Unlicensed and Off-label Medicines Policy for use in Powys Teaching Health Board community hospitals

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The latest approved version of this document is online.

If the review date has passed please contact the Author for advice

Bwrdd Iechyd Addysgu Powys yw enw gweithredol Bwrdd Iechyd Lleol Addysgu Powys

Powys Teaching Health Board is the operational name of Powys Teaching Health Board

Policy authorisation

Approved by the Area Prescribing Group on 14/12/23

Version Control

Version	Summary of Changes/Amendments	Date
	Initial issue	December 2023

Contents

Engagement and Consultation

Key Individuals/Groups Involved in Developing this Document

Role / Designation
Senior Pharmacist Governance and Training

Circulated to the following for Consultation

Date	Role/ Designation
16/08/2023 & 23/11/23	Head of Community Services Medicines Management/Pharmacy
24/11/2023	Medicines Management Team
04/12/2023	Area Prescribing Group

Evidence Base

Please list any National Guidelines, Legislation or Health and Care Standards relating to this subject area

- All Wales Medicines Strategy Group: Understanding Unlicensed Medicines. May 2023. https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/prescribing-guidance/understanding-unlicensed-medicines
- GMC guidance on prescribing unlicensed medicines. Published 5/4/21.https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines
- The supply of unlicensed medicinal products ("specials") MHRA Guidance Note 14 https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf
- Packaging and labelling for safety: Unlicensed imported medicines- Guidance for the overlabelling and provision of translated information. Edition 2. December 2018. Endorsed and supported by the SPS https://www.sps.nhs.uk/wp-content/uploads/2019/01/Unlicensed-imported-medicines-Guidance-for-the-ovelabelling-and-provision-of-translated-information-Dec-2018.pdf
- Quality Assessment of Unlicensed medicines. Specialist Pharmacy Service. 16/11/16 https://www.sps.nhs.uk/articles/quality-assessment-of-unlicensed-medicines/
- Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK (www.gov.uk).11/12/14.
- RPS Prescribing Specials. April 2016. professional-standards---prescribing-specials.pdf (rpharms.com)
- SPS Purchasing Specials. 30 November 2023. https://www.sps.nhs.uk/articles/purchasing-specials/
- SPS Making unlicensed medicines. 30 November 2023. https://sps.nhs.uk/articles/making-unlicensed-medicines/
- SPS Governance principles for unlicensed medicines. 30 November 2023. https://sps.nhs.uk/articles/governance-principles-for-unlicensed-medicines/

Impact Assessments

Equality Impact Assessment Summary					
	No impact	**Adverse**	**Differentia**	**Positive**	**Statement**
Age				√	Please remember policy documents are published to both the **intranet** and **internet.** The version on the internet must be translated to Welsh. Children (aged under 18 years) and the elderly (over 65 years) are more likely to receive unlicensed medicines. The benefits (e.g. better safety, appropriate awareness of unlicensed status of medicines) could be more pronounced in both children and the elderly populations. [taken from AWTTC]
Disability	√				
Gender	√				
Race	√				
Religion/ Belief	√				
Sexual Orientation	√				
Welsh Language	√				
Human Rights	√				

Risk Assessment Summary
Have you identified any risks arising from the implementation of this policy / procedure / written control document? Yes- potential risk regarding access to medicine
Have you identified any Information Governance issues arising from the implementation of this policy / procedure / written control document? Risk of sharing patient names, in some circumstances, to obtain unlicensed products
Have you identified any training and / or resource implications as a result of implementing this? Powys Teaching Health Board (PTHB) staff will need to be made aware when this policy is approved for use.

1. Policy Statement & Introduction

This policy outlines the steps that must be taken to ensure that unlicensed medicines (medicines without a UK marketing authorisation) are used appropriately in Powys Teaching Health Board (PTHB). The policy also provides guidance on using licensed medicines outside of their UK marketing authorisation (off-label).

In the UK, the MHRA (Medicines and Healthcare Products Regulatory Agency) is responsible for ensuring that medicines are safe (following clinical trials), effective, and of an appropriate quality. All licensed medicinal products which conform to internationally agreed standards are granted a marketing authorisation, which states the clinical indication, form, dose, route of administration, the patient age group for whom the medicine can be used, and how the medicine should be stored. Prescribing a medicine within its marketing authorisation does not guarantee that the patient will come to no harm, but a prescriber's responsibility and potential liability are likely to be shared with the manufacturer of the medicine if it is prescribed according to its product license. In addition, not all licensed medicines will be available on an NHS prescription and the use of some medicines may be restricted by local formulary decisions.

A medicine should preferably be prescribed in accordance with the terms of its UK product license, these terms are available via www.medicines.org.uk or https://products.mhra.gov.uk or via the manufacturer. However, following an assessment of an individual patient, a prescriber may conclude, for therapeutic or concordance reasons, that it is necessary to prescribe an unlicensed medicine, or a medicine outside of licence to meet the specific **clinical needs** of the patient (this does not routinely include cost, convenience, or operational needs). Please refer to MHRA advice for information on which healthcare professionals can prescribe an unlicensed medicine and for considerations for prescribing decisions.

The General Medical Council has produced guidance around the prescribing of unlicensed medicines. A prescriber may decide to use an unlicensed medicine in the following circumstances:

- There is no suitably licensed medicine that will meet the patient's need
- A suitably licensed medicine that would meet the patient's need is not available (for example, a temporary shortage in supply)
- The prescribing forms part of a properly approved research project
- There is a serious risk to public health and the MHRA has temporarily authorised the sale or supply of an unlicensed medicine, such as a vaccine or treatment, in response
- For a rare condition for which there is not a UK licensed product

Types of unlicensed products prescribed may include specials manufactured in the UK that have been:

- prepared by or under the supervision of a pharmacist operating under section 10 exemption of the Medicines Act 1968
- prepared by a licensed manufacturing unit e.g hospital pharmacy. The NHS Specials manufacturing units that supply outside their own Trust are listed on ProFile (registration required, NHS only).
- prepared by a licensed UK 'specials' manufacturer, holding a Specials Manufacturing Authorisation (MS) from the MHRA

All MS holders are listed on the MHRA's Human and veterinary medicines: register of licensed manufacturing sites. This shows the MS number, name and address of all Specials manufacturers, and indicates the range of dose forms that the manufacturer is licensed to make. This enables purchasers to check that the prospective supplier has an appropriate licence for the manufacture of the medicine to be purchased. A medicine which has been manufactured under an MS licence is identifiable by the presence of the MS licence number on the label, for example 'MS12345'.

Sometimes, a third party with a wholesale dealer authorisation may offer a UK manufactured Special. The wholesaler should be able to provide information about the manufacturer so that the purchaser can check its authenticity. The MHRA also holds a list of holders of Wholesale Dealer Authorisations (Wholesale Dealer's Licences (WDL)).

Alternatively, a product prepared abroad may be imported. An appropriate MHRA license must be held:

- Medicines from an MHRA approved country must be imported by a Wholesaler with a licence that authorises imports
- Medicines from outside an MHRA approved country must be imported by a Specials manufacturer with a licence covering imports.

Before importing a medicine, an importer must notify the MHRA of their intention and wait for a response (sometimes called a "no objection" letter). The MHRA does not approve unlicensed medicines, but may object to importation if there is no evidence of Special Clinical Need, they have concerns about the pharmaceutical quality of the medicine, or if there are clinical safety issues. There are restrictions on the quantity of any individual unlicensed medicine that may be purchased at one time, so importers hold limited stocks.

In some cases, the "no objection" letter may include conditions such as requiring safety information to be communicated to clinicians.

Examples of "off label" use:

- When there is no UK licensed medicine applicable to a child, and a medicine licensed only for adult patients would meet the needs of the child

- When a medicine licensed to treat a condition or symptom in children would not meet the specific assessed needs of the particular child, but a medicine licensed for the same condition or symptom in adults would do so
- The patient needs a medicine in a formulation that is not specified in an applicable UK license, so a licensed preparation is altered to make administration possible e.g crushing tablets, opening up capsules (where not mentioned in the SPC)
- Use of a medicine (in agreement with a registered Pharmacy Professional) that has been stored outside of its licensing requirements (e.g cold chain breaches)
- Use outside of the licensed parameters, for example, a different dose, or indication, or when a contraindication applies (e.g pregnancy, where recognised guidance exists)
- Adding a medicine to food or drink or thickening it, when not mentioned in the SPC

The MHRA provide guidance on the hierarchy for the use of unlicensed medicines. The MHRA does not recommend off-label use of products; but if a UK licensed product can meet the clinical need, even off-label, it should be used instead of an unlicensed product. A product may be used off-label in a different population, for a different condition, or at a different dose to that which the medicine was originally tested for. The prescriber's responsibility and potential liability are increased when prescribing medicines off-label. If a patient is harmed as a direct result of the prescribing of a medicine in an off-label way, the manufacturer is unlikely to be found culpable unless the harm is directly attributable to a defect in the medicine. For example, the prescriber would be responsible for serious side effects in a patient which arose as a result of prescribing an unlicensed dose, compared to shared prescriber/manufacturer responsibility for medicines used within license. If a licensed product was used in an unlicensed way and there was a product defect, there would be responsibility on the manufacturer. The prescriber's responsibility and potential liability is increased further when prescribing completely unlicensed medicines (for example, an import from abroad), as even a defect may not be covered by the manufacturer. The following are considered as unlicensed medicines:

- products that are licensed in the country of origin, then imported to the UK.
- products that are made in the UK specially, individually or in bulk, in Good Manufacturing Practice (GMP) inspected facilities (which require that manufacture or assembly is carried out under the supervision of appropriately qualified staff, including a named quality controller and production manager, who are acceptable to the MHRA) to fulfil a specific need for a patient. These products are known as 'specials'.

- products that are imported but not licensed in the country of origin. These may or may not be classed as medicinal products in the country of origin, but are classed as medicinal products in the UK.

The quality, safety and efficacy of an unlicensed medicine will not have been formally assessed by the MHRA, meaning there is a potential lack of assurance in relation to quality, safety and efficacy. The unlicensed medicine may be specially manufactured or imported to the order of the prescriber. The purchaser is responsible for assuring that the supplier or manufacturer can meet the product specification- the purchaser must take steps to ensure that the manufacturer has appropriate licences and is capable of supplying a consistently manufactured product. Examples of types of licenses required may include:

- MIA (imports) license required by companies importing medicines from approved countries
- Specials manufacturing license (MS) covering imports from the relevant area is required for companies importing medicines from the rest of the world. A 'Specials' license holder must demonstrate compliance with the European Commission's 'Notes for guidance on minimising the risk of transmitting animal spongiform encephalopathy agents via medicinal products'.
- Specials manufacturing license (MS) is required by companies who manufacture unlicensed medicines in the UK
- Wholesale Dealer Authorisation (WDA) is required by companies who supply but do not manufacture Specials. The importer of a 'Special' into the UK must hold a Wholesale Dealers License if the product is to be imported from an EEA member state

All involved in the supply chain must be aware that the product is unlicensed. A pharmacist may decline to dispense unless appropriate authorisation has been sought and provided. The responsibility for ensuring the quality of any unlicensed medicine lies jointly with the prescriber and the purchasing healthcare professional. The prescriber will take direct responsibility for prescribing the medicine and for overseeing the patient's care.

If a medicine's formulation is altered by crushing tablets or mixing preparations together, the properties of the medicine may be altered, making this unlicensed use. A registered pharmacy professional must be consulted before changing the formulation of a medicine.
The PTHB Formulary Working Group has been charged with risk assessing unlicensed medicines applications and making a recommendation to the Area Prescribing Group. The PTHB Area Prescribing Group has been charged with monitoring and risk assessing unlicensed and off label use of medicines within PTHB and ensuring appropriate governance arrangements are in place for their use.

2.Objective

This policy aims to:

- Ensure licensed medicines are prescribed wherever possible
- Outline the procedure to be followed when requesting an unlicensed medicine or an unlicensed use of a medicine, ensuring that requests are handled efficiently and in accordance with current legislation and guidance
- Specify the information required from the prescriber to allow a risk assessment of an unlicensed medicine to be performed by a pharmacist before referral to the Formulary Working Group. The Formulary Working Group then make a recommendation to the Area Prescribing Group to take into account when considering approval. Urgent requests should be dealt with via the IPFR process.
- Describe the responsibilities of staff members when dealing with unlicensed medicines
- Ensure patients/carers are fully informed about the use of unlicensed medicines
- Ensure patient safety

This policy does not apply to clinical trials. The prescription of unlicensed/off label medicines in primary care is beyond the scope of this document.

3.Definitions

- ABUHB: Aneurin Bevan University Health Board
- APG: Area Prescribing Group
- AWMSG: All Wales Medicines Strategy Group
- EEA: European Economic area
- EMA: European Medicines Agency
- FWG: Formulary Working Group
- GMP: Good Manufacturing Practice
- IPFR: Individual Patient Funding Request
- Licensed medicine: A medicine with a UK marketing authorisation
- MHRA: Medicines and Healthcare Products Regulatory Agency- the licensing authority in the UK for the advertising and selling of all medicinal products
- MIA: Manufacturing and Import Authorisation
- MM: Medicines Management department
- MS: Specials manufacturing authorisation
- Off-label: licensed medicines used outside of their UK marketing authorisation (outside of the parameters listed in the SPC)
- PTHB: Powys Teaching Health Board
- s/c: subcutaneous
- SLA: Service level agreement
- SPC: Summary of Product Characteristics

- Specials: unlicensed medicines that are manufactured or procured specifically to meet the special clinical needs of an individual patient. They may be specially prepared by the holder of a Manufacturer's Specials License or imported in response to, or in anticipation of, the order of a doctor or a non-medical independent prescriber, or prepared by or under the supervision of a Pharmacist; to meet the 'special' needs of individual patients.
- Unlicensed medicine: medicines that do not have a marketing authorisation issued by the MHRA
- WDA: Wholesale Dealer Authorisation

4. Roles and responsibilities

All clinical staff involved in the prescribing, administration and procuring of unlicensed and off-label medicines must adhere to this policy.

4.1 **Prescribers**:

When prescribing an unlicensed medicine (or a licensed medicine outside its marketing authorisation), the prescriber must:

- be legally able to prescribe an unlicensed medicine- refer to MHRA advice regarding non-medical prescribers
- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy and be able to show that they are acting in accordance with a respected body of clinical opinion
- have considered and discontinued all possible licensed or 'off label' options (if applicable) and documented reasons why they are not suitable for the individual patient
- be able to justify their reasons for prescribing an unlicensed / off-label medicine and make a clear, accurate and legible record of these in the patient's clinical record.
- give patients or carers sufficient information about the unlicensed medicine and answer their questions fully and honestly, to allow them to make an informed decision to provide consent. Further guidance may be found in the All Wales Medicines Strategy Group document entitled Understanding Unlicensed Medicines
- ensure the patient or carer provides their consent to use an unlicensed medicine and document this in the patients' clinical record.
- complete **part A** of Appendix A 'request to use an unlicensed medicine'. One copy should be submitted by email to medicines management for review Info.MedicinesManagement.Powys@wales.nhs.uk and a copy of the relevant form should be placed in the patients' clinical record. The prescriber must await authorisation before prescribing the medicine.

A request form will not be required where the current editions of the BNF, BNF for children, AWMSG, NICE guidance, NEWT Guidelines (to be used by registered pharmacy professionals with caution), SPS advice on safety in breastfeeding, BUMPS (best use of medicines in pregnancy), or Immunisation against Infectious Diseases (Green book) suggests a use (indication, route, dose or age group) that is outside of the licensed indication of a product. This will be accepted as peer group approved.

- be aware that they will be solely liable for any harm to a patient caused by an unlicensed medicine, or a medicine being used in an unlicensed way (liability may be shared/transferred where due diligence in terms of suitable procurement has not been applied or the product itself has a defect)
- take responsibility for prescribing the medicine and for overseeing the patient's care:
  - consider prescribing the medicine at a low dose initially (unless there is a reasonable body of evidence to support the prescribed dose)- if well tolerated but ineffective, consider cautiously increasing the dose whilst carefully monitoring its effects
  - monitor and record the effects of the medicine carefully: regularly review for beneficial effect to ensure use remains justified. If no benefit, or if there are emerging risks and hazards which outweigh the benefits, withdraw the medicine (gradually if necessary) and document the reasons for withdrawal in the patient's clinical record.
  - take care if using an electronic prescribing system - Unlicensed medicines are often absent from electronic prescribing systems. This can lead to added risks in terms of prescribing accuracy and selection of the correct formulation. This also means that clinical decision support software may not be available.
  - ensure ongoing monitoring and review- the optimal treatment for the patient may change over time as circumstances change, for example the patient's needs, the care setting and the availability of alternative or newly licensed medicines
  - involve the patient (or carer) in all decisions made
  - arrange any follow up treatment (if treatment is to be continued in the community, this may involve discussion with the patients GP around how further prescriptions are going to be issued, or may include a shared care agreement)

Prescribers may find further guidance in the All Wales Medicines Strategy Group document entitled Understanding Unlicensed Medicines, and may wish to refer to professional guidance provided by the GMC or the MHRA guidance.

4.2 **Nursing Staff are responsible for:**

- appropriate storage of the medicine

- administration of the medicine in accordance with the prescription and professional standards
- adhering to the PTHB Medicines Policy MMP 001 (PTHB staff)
- requesting further information from the prescriber or pharmacy professional if they are unsure about any of the following:
    - Suitability for use
    - unclear label or prescription
    - any aspects of the use
    - administration instructions
    - possible side effects or any requirements for monitoring

4.3 Medicines management/Pharmacy:

- staff must be aware of and familiar with this policy
- admin staff will maintain a log of all unlicensed/ off- label requests in the agreed Sharepoint location and document any 'approval' or 'rejected' decisions made by the APG
- upon receipt of Appendix A-part A: **Request to use an Unlicensed medicine-** patient requests marked as urgent will be referred as an Individual Patient Funding Request (IPFR) – as detailed in the national IPFR process {link included}
- ward pharmacy staff will ensure the prescriber, nurse and patient (if appropriate) is aware of the unlicensed status of the product before it is ordered. If appropriate, the pharmacy professional may provide advice on other potential treatment options.
- a pharmacist will verify relevant clinical information from request forms, risk assess the request (completing **parts B** and **D** of the form), then forward the application to the Formulary Working Group (FWG) as appropriate. When completing the risk assessment, if the pharmacist finds that the current edition of the BNF, BNF for children, AWMSG, NICE guidance, NEWT Guidelines *(to be used by registered pharmacy professionals with caution)*, *SPS advice on safety in breastfeeding*, *BUMPS (best use of medicines in pregnancy)*, or Immunisation against Infectious Diseases (the Green book) suggest the use of the medication (indication, route, dose or age group) outside of the licensed indication of a product, they may authorise the off-label request without submission to the FWG, providing the prescribing information in the text is followed. The pharmacist may also authorise an off-label application in the following circumstances:
    - if a tablet is to be crushed/dispersed or a capsule is to be opened in accordance with relevant medicines

information advice, for example NEWT guidelines *(to be used by registered pharmacy professionals with caution)* or Handbook of drug administration via enteral feeding tubes.
    - using a liquid where the equivalent medicine is licensed in other dosage forms e.g. tablet, capsule etc.
    - recognised alternative route e.g. use of parenterals s/c in the palliative care setting
- will complete **part C** of the request form if the medication is to be ordered directly, instead of being obtained from a DGH under a SLA
- will advise prescribers on alternative options where appropriate and inform prescribers of licensed alternatives as they become available
- ward pharmacists will only authorise supply of the unlicensed medicine (or licensed medicine outside its marketing authorisation) if it has been prescribed and approved in accordance with this policy
- will endorse inpatient medication records with 'off-label' or 'unlicensed' as appropriate to ensure all are aware of the status of the medicine
- will provide appropriate information to allow safe administration of the medicine
- On discharge establish how ongoing supplies will be maintained e.g remain in hospital services or agreement is in place to transfer to Primary Care
- On discharge, ensure the patient has a sufficient quantity of medicines to allow time for re-supply
- Where agreed will ensure relevant information is communicated to the patient's GP and community pharmacy or GP dispensary on discharge, including the indication, the special clinical need of the patient, expected length of treatment, timescales for review, ongoing monitoring requirements, formulation, source of the initial supply and contact details of the original prescriber
- where applicable, will ensure the patient/ carer understands the process for obtaining a repeat prescription for their unlicensed medicine (this may differ from their other medicines)
- will inform the prescriber of any serious problems with the unlicensed medicines as they occur
- will report any defects in the product to the dispensing pharmacy or GP practice dispensary
- will be able to verify previously authorised 'unlicensed' and 'licensed medicines outside its marketing authorisation', by accessing the log of requests on the agreed Sharepoint

folder and referring to the PTHB formulary (where cohort decisions will be documented)
- will routinely monitor the prescribing of unlicensed medicines and 'specials', through prescribing data and audit and ensure ongoing appropriateness with the relevant prescribers.

4.4 Formulary Working Group

- Consider and appraise unlicensed medicines applications
- Will consider if there is a suitable licensed product available or other appropriate option
- Will review the supporting information to ensure that use is justified (based on the clinical information provided by the requesting clinician and pharmacist review)
- Will consider the likelihood of supply chain difficulties, the possibility of interruption to patient treatment and any consequences
- Make a recommendation to the Area Prescribing Group

4.5 The Area Prescribing Group

- Are responsible for approving and monitoring all unlicensed medicines and the off-label use of medicines
- Will review the supporting information to ensure that use is justified (based on the information assessed by the Formulary Working Group)
- Will ensure that both the Chief Pharmacist and the Medical Director sign the 'request to use an unlicensed medicine application form' on behalf of the Area Prescribing Group for all medicines which are granted approval
- Will ensure completion of **part E** of the request form and inform the requestor of the decision made and reasons (template letter is available in Appendix B)
- Appeals process: If the proposer wishes to request an appeal of the decision, this must be submitted before the next APG meeting, along with any additional supplementary information

4.5 The dispensing hospital pharmacy

- will respond to any initial product enquiries
- will require access to signed approvals by the Area Prescribing Group to acknowledge PTHB acceptance of the use of the unlicensed product and risks
- where Aneurin Bevan University Health Board are to supply the medicine, they may have already completed a Quality Assurance Risk Assessment for the unlicensed product. This may be used (instead of completing **part C** of the Powys

application request form) to help inform the risk assessment outcome (section D of the PTHB Unlicensed Medicine application form)
- will source unlicensed medicines that are on an All Wales Procurement Contract, where possible
- will purchase standardised formulations wherever practicable. These may include, but are not limited to:
  - Neonatal and Paediatric Pharmacy Group (NPPG) Using Standardised Strengths of Liquid Medicines in Children
  - Dermatology Special Medicines
  - Chemotherapy dose banding
- will ensure that a certificate of analysis or conformance is requested for each medicine unlicensed in the country of origin
- will ensure that unlicensed medicines are procured from reputable suppliers, with the correct MHRA license and that the product meets suitable packaging and labelling requirements
- will ensure that all specials are quarantined on receipt until they can be checked by a suitably competent person for compliance with the purchasing specification, according to local procedures
- will ensure that the medication is dispensed in accordance with procedures for labelling and dispensing of medicines
- will record batch numbers/ patient names where required
- will ensure that an English translation (or equivalent) patient information leaflet is issued with all unlicensed medicines where available

5. Process

This policy clearly sets out the actions to follow when requesting the use of an unlicensed medicine, or a licensed medicine outside its marketing authorisation.

5.1	**Request to use an unlicensed medicine in a PTHB community hospital** • The clinician/prescriber must complete Part A of the 'request to use an unlicensed medicine' form in Appendix A. *A request form will not be required where the current editions of the BNF, BNF for children, AWMSG , NICE guidance, NEWT Guidelines (to be used by registered pharmacy professionals with caution), SPS advice on safety in breastfeeding, BUMPS (best use of medicines in pregnancy), or Immunisation against Infectious Diseases (Green book) and other suitable reference sources suggest a*

	use (indication, route, dose or age group) that is outside of the licensed indication of a product. This will be accepted as peer group approved. • This form should be submitted to medicines management for review: Info.MedicinesManagement.Powys@wales.nhs.uk. • When received, a member of the MM admin team will add the request to the log of requests on agreed sharepoint location (for handling of urgent patient requests, see 5.2) • The request will be risk assessed by a medicines management pharmacist. If applicable, the pharmacist will enquire if ABUHB pharmacy has already completed a Quality Assurance Risk assessment for the product, if so, this may be used to help inform the risk assessment outcome (instead of completing part C of the Powys Application request form) • The request and completed risk assessment may be checked by a second pharmacist, then will be referred to the Formulary Working Group for consideration, before making a recommendation regarding approval to the Area Prescribing Group. • Any authorisation granted by the Area Prescribing Group will acknowledge the use of the unlicensed product and risks by the group, the Chief Pharmacist and the Medical Director • Medicines management admin staff will upload completed and signed approval forms to the unlicensed medicines approval folder in sharepoint and ensure the review date is recorded. • The medicine will be added to the 'spreadsheet of unlicensed medicines to be kept as ward stock' (if appropriate) and a medicines management technician will ensure the medicine is added to the appropriate ward stock lists. • Any approved use of an unlicensed medicine will clearly be reflected in the PTHB InForm formulary • For patient-specific requests, the ward based Pharmacy technician or pharmacist will be informed of the decision • The signed approval form will be forwarded to ABUHB when a request is made to add an unlicensed medicine to a stocklist, or when a patient- specific unlicensed medicine is first ordered • Risk assessments and APG decisions or further actions will be fed back to the requesting prescriber within 5 days of the APG meeting. The template letter in Appendix B may be used. Following an unsuccessful decision, a further application may be made if extra evidence is submitted.

5.2	**Urgent requests** • Any urgent requests will be forwarded to the Individual Patient Funding Request (IPFR) panel for review. See IPFR application form. • Consideration by the APG could be a retrospective process in the case of urgent clinical need
5.3	**Patient consent** • Patients or carers must be given sufficient information about the unlicensed or off-label medicine to allow them to make an informed decision about whether or not to receive that medicine. The prescriber may wish to discuss alternative treatment options, potential risks, adverse reactions and benefits. They should give as much information as patients or carers require and answer questions fully and honestly. Further guidance may be found in the All Wales Medicines Strategy Group document entitled Understanding Unlicensed Medicines. • The discussion should be documented in the patients' clinical record, along with a record of who provided the consent, if provided. • An appropriate AWMSG patient information leaflet entitled 'Use of unlicensed medicines – information for patients and carers', to explain the unlicensed use of medicines (appendix C) should be supplied.

5.4	**Records**
	• The medicines management team will maintain a record of all unlicensed/ off- label requests in agreed Sharepoint location and document 'approval' or 'rejected' decisions made by the APG.
	• Any unlicensed/off-label medicines approved for cohort use should clearly be detailed and documented in the PTHB formulary
	• PTHB expects that the following records will be maintained (for at least 5 years) for the sale or supply of a "special" or unlicensed medicine by the supplier
	  ○ the source from which and the date on which the person obtained the product
	  ○ the person to whom and the date on which the sale or supply was made
	  ○ the quantity of the sale or supply
	  ○ the batch number of the batch of that product from which the sale or supply was made
	  ○ details of any suspected adverse reaction to the product so sold or supplied of which the person is aware or subsequently becomes aware (serious

	suspected Adverse Drug Reactions should be reported to the MHRA using a yellow card, stating the manufacturer and indicating that the product is unlicensed). ○ Certificates of Analysis (COA) and Certificates of Conformity (COC)(if applicable) • The prescriber will document consent in the patients' medical notes, along with a record of who provided the consent.
5.5	**Storage** • Any specified storage requirements must be complied with
5.6	**Follow up** • The prescriber will be responsible for monitoring the effects of the medicine • Adverse drug reactions involving unlicensed and 'off-label' medicines should be reported in the same manner as for licensed medicines, via the yellow card website at https://yellowcard.mhra.gov.uk/ • Medication incidents involving unlicensed and 'off-label' medicines should be reported in the same manner as for licensed medicines, via the once for Wales reporting system • The prescriber must ensure that where treatment is to be continued in the community, there is discussion and agreement with the patient's GP and community pharmacy to inform them about the use of an unlicensed medicine or a licensed medicine outside of its marketing authorisation around how further prescriptions are going to be issued. • If prescribing responsibility is to be shared with primary care, ensure that the risk assessment and consent issues are shared with the GP in writing. • The full agreement of the GP should be sought before transfer of clinical responsibility, as they may refuse to prescribe within primary care if they have not been given sufficient information to prescribe safely, or if this is outside their level of expertise. • It is good practice to provide the GP with a signed copy of the approved 'Request to use an Unlicensed medicine form. • The prescriber must ensure there is a system in place for the need for the unlicensed medicine to be regularly reviewed.
6. Resources Time requirements for the listed activities	
7. Training Staff will need to be made aware of this policy.	

8. Implementation

Clinical policies which should be read in conjunction with this include:
MMP 001 Medicines Policy
MMP 006 Non Medical Prescribing Policy for Nurses, Midwives, Pharmacists and Allied Health Professionals
National IPFR Policy - https://awttc.nhs.wales/accessing-medicines/access-to-medicines-in-wales/

9. Monitoring compliance, audit and review

This document will be reviewed every three years or earlier should audit results or changes to legislation / practice within PTHB indicate otherwise.

10. References

- All Wales Medicines Strategy Group: Understanding Unlicensed Medicines. May 2023. https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/prescribing-guidance/understanding-unlicensed-medicines
- GMC guidance on prescribing unlicensed medicines. Published 5/4/21. https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines
- The supply of unlicensed medicinal products ("specials") MHRA Guidance Note 14 The_supply_of_unlicensed_medicinal_products__specials_.pdf (publishing.service.gov.uk)
- Packaging and labelling for safety: Unlicensed imported medicines- Guidance for the overlabelling and provision of translated information. Edition 2. December 2018. Endorsed and supported by the SPS. https://www.sps.nhs.uk/wp-content/uploads/2019/01/Unlicensed-imported-medicines-Guidance-for-the-ovelabelling-and-provision-of-translated-information-Dec-2018.pdf
- Quality Assessment of Unlicensed medicines. Specialist Pharmacy Service. 16/11/16 https://www.sps.nhs.uk/articles/quality-assessment-of-unlicensed-medicines/
- Using unlicensed medicines 28/07/2023 https://www.sps.nhs.uk/articles/using-unlicensed-medicines/
- Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK (www.gov.uk).11/12/14
- RPS Prescribing Specials. April 2016. professional-standards---prescribing-specials.pdf (rpharms.com)
- SPS Purchasing Specials. 30 November 2023. https://www.sps.nhs.uk/articles/purchasing-specials/
- SPS Making unlicensed medicines. 30 November 2023. https://sps.nhs.uk/articles/making-unlicensed-medicines/
- SPS Governance principles for unlicensed medicines. 30 November 2023. https://sps.nhs.uk/articles/governance-principles-for-unlicensed-medicines/

Appendix A-part A: **Request to use an Unlicensed medicine**

Application reference number**:**

- Part A of the form should be completed electronically by the clinician/prescriber, then submitted to medicines management for review: Info.MedicinesManagement.Powys@wales.nhs.uk. Following review, if necessary, the application will be considered by the Formulary Working Group and the Area Prescribing Group. If use of the product is deemed to have significant risks, the request will be referred to the Medical Director.
- See PTHB Unlicensed and Off-label Medicines Policy and GMC guidance on prescribing unlicensed medicines. If a product is unlicensed or used outside its licensed indications, the manufacturer carries no legal liability should an untoward event arise (they are only likely to be found liable if harm results from a defect in the product). The ultimate responsibility for prescribing any medicine lies with the prescriber who signs the prescription and is professionally accountable for their judgement. A pharmacist may decline to dispense unless appropriate authorisation has been provided.
- **Informed consent** must be obtained from the patient/relative/carer to receive an unlicensed medicine and documented in their medical notes. It is considered good practice to place a copy of this form in the patients' medical notes.

Product Details	
Product type: drug/ dressing/ supplement/ device or other (please specify): Approved name: Proprietary (brand) name and manufacturer, if known: Drug form, strength, route of administration, dose and frequency:	
Licensed drug for unlicensed use ("off-label") ☐	Unlicensed drug ☐
Intended therapeutic use (please specify how use is "off label" e.g unlicensed dose, route, indication):	
List the serious and common side effects of this medicine:	
Is the application for a **specific patient** or a **cohort group**? (please circle, then complete relevant section below)	
Patient Details	**Cohort Group**
Ward/ unit: Site:	How many patients are anticipated to require this medication annually?
If to be continued on discharge, who will provide further prescriptions? GP / Hospital	

Please tick if urgent ☐ (IPFR process to be followed)	
Expected duration of treatment:	
Where will the medication be stored?	

REASONS/ CLINICAL EVIDENCE FOR UNLICENSED MEDICINE REQUEST

Equivalent UK licensed product *(please delete as appropriate*) **unavailable** /**unsuitable** *(if unsuitable, record alternative & state why unsuitable*):

Evidence to support the use for the proposed indication: YES/NO

Evidence from NICE or 'expert body' or other references:

PLACE IN THERAPY/ALTERNATIVE TREATMENT OPTIONS

How is this currently treated (please specify previous, and current treatment for this condition and why a licensed drug/licensed use of a drug is not suitable)?

What are the proposed benefits of the unlicensed medicine, in preference to licensed alternatives, and what is its place in therapy (1st,2nd,3rd line)?

Are other centres using the medicine for this indication (if so, please give details):

Service Implications e.g. specialist assessment, monitoring requirements

PROCUREMENT DETAILS (to be completed by pharmacy)

1. To be obtained from: _____
2. Expected problems associated with continuity of supply: _____
3. Cost of the product: _____
4. Any indirect cost associated if known: _____

REQUESTING PRESCRIBER/SUPPORTING PHARMACIST details

Date:	Prescriber name: Signature: Contact details:	Pharmacist name: Signature:

Appendix A-part B: **Off label or Unlicensed use Risk Assessment tool for the authorisation of use of an unlicensed medicinal product**: (for each line, please circle low/intermediate/high, then include detail of areas of high concern in summary)

Risk level	Low	Intermediate	High risk:
Evidence	• Established product & evidence of therapeutic benefit • Robust clinical trials • Published recognised Guidelines • National reference source	• Limited evidence for therapeutic benefit • Non-randomised studies, or clinical trials with low patient numbers or non-relevant comparator	• Evidence for therapeutic benefit is questionable or none exists • Only evidence for use: phase 1 clinical trials • Clinical reports published • Expert opinion
Route	• Oral • Topical • Rectal • sublingual • Nasal • Buccal	• Subcutaneous • Intramuscular • Instillation into the cavity or bone • Conjunctival • Novel or infrequent route	• Intrathecal • Epidural • Intravenous • Nebulised • Intra-ocular If these routes are novel or infrequently used
Dose	No requirement for significant dose titration / monitoring	Requirement for significant dose titration / monitoring	Requirement for significant dose titration / monitoring Exceeds maximum usual dose
Source	Product licenced in a country of origin with EU mutual recognition status or licence withdrawn for commercial status	Product licenced in a country **NOT** within the EU or included in mutual recognition status	Product supplier (manufacturing license holder) with unknown history No product license or product license withdrawn for safety reasons. Product license for veterinary use. Product made by/under supervision of a pharmacist
Product characteristics	Product quality assessment documents available and approved		Product quality not assessed and/or no documentation available TSE status unknown
Procurement details	Produced by manufacturing licence holder COC/COA available English labelling & PIL		COC/COA unavailable Labelling and PIL not in English

Application reference number:

Product information	
Confirmation of justification for off label or unlicensed use & reference documents (are there any suitable licensed alternatives to consider?)	

Assessment of potential harm/risk to the patient:

- Unlicensed risk (please tick as appropriate):
  - Licensed preparations used outside the licensed indication
  - Unlicensed in the UK, but licensed in the country of the origin

- **MHRA/ CHM advice found:**

- **Monitoring:**

- **Cautions:**
  - BNF cautions
- **Use in pregnancy:**
  - BNF
- **Use in breastfeeding:**
  - BNF
- **Significant interactions:**
  - Product SPC
- **Contra-indications**:
  - BNF contraindications
  - Product SPC
- **Side effects:** BNF states:
  - Common or very common:
  - Uncommon:
  - Rare or very rare:
  - Unknown frequency:

Risk categorization of **Side effects** (Green indicates low risk, yellow indicates moderate risk, red indicates high risk). Any side effects of unknown frequency that have the potential to cause harm should be listed in the summary (part D of form)

Clinical risk		**Categorisation of risk**					
Harm to patient	Harm due to permanent or long-lasting side effects	**5**					
	Some harm Side effects are significant Significant contra-indications for use	**4**					
	No permanent harm. Some contra-indications for use.	**3**					
	No permanent harm. Side effects are transient and/or readily manageable. Some contra-indications for use.	**2**					
	None. No obvious harm likely to be caused. No obvious contra-indications for use.	**1**					
	LIKELIHOOD OF OCCURENCE		**1**	**2**	**3**	**4**	**5**
			Very rare <1/10 0000	Rare >1/10 000 <1/100 0	Uncom mon >1/100 0 & <1/100	Commo n >1/100 & ≤1/10	Very common ≥1/10

Appendix A-part C**: Quality assurance risk assessment for medicines unlicensed in the UK:** *Before completion of this table, check if the* ***supplying pharmacy*** *already has a quality assurance risk assessment available for the product, that could be used*

Application reference number:

Name and address of manufacturer	Name and address of supplier/ importer (if different)	
Country that issued product licence: For imports, state importer's relevant MHRA licence type and number (check current list on MHRA website): For specials, Manufacturer's MHRA licence number (check current list on MHRA website):		
UK manufacturer with no Specials licence		
For imports, country of licensing is within the EU or included on the EMA Mutual Recognition Agreement (MRA) list		
Imported from the EU or included on the EMA Mutual Recognition Agreement (MRA) list and not licensed in country of origin		
Country of licensing is **NOT** within the EU or included on the EMA Mutual Recognition Agreement (MRA) list		
Elsewhere – not licensed in country of origin		
Certification		
Full analytical report	Batch specific Certificate of Analysis /Certificate of Conformance	No certificate available
Specification		
BP/EP/USP monograph product	Other pharmacopeia product	Manufacturer specification
Route of administration		
Topical to intact skin/non-sterile	Oral	Sterile intrathecal
Topical to mucous/membrane or broken skin	Sterile all routes except intrathecal	
Transmissable Spongiform Encephalopathies compliance		
Fully licensed product in EEA / country with full MRA: TSE compliance automatically assured		
All other products: statement of TSE compliance provided		
Supplier unable to provide TSE compliance information		
GMP Compliance		
Fully licensed product in USA / EEA / country with full MRA: GMP compliance automatically assured		
All other products: evidence of GMP compliance provided		
Supplier unable to provide GMP compliance information		

<table>
<tr><td colspan="4">Therapeutic agent</td></tr>
<tr><td>Established therapeutic agent</td><td>Recognised agent – but no significance evidence of use</td><td>Novel agent or unusual use with some supporting information for use</td><td>Unrecognised agent with some supporting evidence for use</td></tr>
<tr><td colspan="4">Unrecognised agent with no information available</td></tr>
<tr><td colspan="4">Recognised therapeutic agent with known problems</td></tr>
<tr><td colspan="4">Products containing material of animal or human origin</td></tr>
<tr><td colspan="3">Pack size:</td><td></td></tr>
<tr><td colspan="3">Is the packaging satisfactory?</td><td>Yes / No</td></tr>
<tr><td colspan="3">Language on packaging:</td><td></td></tr>
<tr><td colspan="3">Have non-English language packs been over-labelled in English language?</td><td>Yes / No</td></tr>
<tr><td colspan="3">Does the labelling format conform to UK standards?</td><td>Yes</td></tr>
<tr><td colspan="4">NO
additional English language labelling will be required to ensure it includes:
1. The generic name of the active ingredient(s)
2. The pharmaceutical form and route of administration
3. The product strength
4. The contents of each container (by number of dosage forms, weight or volume)
5. Instructions for use
6. Any applicable additional warnings e.g. ‘Shake the bottle’, ‘Store in a refrigerator’)
7. Excipients of known effect
See excipients of known effect guidance here
8. ‘Keep out of reach and sight of children’
9. The expiry date expressed in unambiguous terms (mm/yy)
10. Storage conditions, ideally expressed as temperature range in degrees Celsius and special storage precautions
11. “This medicine is unlicensed in the UK”</td></tr>
<tr><td colspan="3">Is PIL available and appropriate for intended use?</td><td>Yes / No</td></tr>
<tr><td colspan="3">Storage conditions (please specify)</td><td></td></tr>
</table>

For further information/ clarification, please refer to ‘Quality Assessment of Unlicensed Medicines’

Please summarise any risks identified above in the Quality Assurance section of part D

Appendix A-part D**:**

Risk assessment outcome for completion by medicines management

Application reference number:

State if there are any licensed alternatives to consider

State if there is evidence/documents to support the application

Unlicensed/off label use risk:

Potential harm/ side effect risk:

Quality assurance risk assessment:

Any actions recommended to mitigate risks:

	Pharmacist Name	Signature	Date
Risk assessment completed by			
Information accuracy check			
Authorisation to be used if APG approval not required			
Referred to formulary working group, for their recommendation to the area prescribing group			

Appendix A-part E: **Area Prescribing Group conclusion:**

APPROVAL FOR USE	**Signature / date**
Authorisation to be used following medicines management risk assessment (for full details see sections B,C and D)	
For consideration by Area Prescribing Group on……	
Any restrictions for use	
Reason, if not approved	
Date of review (max 3 years)	
Approval by Chief Pharmacist	
Approved by Medical Director	

Appendix B: Letter to feed back APG decision to requesting prescriber

Dear Sir/ Madam,

Re: Unlicensed medicine application reference number:

Medication

Include details of the risk assessment outcome, including evidence and rationale for use, cautions, contra-indications, potential side effects, monitoring, etc.

Recommendation:

Include any actions recommended to mitigate risks.

Yours sincerely,

Area Prescribing Group

Appendix C:

Appendix 1a. Use of unlicensed medicines – information for patients and carers

Why have I been given this leaflet?

This leaflet will provide you with information about unlicensed medicines, which include "specials", and medicines that are being used differently to their licence (off-label). It should help to answer any questions you may have. Please read it carefully and talk to your prescriber or pharmacist if you have any more questions.

Medicine name: _____

What are licensed, unlicensed, 'specials' and medicines used off-label?

Medicines sold in the UK must have marketing authorisation or be "licensed". This is granted by the medicines regulator after they have checked the quality and safety of the medicine, and how well it works. The licence describes how the medicine should be used including:

- who can take it;
- what illness(es) it can be used to treat;
- how much should be taken (the dose);
- what form it is in (e.g., tablet, capsule, liquid).

An unlicensed medicine doesn't have a UK licence. It may be licensed abroad and imported to the UK, or be made specially (in which case, it is called a 'special').

If a medicine with a UK licence is being used differently to what its licence describes, this is called "off-label" use, for example:

- treating a different illness;
- treating a different group of patients (e.g., children or during pregnancy);
- using a different dose.

This leaflet uses the term "unlicensed" to describe all unlicensed medicines, including 'specials' and medicines used off-label.

Why are unlicensed medicines used?

Usually you will only be prescribed an unlicensed medicine when there is no suitable licensed medicine to treat your condition. The decision to use an unlicensed medicine is a joint one between you and your prescriber. The person treating you will have considered the best choice of medicine, discussed options with you, and will review it regularly to ensure it remains the best option for you.

Reasons for using an unlicensed medicine include:

- a licensed medicine may not be available yet;
- the medicine may be in the process of getting a licence or may still be undergoing testing in a clinical trial;
- there may be limited information available about treating certain conditions or for certain patient groups;
- the medicine may need to be taken in a form that is not normally available (e.g., liquid), and must be made specially to order;
- there may be a temporary shortage of the licensed medicine;
- the medicine may have a licence but needs to be given in an unlicensed way. For example, crushing tablets to make them easier to swallow.

Are unlicensed medicines commonly used?

Unlicensed medicines have often been widely used and their effects are well known. However, if the medicine comes with a leaflet, it may not say anything about the unlicensed use. This does not mean that it cannot be used safely to treat your condition – it means that the drug company does not have a licence for using it this way and is not allowed to promote or give information about this use.

If you are worried about taking the medicine, talk to your prescriber or pharmacist about your concerns.

If you experience any unpleasant or unexpected effects whilst taking the medicine, you should report this to your prescriber or pharmacist. You can also report any suspected side effects to the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/

Can children be prescribed unlicensed medicines?

Yes. Medicines need to be tested in clinical trials to be granted a licence. It is not always possible to do clinical trials in children, particularly if the medicine is for a rare illness. Therefore, the prescriber may choose an unlicensed medicine to treat your child.

An unlicensed medicine may have advantages over a licensed one, for example:

- it might be in a form your child can take more easily;
- the prescriber may think it will work better for your child's illness;
- the unlicensed medicine may be safer than a licensed one (for example, it could be alcohol free).

As with use of unlicensed medicines in adults, you will have agreed the best option for your child with the prescriber, and the prescription will be reviewed regularly to ensure it remains the best option.

Can I get an unlicensed medicine from a private prescriber?

You may obtain an unlicensed medicine from a private prescriber (for example an optometrist). However, you will need to pay for the medicine. Please speak to the prescriber and your community pharmacist about how much this is likely to cost. You will need to tell your GP surgery, so they can add a note to your medical records.

How can I get more of my unlicensed medicine?

If your medicine is first prescribed at your GP practice and you need more, it is likely that the practice will provide a further prescription. If your medicine is first prescribed in hospital, this may not be the case and you may need to get further supplies from the hospital. If your medicine has been prescribed by a non-medical prescriber, such as a pharmacist or an optometrist, please contact them first. In all cases, please confirm with the prescriber how you will access further supplies.

After speaking with your prescriber and pharmacist, make a note of when you need to order more of your medicine. You should check the expiry date of your medicine as this can affect how frequently you need to order it. Unlicensed medicines often have short expiry dates. This means it may not be possible to order large quantities to keep in the pharmacy or in your home. If you already take other medicines and have a repeat prescription, you may need to order the unlicensed medicine at a different time.

It may take longer for the pharmacy to get an unlicensed medicine when you need it. Depending on the medicine this could be up to two or more weeks. **You should tell the pharmacy in plenty of time before you run out**.

What if I lose, destroy, or run out of my unlicensed medicine?

If you don't have any of your medicine speak to your pharmacist. They can provide advice about what to do, and whether you can access an emergency supply of the medicine. **Do not take any medicine that may have been compromised (e.g., spilled or damaged).**

What should I do if the pharmacy tells me the supply of my unlicensed medicine is going to be delayed?

If you have enough of the medicine to last until the pharmacy can arrange more supplies, you will not need to do anything. However, if you think that the delay may cause you to run out of your medicine, inform your prescriber as they may need to monitor you until further supplies can be provided. **Please do not take less medicine than advised unless you discuss this with your prescriber first.**

Should I use the medicine past its expiry date if I can't get more supplies in time?

In general, you should not use any medicine past its expiry date. To find out what would be the safest thing for you to do, speak to your pharmacist or prescriber.

My prescriber has decided not to continue the prescription for the unlicensed medicine issued by the hospital, what should I do?

If you have been prescribed an unlicensed medicine through the hospital and a prescriber in your GP surgery does not feel they can take responsibility for writing a prescription for further supplies, please discuss the reasons with them. Another prescriber in the surgery may be willing to take responsibility. If there is no one who can take responsibility, contact the hospital where your medicine was first prescribed and they may be able to arrange further supplies for you.

What if I do not want to receive an unlicensed medicine?

You will only be prescribed an unlicensed medicine if you and your prescriber have agreed it's the best treatment for you. However, if you are not happy, you can discuss your options with your prescribing team or pharmacist.

With some unlicensed medicines you are required to give consent in writing before you start taking them. You can change your mind about this at any time.

How can I find out more?

If you are concerned or have any questions about unlicensed medicines, please speak to your pharmacist or prescriber.

The NHS website also has some information about licensed and unlicensed medicines. Available at: *https://www.nhs.uk/conditions/medicines-information/*

Information leaflets about using unlicensed medicines in children, specifically aimed at parents can be found on the Medicines for Children website: https://www.medicinesforchildren.org.uk/

You can contact the Welsh Medicines Advice Service. Available at: https://www.wmic.wales.nhs.uk/

Access this leaflet on your phone:

Atodiad 1b. Defnyddio meddyginiaethau didrwydded – gwybodaeth i gleifion a gofalwyr

Pam y rhoddwyd y daflen hon i mi?

Bydd y daflen hon yn rhoi gwybodaeth i chi am feddyginiaethau didrwydded, sy'n cynnwys meddyginiaethau "arbennig", a meddyginiaethau sy'n cael eu defnyddio'n wahanol i'w trwydded (oddi ar y label). Dylai helpu i ateb unrhyw gwestiynau sydd gennych. Darllenwch hi'n ofalus a siaradwch â'ch presgripsiynydd neu fferyllydd os oes gennych ragor o gwestiynau.

Enw'r feddyginiaeth: _____

Beth yw meddyginiaethau trwyddedig, didrwydded, meddyginiaethau 'arbennig' a meddyginiaethau a ddefnyddir oddi ar y label?

Rhaid i feddyginiaethau a werthir yn y DU gael awdurdodiad marchnata neu fod yn "drwyddedig". Rhoddir yr awdurdodiad hwn gan y rheoleiddiwr meddyginiaethau ar ôl gwirio ansawdd a diogelwch y feddyginiaeth, a pha mor dda y mae'n gweithio. Mae'r drwydded yn disgrifio sut y dylid defnyddio'r feddyginiaeth gan gynnwys:

- pwy all ei chymryd;
- pa salwch y gellir ei defnyddio i'w drin;
- faint ddylid ei gymryd (y dos);
- ar ba ffurf y mae (e.e. tabled, capsiwl, hylif).

Nid oes gan feddyginiaeth ddidrwydded drwydded y DU. Efallai ei bod wedi'i thrwyddedu dramor a'i mewnforio i'r DU, neu wedi cael ei gwneud yn arbennig (ac os felly, fe'i gelwir yn feddyginiaeth 'arbennig').

Os yw meddyginiaeth sydd â thrwydded y DU yn cael ei defnyddio'n wahanol i'r hyn a ddisgrifir yn ei thrwydded, gelwir hyn yn ddefnydd "oddi ar y label". Er enghraifft:

- trin salwch gwahanol;
- trin grŵp gwahanol o gleifion (e.e. plant neu yn ystod beichiogrwydd);
- defnyddio dos gwahanol.

Mae'r daflen hon yn defnyddio'r term "didrwydded" i ddisgrifio pob meddyginiaeth ddidrwydded, gan gynnwys meddyginiaethau 'arbennig' a meddyginiaethau a ddefnyddir oddi ar y label.

Pam y defnyddir meddyginiaethau didrwydded?

Fel arfer dim ond pan nad oes meddyginiaeth drwyddedig addas i drin eich cyflwr y cewch bresgripsiwn am feddyginiaeth ddidrwydded. Mae'r

penderfyniad i ddefnyddio meddyginiaeth ddidrwydded yn benderfyniad ar wneir y cyd rhyngoch chi a'ch presgripsiynydd. Bydd y person sy'n eich trin wedi ystyried y dewis gorau o ran meddyginiaeth, wedi trafod opsiynau gyda chi, a bydd yn adolygu hyn yn rheolaidd i sicrhau mai dyma'r opsiwn gorau i chi o hyd.

Mae'r rhesymau dros ddefnyddio meddyginiaeth ddidrwydded yn cynnwys:

- efallai nad yw meddyginiaeth drwyddedig ar gael eto;
- efallai bod y feddyginiaeth yn y broses o gael trwydded neu efallai ei bod yn dal i gael ei phrofi mewn treial clinigol;
- efallai mai prin yw'r wybodaeth sydd ar gael ynglŷn â thrin rhai cyflyrau penodol neu ynglŷn â rhai grwpiau cleifion;
- efallai y bydd angen cymryd y feddyginiaeth ar ffurf nad yw ar gael fel arfer (e.e. hylif), a rhaid ei gwneud yn arbennig yn ôl archeb;
- efallai bod prinder dros dro o'r feddyginiaeth drwyddedig;
- efallai bod gan y feddyginiaeth drwydded ond mae angen ei rhoi mewn ffordd ddidrwydded. Er enghraifft, malu tabledi i'w gwneud yn haws i'w llyncu.

A ddefnyddir meddyginiaethau didrwydded yn gyffredin?

Mae meddyginiaethau didrwydded wedi cael eu defnyddio'n eang yn aml ac mae eu heffeithiau yn hysbys iawn. Fodd bynnag, os bydd taflen gyda'r feddyginiaeth, efallai na fydd yn dweud unrhyw beth am y defnydd didrwydded. Nid yw hyn yn golygu na ellir ei defnyddio'n ddiogel i drin eich cyflwr - mae'n golygu nad oes gan y cwmni cyffuriau drwydded i'w defnyddio fel hyn ac ni chaniateir iddo hyrwyddo na rhoi gwybodaeth am y defnydd hwn.

Os ydych chi'n poeni am gymryd y feddyginiaeth, siaradwch â'ch presgripsiynydd neu fferyllydd am eich pryderon.

Os byddwch yn cael unrhyw effeithiau annymunol neu annisgwyl wrth gymryd y feddyginiaeth, dylech roi gwybod i'ch presgripsiynydd neu fferyllydd am hyn. Gallwch hefyd roi gwybod am unrhyw sgîl-effeithiau a amheuir wrth y Cynllun Cerdyn Melyn yn https://yellowcard.mhra.gov.uk/

A ellir presgripsiynu meddyginiaethau didrwydded i blant?

Gellir. Mae angen profi meddyginiaethau mewn treialon clinigol i gael trwydded. Nid yw bob amser yn bosibl cynnal treialon clinigol mewn plant, yn enwedig os yw'r feddyginiaeth ar gyfer salwch prin. Felly, gall y presgripsiynydd ddewis meddyginiaeth ddidrwydded i drin eich plentyn.

Gall fod gan feddyginiaeth ddidrwydded fanteision dros feddyginiaeth drwyddedig, er enghraifft:

- gallai fod ar ffurf y gall eich plentyn ei chymryd yn haws
- efallai y bydd y presgripsiynydd yn meddwl y bydd yn gweithio'n well ar gyfer salwch eich plentyn
- gall y feddyginiaeth ddidrwydded fod yn fwy diogel nag un drwyddedig (er enghraifft, gallai fod yn ddi-alcohol)

Yn yr un modd â defnyddio meddyginiaethau didrwydded mewn oedolion, byddwch wedi cytuno ar yr opsiwn gorau ar gyfer eich plentyn gyda'r presgripsiynydd, a bydd y presgripsiwn yn cael ei adolygu'n rheolaidd i sicrhau mai dyma'r opsiwn gorau o hyd.

A allaf gael meddyginiaeth ddidrwydded gan bresgripsiynydd preifat?

Gallwch gael meddyginiaeth ddidrwydded gan bresgripsiynydd preifat (er enghraifft optometrydd). Fodd bynnag, bydd angen i chi dalu am y feddyginiaeth. Siaradwch â'r presgripsiynydd a'ch fferyllydd cymunedol ynglŷn â faint mae hyn yn debygol o gostio. Bydd angen i chi ddweud wrth eich meddygfa, fel y gallant ychwanegu nodyn at eich cofnodion meddygol.

Sut gallaf gael rhagor o fy meddyginiaeth ddidrwydded?

Os caiff eich meddyginiaeth ei phresgripsiynu gyntaf yn eich practis meddyg teulu a bod angen rhagor arnoch, mae'n debygol y bydd y practis yn darparu presgripsiwn pellach. Os caiff eich meddyginiaeth ei phresgripsiynu gyntaf yn yr ysbyty, efallai na fydd hynny'n bosibl ac efallai y bydd angen i chi gael cyflenwadau pellach gan yr ysbyty. Os yw'ch meddyginiaeth wedi'i phresgripsiynu gan bresgripsiynydd anfeddygol, fel fferyllydd neu optometrydd, cysylltwch â nhw yn gyntaf. Ym mhob achos, cadarnhewch gyda'r presgripsiynydd sut y byddwch yn cael gafael ar gyflenwadau pellach.

Ar ôl siarad â'ch presgripsiynydd a'ch fferyllydd, gwnewch nodyn o pryd y mae angen i chi archebu mwy o'ch meddyginiaeth. Dylech wirio dyddiad dod i ben eich meddyginiaeth gan y gall hyn effeithio ar ba mor aml y mae angen i chi ei harchebu. Yn aml mae gan feddyginiaethau didrwydded ddyddiadau dod i ben byr. Mae hyn yn golygu efallai na fydd yn bosibl archebu symiau mawr i'w cadw yn y fferyllfa neu yn eich cartref. Os ydych eisoes yn cymryd meddyginiaethau eraill a bod gennych bresgripsiwn amlroddadwy, efallai y bydd angen i chi archebu'r feddyginiaeth ddidrwydded ar amser gwahanol.

Gall gymryd mwy o amser i'r fferyllfa gael gafael ar feddyginiaeth ddidrwydded pan fydd ei hangen arnoch. Yn dibynnu ar y feddyginiaeth, gall hyn fod hyd at bythefnos neu fwy. **Dylech ddweud wrth y fferyllfa mewn da bryd cyn i chi redeg allan.**

Beth os byddaf yn colli, yn dinistrio, neu'n rhedeg allan o fy meddyginiaeth ddidrwydded?

Os nad oes gennych unrhyw feddyginiaeth yn weddill, siaradwch â'ch fferyllydd. Gall roi cyngor ar beth i'w wneud, ac a allwch gael gafael ar gyflenwad brys o'r feddyginiaeth. **Peidiwch â chymryd unrhyw feddyginiaeth a allai fod wedi'i pheryglu (e.e. wedi'i dod allan o'r cynhwysydd neu ei difrodi).**

Beth ddylwn wneud os bydd y fferyllfa yn dweud wrthyf y bydd oedi mewn cyflenwi fy meddyginiaeth ddidrwydded?

Os oes gennych ddigon o'r feddyginiaeth i bara hyd nes y gall y fferyllfa drefnu mwy o gyflenwadau, ni fydd angen i chi wneud unrhyw beth. Fodd bynnag, os credwch y gallai'r oedi olygu y byddwch yn rhedeg allan o'ch meddyginiaeth, rhowch wybod i'ch presgripsiynydd oherwydd efallai y bydd angen iddo/iddi eich monitro hyd nes y gellir darparu cyflenwadau pellach. **Peidiwch â chymryd llai o feddyginiaeth na'r hyn a argymhellir oni bai eich bod yn trafod hyn gyda'ch presgripsiynydd yn gyntaf.**

A ddylwn i ddefnyddio'r feddyginiaeth ar ôl ei ddyddiad dod i ben os na allaf gael mwy o gyflenwadau mewn pryd?

Yn gyffredinol, ni ddylech ddefnyddio unrhyw feddyginiaeth ar ôl y dyddiad dod i ben. I ddarganfod beth fyddai'r peth mwyaf diogel i chi ei wneud, siaradwch â'ch fferyllydd neu bresgripsiynydd.

Mae fy mhresgripsiynydd wedi penderfynu peidio â pharhau â'r presgripsiwn ar gyfer y feddyginiaeth ddidrwydded a roddwyd gan yr ysbyty, beth ddylwn ei wneud?

Os ydych wedi cael presgripsiwn am feddyginiaeth ddidrwydded drwy'r ysbyty ac nad yw presgripsiynydd yn eich meddygfa yn teimlo y gall gymryd cyfrifoldeb am ysgrifennu presgripsiwn ar gyfer cyflenwadau pellach, trafodwch y rhesymau gydag ef neu hi. Efallai y bydd presgripsiynydd arall yn y feddygfa yn fodlon cymryd cyfrifoldeb. Os nad oes unrhyw un a all gymryd cyfrifoldeb, cysylltwch â'r ysbyty lle y presgripsiynwyd eich meddyginiaeth gyntaf ac efallai y gallant drefnu cyflenwadau pellach i chi.

Beth os nad wyf am dderbyn meddyginiaeth ddidrwydded?

Dim ond os ydych chi a'ch presgripsiynydd wedi cytuno mai dyma'r driniaeth orau i chi y cewch bresgripsiwn am feddyginiaeth ddidrwydded. Fodd bynnag, os nad ydych yn hapus, gallwch drafod eich opsiynau gyda'ch tîm presgripsiynu neu'ch fferyllydd.

Gyda rhai meddyginiaethau didrwydded mae'n rhaid i chi roi caniatâd

ysgrifenedig cyn i chi ddechrau eu cymryd. Gallwch newid eich meddwl ynglŷn â hyn unrhyw bryd.

Sut allaf gael rhagor o wybodaeth?

Os ydych yn bryderus, neu os oes gennych unrhyw gwestiynau am feddyginiaethau didrwydded, siaradwch â'ch fferyllydd neu bresgripsiynydd.

Mae gwefan y GIG hefyd yn cynnwys rhywfaint o wybodaeth am feddyginiaethau trwyddedig a didrwydded. Ar gael yn: *https://www.nhs.uk/conditions/medicines-information/*

Gellir dod o hyd i daflenni gwybodaeth ynglŷn â ddefnyddio meddyginiaethau didrwydded gyda phlant, sydd wedi'u hanelu'n benodol at rieni ar wefan Meddyginiaethau i Blant: https://www.medicinesforchildren.org.uk/

Gallwch gysylltu â Gwasanaeth Cyngor Meddyginiaethau Cymru. Ar gael yn: https://www.wmic.wales.nhs.uk/

Gweld y daflen hon ar eich ffôn:

Appendix 2a. Use of unlicensed medicines– information for patients and carers

Use of unlicensed "specials" and off-label medicines

You have been given this leaflet because you have been prescribed a medicine that does not have a licence or is being used differently to what is described in its licence (off-label).

What are licensed, unlicensed "specials" and off-label medicines?

For a medicine to be sold in the UK, it must have marketing authorisation or be "licensed". The licence describes how the medicine should be used including:

- Who it can be given to
- What condition(s) it can be used to treat
- How much should be taken (the dose)
- What form it is in (e.g. tablet, capsule, liquid)

An unlicensed medicine doesn't have a UK licence. It may be licensed in another country and imported to the UK, or be made specially (known as a "special" medicine).

If a licensed medicine is used differently to their licence, this is called "off-label" use of the medicine. Examples of off-label uses include:

- treating a different condition
- treating a different group of patients such as children or during pregnancy
- using a different dose

This leaflet uses the term "unlicensed" to describe both off-label and unlicensed 'specials' medicines.

Why are unlicensed medicines used?

Usually you will only be prescribed an unlicensed medicine when there is no suitable licensed alternative to treat your condition. Reasons for using an unlicensed medicine include:

A licensed medicine may not be available yet.

The medicine may be in the process of getting a licence or may still be undergoing testing in a clinical trial.

There may be a temporary shortage of the licensed medicine.

The medicine needs to be taken in a form that is not normally available (e.g. liquid), and must be specially made to order.

The medicine has a license but needs to be given in an unlicensed way. For example, crushing tablets to make them easier to swallow.

There is limited information available about treating certain conditions or for certain patient groups.

Can children be prescribed unlicensed medicines?

Yes. It is not always possible to do clinical trials in children, particularly for rare illnesses, so the prescriber may have to choose an unlicensed medicine. This might have benefits over a licensed one, for example it may:

Are unlicensed medicines commonly used?

Often, unlicensed medicines have been widely used and their effects are well known. The person treating you will have carefully considered the best choice of medicine for you and will explain:

why the medicine is right for you

and the possible risks

They will review the medicine regularly to make sure it remains the best one for you.

If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should tell your prescriber or pharmacist. You can also report any suspected side effects to the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/

If you are worried about taking the medicine, talk to your prescriber or pharmacist about your concerns.

How can I make sure I always have enough of my unlicensed medicine?

Unlicensed medicines often have short expiry dates. Check the expiry date so you will know when you need to order it.

It may take longer for the pharmacy to get an unlicensed medicine, up to one to two weeks. Tell the pharmacy in plenty of time.

If the pharmacist thinks that you may run out of your medicine, for example due to a supply issue, tell your prescriber. They may need to monitor you until your next supply arrives.

Do not take less medicine than advised unless you discuss this with your prescriber first. Do not take any medicine that may have been compromised (e.g., spilled or damaged).

For further information

The NHS website also has information about licensed and unlicensed medicines: https://www.nhs.uk/conditions/medicines-information/

Information leaflets about using unlicensed medicines in children, specifically aimed at parents can be found on the Medicines for Children website: https://www.medicinesforchildren.org.uk/

Alternatively, you can contact the Welsh Medicines Advice Service: https://www.wmic.wales.nhs.uk/

Access this leaflet on your phone:

Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group

Atodiad 2b. Defnyddio meddyginiaethau didrwydded – gwybodaeth i gleifion a gofalwyr

Defnyddio meddyginiaethau "arbennig" didrwydded ac oddi ar y label

Rhoddwyd y daflen hon i chi oherwydd eich bod wedi cael presgripsiwn am feddyginiaeth sydd heb drwydded neu sy'n cael ei defnyddio'n wahanol i'r hyn a ddisgrifir yn ei thrwydded (all-drwydded).

Beth yw meddyginiaethau trwyddedig, "arbennig" didrwydded ac oddi ar y label?

Er mwyn gwerthu meddyginiaeth yn y DU rhaid iddi gael awdurdodiad marchnata neu fod yn "drwyddedig". Mae'r drwydded yn disgrifio sut y dylid defnyddio'r feddyginiaeth gan gynnwys:

- I bwy y gellir ei rhoi
- Pa gyflwr neu gyflyrau y gellir ei defnyddio i'w trin
- Faint y dylid ei gymryd (y dos)
- Ar ba ffurf y mae (e.e. tabled, capsiwl, hylif)

Nid oes gan feddyginiaeth ddidrwydded drwydded y DU. Efallai ei bod wedi'i thrwyddedu mewn gwlad arall a'i mewnforio i'r DU, neu wedi cael ei gwneud yn arbennig (a elwir yn feddyginiaeth "arbennig").

Os defnyddir meddyginiaeth drwyddedig yn wahanol i'w trwydded, gelwir hyn yn "oddi ar y label". Mae enghreifftiau o ddefnydd oddi ar y label yn cynnwys:

- trin cyflwr gwahanol
- trin grŵp gwahanol o gleifion megis plant neu yn ystod beichiogrwydd
- defnyddio dos gwahanol

Mae'r daflen hon yn defnyddio'r term "didrwydded" i ddisgrifio meddyginiaethau oddi ar y label a meddyginiaethau "arbennig" didrwydded.

Pam y defnyddir meddyginiaethau didrwydded?

Fel arfer, dim ond pan nad oes dewis trwyddedig addas arall i drin eich cyflwr y cewch bresgripsiwn am feddyginiaeth ddidrwydded. Mae rhesymau dros ddefnyddio meddyginiaeth ddidrwydded yn cynnwys:

Efallai nad yw meddyginiaeth drwyddedig ar gael eto.

Efallai bod y feddyginiaeth yn y broses o gael trwydded neu efallai ei bod yn dal i gael ei phrofi mewn treialon clinigol.

Efallai bod prinder dros dro o'r feddyginiaeth drwyddedig.

Mae angen cymryd y feddyginiaeth ar ffurf nad yw ar gael fel arfer (e.e. hylif), a rhaid ei gwneud yn arbennig ar gyfer archeb.

Mae gan y feddyginiaeth drwydded ond mae angen ei rhoi mewn ffordd ddidrwydded. Er enghraifft, malu tabledi i'w gwneud yn haws i'w llyncu.

Prin yw'r wybodaeth sydd ar gael am drin rhai cyflyrau penodol neu ar gyfer rhai grwpiau cleifion.




A ellir presgripsiynu meddyginiaethau didrwydded i blant?

Gellir. Nid yw bob amser yn bosibl cynnal treialon clinigol mewn plant, yn enwedig ar gyfer salwch prin, felly efallai y bydd angen i'r presgripsiynydd ddewis meddyginiaeth ddidrwydded. Gall fod gan feddyginiaeth ddidrwydded fanteision dros feddyginiaeth drwyddedig, er enghraifft gallai:

A ddefnyddir meddyginiaethau didrwydded yn gyffredin?

Yn aml, mae meddyginiaethau didrwydded wedi cael eu defnyddio'n eang ac mae eu heffeithiau yn hysbys iawn. Bydd y person sy'n eich trin wedi ystyried yn ofalus y dewis gorau o ran meddyginiaeth i chi a bydd yn esbonio:

pam fod y feddyginiaeth yn iawn i chi

a'r risgiau posibl

Bydd yn adolygu'r feddyginiaeth yn rheolaidd i wneud yn siŵr mai dyma'r un orau o hyd i chi.

Os byddwch yn cael unrhyw effeithiau annymunol neu annisgwyl wrth gymryd y feddyginiaeth, dylech roi gwybod i'ch presgripsiynydd neu fferyllydd. Gallwch hefyd adrodd am unrhyw sgîl-effeithiau a amheuir wrth y Cynllun Cerdyn Melyn yn https://yellowcard.mhra.gov.uk/

Os ydych chi'n poeni am gymryd y feddyginiaeth, siaradwch â'ch presgripsiynydd neu fferyllydd am eich pryderon.

Sut allaf wneud yn siŵr fod gennyf bob amser ddigon o fy meddyginiaeth ddidrwydded?

Yn aml mae gan feddyginiaethau didrwydded ddyddiadau dod i ben byr. Gwiriwch y dyddiad dod i ben fel eich bod yn gwybod pryd y bydd angen i chi ei harchebu.

Gall gymryd mwy o amser i'r fferyllfa gael meddyginiaeth ddidrwydded, hyd at wythnos neu bythefnos. Dywedwch wrth y fferyllfa mewn da bryd.

Os yw'r fferyllydd yn meddwl y gallech redeg allan o'ch meddyginiaeth, er enghraifft oherwydd problemau gyda chyflenwadau, dywedwch wrth eich presgripsiynydd. Efallai y bydd angen iddynt eich monitro hyd nes y bydd eich cyflenwad nesaf yn cyrraedd.

Peidiwch â chymryd llai o feddyginiaeth na'r hyn a argymhellir oni bai eich bod yn trafod hyn gyda'ch presgripsiynydd yn gyntaf. Peidiwch â chymryd unrhyw feddyginiaeth a allai fod wedi'i pheryglu (e.e. wedi'i sarnu neu ei ddifrodi).

Rhagor o wybodaeth

Mae gan wefan y GIG hefyd rhywfaint o wybodaeth am feddyginiaethau trwyddedig a didrwydded: https://www.nhs.uk/conditions/medicines-information/

Gellir dod o hyd i daflenni gwybodaeth am ddefnyddio meddyginiaethau didrwydded mewn plant, sydd wedi'u hanelu'n benodol at rieni, ar wefan Meddyginiaethau i Blant: https://www.medicinesforchildren.org.uk/

Neu gallwch gysylltu â Gwasanaeth Cyngor Meddyginiaethau Cymru: https://www.wmic.wales.nhs.uk/

Gweld y daflen hon ar eich ffôn:

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