on medicine administration errors and near misses reported via the Incident Reporting system and appropriate retentions of documents in relation to these aspects.
- The transport of medicines and other pharmaceuticals.
- The mechanisms in place to monitor and report on the usage on medicines throughout Public Health Wales and to advise on strategies to promote cost effective prescribing
- The supply of drugs to service users/staff in accordance with Patient Group Directions

4. Control of prescribing

Any prescribing, supply or administration of medicines within Public Health Wales should adhere to policies and guidelines approved by the Quality, Safety and Improvement Committee. These will be developed by working groups including senior medical, pharmaceutical and healthcare professional and management staff that are appropriate to the range of prescribing undertaken.

4.1 Prescribing medicinal products – Who may prescribe?

Medicinal products may only be prescribed by persons who are legally qualified to do so. Prescribers must be currently registered with the appropriate professional body. They must be employed and authorised by Public Health Wales to prescribe, and have the appropriate knowledge, competency and experience to prescribe, such as a doctor, a dentist, or a non-medical prescriber, e.g. a Nurse or Pharmacist Independent Prescriber. Prescribers may only prescribe from the appropriate list of medicinal products within their scope of practice. Dentists are required by their registration to restrict their prescribing

to their areas of competence. Non-medical prescribers must have gained signed authorisation from their appropriate line manager and in the case of a nurse or midwife Non-Medical Prescriber (NMP) signed authorisation from the appropriate Executive Nurse Director. NMPs must also be registered on an NMP database before prescribing within their area of competence.

Each prescriber has a duty of care when prescribing for service users, to ensure medicines are issued appropriately.

When prescribing for service users, the principles of prudent health care should be followed.

Prescriptions should be issued on prescription forms approved by the PHW Office of the Medical Director.

4.2 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. These include naloxone, glucagon and hydrocortisone. Adrenaline 1 in 1000 (1mg/mL) by intramuscular injection can be administered for the emergency treatment of anaphylaxis. Current clinical guidelines should be followed. The full list of exemptions can be found at: http://www.legislation.gov.uk/uksi/2012/1916/schedule/19/made [2]

4.3 Patient Group Directions (PGD)

A patient group direction is a specific written instruction for the supply and administration, or administration, of a named medicine in an identified clinical situation. It applies to groups of patients 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 written direction. The template for a PGD is available at NICE[3]

4.4 Healthcare Professions able to operate under a PGD

Please refer to MHRA[4] for advice on who may use a PGD.

NB: 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 PGD directions.

[2] http://www.legislation.gov.uk/uksi/2012/1916/schedule/19/made
[3] Tools and resources | Patient group directions | Guidance | NICE
[4] Patient group directions: who can use them - GOV.UK (www.gov.uk)

4.5 Circumstances under which Patient Group Directives are permissible within Public Health Wales

To authorise the supply or administration of medicines by Public Health Wales employed staff where Public Health Wales is directly responsible for the care of patients or group of individuals for example Influenza immunisation

4.6 Criteria required to ensure valid PGD within Public Health Wales

Within Public Health Wales 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 and Medicines Management Cardiff and Vale University Health Board (CVUHB) a senior person in each profession should be designated with the responsibility to ensure that only fully competent, fully qualified and trained professionals operate within directions.
- It must be signed by the individual or individuals that may supply administer medicines under the PGD, who must belong to one of the classes of person specified above
- Be in effect at the time of administration or supply
- The PGD for the administration of the flu vaccine must be reviewed annually

5. Drugs Requiring Special Consideration

5.1 Controlled drugs

Controlled drugs can only be supplied and administered in accordance with the requirements of the Misuse of Drugs Regulations 2001. No circumstances have been identified where a controlled drug should be permitted to be supplied or administered within Public Health Wales. Consequently, a Controlled Drug Accountable Officer has not been appointed by Public Health Wales. This position will be reviewed if the situation changes.

5.2 Medicines not considered appropriate for inclusion in a PGD

Medicines without a UK marketing authorisation and those used outside the terms of the Summary of Product Characteristics (SPC) are not considered appropriate for inclusion in a PGD. The regulations specifically state that a medicine can only be included if it has a current UK marketing authorisation or a homeopathic certificate of registration. Only medicines with a marketing authorisation can have guarantees of safety, quality and efficacy.

5.3 Exceptional Circumstances

In certain exceptional circumstances, medicines with a marketing authorisation may be used outside the summary of product characteristics e.g. in paediatrics where no licensed drug exists. This includes vaccines used according to Joint Committee on Vaccination and Immunisation (JCVI) advice. Any National Institute for Health and Care Excellence (NICE) guidance should be followed to ensure that a medicine used in this way is justified. The PGD must clearly state that the product is being used outside the terms of the SmPC, state the reasons why its use is necessary and ideally a gold standard reference in support of its use, e.g. JCVI, NICE or British National Formulary guidance. Where the medicine is for children, particular attention will be needed to specify any restrictions on the age, size and the maturity of the child and the need for consent.

5.4 Newly Licensed Drugs

Newly licensed drugs subject to special reporting arrangements, ("black triangle" drugs) should also only be considered in exceptional circumstances. Good clinical practice guidelines must be followed and the PGD must clearly state the status of the product and why a black triangle drug has been chosen. Black triangle vaccines used in immunisation programmes may be included in PGD's provided they are in accordance with the schedules recommended by the JCVI and specified in the Green Book *Immunisation against Infectious Disease* published electronically by the Department of Health.

The black triangle symbol ▼ identifies those preparations in the BNF that are monitored intensively by the Medicines and Healthcare Products Regulatory Agency (MHRA). Prescribers are urged to exercise caution when prescribing these preparations and should report adverse drug reactions to the MHRA https://yellowcard.mhra.gov.uk

5.5 Antimicrobial Resistance

Antimicrobial resistance is a major public health concern. The use of antibiotics in PGD's must therefore be given careful consideration. Inclusion in a PGD can only be considered where absolutely necessary and justifiable and where measures to combat resistance will not be compromised. Any PGD involving antibiotics must have the involvement and authorisation of a consultant microbiologist and the all-Wales Consultant Antimicrobial Pharmacist, and be audited regularly.

6. Additional Public Health Wales requirements

6.1 Security, Storage and Audit

All medicines to be supplied in accordance with a PGD authorised by Public Health Wales 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 use under the PGD. This will

include the reconciliation of receipts and supplies of medicines on an individual service user/staff member basis. It must be possible to identify what service user/staff member has had which medicine. The names of the health professionals providing treatment must also be recorded.

6.2 Labelling and Patient Information Leaflets

It is a legal requirement that the manufacturer's patient information leaflet (PIL) is provided each time a medicine is supplied. Specific labelling requirements apply equally to medicines supplied under PGD's. The labelling requirements for medicines are reproduced in the Royal Pharmaceutical Society's *Medicines, Ethics and Practice: The professional guide for pharmacists.*

6.3 Master Copies

A copy of all PGDs authorised by the Executive Medical Director will be held by the Office of the Medical Director.

6.4 PGD Advisory Functions

It should be noted that Public Health Wales has a dual role in relation to PGDs as follows:

i) the development and approval of a range of PGDs for use internally by Public Health Wales staff. This activity is covered by the policy document.

ii) the production and maintenance of an extended range of PGD template documents as advisory documents to support LHBs and Trusts in the implementation of their immunisation programmes and other infectious disease management campaigns. These documents are available as advisory documents only and must be checked and authorised by individual LHBs and Trusts. Public Health Wales accepts no responsibility for the secondary use of this information.

6.5 Staff's own Medication

There are situations where staff will need to bring in or keep their own medication in a work environment. If the staff member works in an area to which service users have access, the medication must be stored securely in a location that does not permit service user access. The Trust 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. If necessary to save a life e.g. an Adrenaline auto-injector for anaphylaxis, another staff member could administer the medication under common law.

7. Ordering stock drugs and pharmaceuticals

7.1 Responsibility

The most senior health 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 most senior departmental health professional. A list of designated lead health professionals will be compiled and updated by the Office of the Medical Director.

Medicinal products may only be supplied or administered in accordance with this policy. Public Health Wales employees must not take medicinal products 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.

7.2 Stock Drugs and Ordering

The process of ordering and receiving medication from pharmacy as stock medication must ensure that certain controls are in place to cover the safety and security of the medicines (to include a clear documented 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 most senior departmental health professional in charge of 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 supplying pharmacy department must each keep a copy of this list. This will be reviewed at regular intervals (minimum annually). A named pharmacist will be provided as a point of contact to discuss and address any ongoing issues or concerns.

The person in charge has responsibility for all the medicines in that department. This 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. Medicinal products with the earliest expiry date must be used first.

7.3 Delivery and Transport

Drugs may be carried for delivery by any authorised Public Health Wales employee. Medicines must never be given to patients to deliver.

7.3.1 Transport of Medicines from the supplying pharmacy department by authorised transport

Order assembly and transfer from pharmacy to the department will be the responsibility of the pharmacy department. 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 department

All medicines will be transported in sealed, tamper evident containers. Containers will be kept securely or under surveillance whilst awaiting collection from, or on receipt at, the designated Trust area. On arrival at the department/clinic, containers should be placed in a designated area and the delivery signed for. Once delivered to the department/clinic, the responsibility for the security of the medicines 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.

The authorised person accepting the delivery must sign the documentation on receipt and deal with it as specified in the Medicines Policies and Standard Operating Procedure (SOP) of the Health Boards or Trusts providing pharmacy services under a Service Level Agreement or SOP of an external private provider. 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. When sending out items with highly sensitive temperature conditions, e.g. vaccines, it is good practice to notify the receiving unit of the day/date of transportation to maintain the cold chain as described in the NPSA Rapid Response directive (RRR008 Cold Storage)

7.3.2 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 container) in order to remain intact and present no external hazard throughout the transport process. It is essential that when the item reaches its destination it is still intact and can be used for a patient.

7.3.3 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 record of collection will be maintained by Public Health Wales.

Staff involved in the transport of medicines will be kept to a minimum and be appropriate to the task, e.g. employee, or contracted driver

All staff involved in the transport of medicines will be trained to ensure understanding of the procedures, and the need for security.

8. Storage and Administration of Medicinal Products

Medicinal products received by departments must immediately be placed in the appropriate locked cupboard or locked refrigerator (with the exception of emergency drug boxes).

Storage of medicines no longer in use should be returned as set out in this policy. If it is found that the storage conditions are inappropriate, the responsible person must be informed.

The department must have sufficient and proper storage cupboards to safely and securely store medication in a dedicated room or area. Each area where medicines are stored must be kept clean, be well ordered and comply with legislation for storage of medicines. PSN055 sets out the current requirements. Internal and external medicines should be stored in separate cupboards or, where this is not possible, on separate shelving within a cupboard. Testing reagents shall be stored in a separate locked cupboard. Disinfectants shall be stored in a locked cupboard, separate to internal medicines. Medicines that do not have to be stored in a refrigerator must be stored between 8°C and 25°C. The room temperature must be monitored with a thermometer and recorded on a temperature chart.

8.1 Medicine refrigerators

Medicines labelled 'Store in a refrigerator' shall be stored between 2°C and 8°C in a dedicated locked medicines refrigerator. Guidance is set out in Patient Safety Notice PSN015. Medicines refrigerators should preferably be hard wired to the electrical supply to prevent accidental switching off. If not, a cautionary notice must be placed on plugs or sockets to prevent accidental interruption of power supply. The use of refrigerators with temperature recording charts is preferred. Medicines refrigerators must have the temperature monitored and recorded daily, and this should be regularly audited by a named individual. Immediate action must be taken if the temperature is not within the acceptable limits as per Public Health Wales Vaccines (Handling and Storage) Cold Chain Management Procedure Chain Management Procedure 2022

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

8.2 Emergency medication, anaphylaxis kits

These medicines are provided to clinical areas to provide immediate lifesaving treatment and should not, therefore, be stored in locked cupboards, but be kept in a safe location in the clinical area so as to be readily available when needed. This must be balanced against the need for medicine security so that wherever possible, they should be stored out of direct view of the public.

8.3 Safe custody

The responsibility for safe custody (continuing responsibility) is that of the person in charge of the department. 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.

8.4 Loss/discrepancy of medication

Each member of staff will maintain their own record of any incident and their subsequent action. The person in charge will make initial enquiries to establish if any suspected theft or fraud may have occurred.

9. 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. It is aligned to the All Wales Policy for Medicines Administration, Recording, Review, Storage and Disposal (MARRS 2015) and the https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines/professional-guidance-on-the-safe-and-secure-handling-of-medicines

Definition of administration: Administer is 'to give a medicine either by introduction into the body, whether by direct contact with the body or not (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.

Medicinal products may only be administered by persons who are qualified to do so. They must be employed and authorised by Public Health Wales to administer, and have the appropriate knowledge and experience to administer e.g. a doctor, a dentist, or an appropriately accredited practitioner e.g. a Nurse. All employees administering medicines will be held individually accountable for their actions.

9.1 Standards of Practice for the administration of Medicinal Products

When administering medical products health professionals must act within the framework of current Service Level Agreement and in accordance with their Code of Professional Conduct, and the current standards of administration of medicines. They must also act in accordance with the relevant policies of Public Health Wales.

A registered health professional is accountable for their actions and omissions. In administering any medication, or assisting or overseeing any self-administration of medication, the health professional must exercise their professional judgement and apply their knowledge and skills in a given situation.

They will be guided by the WHO 5Rs principles (RIGHT patient, medication, time, route, dose, NO allergy)

Medicinal products may only be administered to a patient:

- On the written patient specific instructions of a doctor or appropriate non-medical prescriber;
- By a person working under a Patient Group Direction.

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

- Establish the identity of the service user/staff member patient in accordance with the PHW Patient Identification Policy.
- Check the prescription is clearly written, unambiguous and appropriate for the condition being treated
- Check that the service user/staff member is not allergic to medicine to be administered.
- Check the medicine to ensure correct dosage, route and timing of the administration.
- 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 (Patient Information Leaflet PIL)
- 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

The administration of medicinal products must be guided by the relevant nursing procedures in the current edition of the Royal Marsden Manual of Clinical Nursing Procedures, (the Royal Marsden can be accessed via

www.blackwellroyalmarsdenmanual.com

9.2 Safe Administration of medicines

It is the responsibility of the Health Care Professional to ensure that standards of medicines practice are adhered to and ensure that has received the relevant training and education to enable them to safely administer medicines.

To ensure medicines are safely administered the administrator must-

- Know the therapeutic use of the medicine to be administered, its normal dose, side effects, precautions, contra-indications and monitoring requirements. In the event that the administrator is not aware of this information, they must

be able to locate the information before administration. (Sources include BNF and SmPC).
- Be alert to potential errors in dispensing.
- Contact the prescriber without delay if :-
    - Contraindications to the medicine are identified
    - The patient develops a reaction to the medicine
    - Assessment of the service user/staff member indicated that the medicine may no longer be suitable for them

9.3 Managing errors

If a medicine is administered in error, the person administering the medicine must report the incident to the responsible person 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. A clinical incident entry on Datix must be completed

10. Incident reporting

It is important that both 'near misses' and 'incidents' are reported via the Once for Wales Concerns Management System, Datix Cloud, in accordance with Public Health Wales policy:

- Whenever 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 action.
- If at any time, during or following the prescribing, administration, or supply of medication, it is suspected that an incident has occurred which could result in incorrect administration of a drug to a patient, it must be immediately reported to the most senior healthcare professional in charge of the department or division. This individual should inform the relative and it should be recorded in the clinical notes.
- Where equipment is involved in the incident, staff must ensure that the item is removed from use immediately and defects are reported to the appropriate manufacturer and the Medicines and Healthcare Regulatory Agency (MHRA).
- The patient's GP should normally be informed
- The incident must be reported onto Datix Cloud as soon as possible once the incident has been made safe and any required remedial action has been taken.
- Adverse Drug Reactions can be reported to the MHRA by the Yellow Card system Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

10.1 Disposal and Defects

All waste must be disposed of in line with the Public Health Wales (and/or local clinical waste disposal procedures) policy on waste which must concur with current environmental Service Level Agreement. Any material that has been in contact with the patient should be classed as hazardous clinical waste and

disposed of via the standard method for clinical waste. Any item deemed as 'sharps' should be disposed of by being placed in a 'sharps' bin even if they have a small amount of medication left inside them.

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.

When a defect in a medicinal product or dressing is discovered or suspected, medical, nursing or other professional staff must immediately report the defect to a senior pharmacist at the supplying pharmacy department, the senior health professional in the unit and the lead CPPH. All suspect material must be identified and quarantined in a safe place for analysis.

The health professional that reports an incident or defect should make themselves available to discuss the incident or defect with the senior pharmacist on duty. Instructions will be issued to all concerned regarding further use of the drug or dressing. On completion of the investigation the pharmacy department will report back to the staff concerned at departmental level.

The Medicines and Healthcare products Regulatory Agency collects and monitors information on suspected safety concerns involving healthcare products for example medicines. The purpose of the "Yellow Card" [5]scheme is to provide an early warning that a product may require further investigation.

10.2 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.

10.3 Unlicensed medicines

Public Health Wales recognises that the informed use of unlicensed medicines or licensed medicines for an unlicensed indication (Off-label use) is sometimes necessary in medical practice. This is accepted by the Welsh Risk Pool which will indemnify participants against incidents arising out of these uses subject to a policy covering the use of drugs in such circumstances. However, the Welsh Risk Pool Services Technical note on prescribing of unlicensed drugs or using drugs for unlicensed conditions are under review. It is also in keeping with policy statements from a number of professional organisations, e.g. The Royal College of Paediatrics and Child Health.

The Medical Protection Society have stated that the fact that a drug is not licensed does not preclude it's use but the prescriber would have to demonstrate

[5] Medicines and Healthcare products Regulatory Agency Information | Making medicines and medical devices safer (mhra.gov.uk)

that the prescription was in accordance with responsible medical practice by reference to other practitioners, authoritative journals, medical texts or other reliable sources. In addition, the Medicines Act and its Regulations provides exemptions, which enable doctors to prescribe unlicensed medicines.

The responsibility that falls on healthcare professionals when using an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its license. Prescribers have a duty to ensure they are aware of the legal status of the medicines they prescribe. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label. These risks may include: adverse reactions; product quality; or discrepant product information or labelling, e.g. absence of information for some unlicensed medicines, information in a foreign language for unlicensed imports, and potential confusion for patients or carers when the Patient Information Leaflet is inconsistent with a medicine's off-label use.

11. Prescribing for Members of Staff and Families

Self-prescribing and prescribing for members of one's family is not allowed. Public Health Wales staff should obtain their prescription medicines from their GP and should not ask colleagues to prescribe routine or incidental items for them.

12. Training and/or Communication with Staff

Public Health Wales will ensure that all healthcare professional staff directly involved in medicines use have the appropriate levels of awareness and training to comply with the medicines management policy. Training will be delivered in various ways (group sessions, self-learning via Intranet, etc).

This policy may be communicated to all staff via:

- Staff Induction
- E-learning
- Intranet
- e-bulletin

13. Monitoring and auditing

An annual audit should be undertaken within each division with operational responsibilities for the prescribing, supply or administration of medicines to ensure compliance with the policy. The Lead CPPH is responsible for collating the audits and reporting to the Quality, Safety and Improvement Committee as appropriate.

Adherence to this policy will be audited through:

- Incident reporting

- Annual audits
- Standards for Health Services in Wales (Standard 15)

14. Information Governance

A proper audit trail must be in place for any medicines prescribed, supplied or administered by Public Health Wales staff. This includes the reconciliation of receipts and supplies of medicines on an individual patient basis.

The same rules apply to prescribing and PGD records as to all other patient records. 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.

In the case of outbreak management the patient's GP should be notified of any prophylactic treatment supplied or administered.