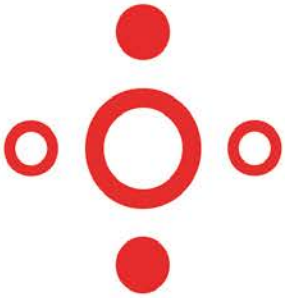
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan
All Wales Medicines Strategy Group



Understanding unlicensed medicines

May 2023

This document has been prepared by a multi-professional collaborative group, led by Dr Efi Mantzourani, with support from the All Wales Prescribing Advisory Group (AWPAG) and the All Wales Therapeutics and Toxicology Centre (AWTTC) and has subsequently been endorsed by the All Wales Medicines Strategy Group (AWMSG).

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Contents

1.0 Introduction

1.1 What is the purpose of these resources?

To provide guidance for improving the management of unlicensed medicines in all sectors of healthcare in NHS Wales. This guidance encompasses prescribing and dispensing settings in primary care (e.g. general practice and community pharmacy), secondary care, and patients and carers. This guidance can also be used in other relevant settings such as care homes, community services and prisons. The colours in the document and accompanying infographic are coordinated for ease of navigation.

1.2 Who is this guidance for?

- Healthcare professionals who prescribe or review unlicensed medicines
- Members of the primary care team who dispense unlicensed medicines
- Patients who are treated with unlicensed medicines
- Parents and carers of patients treated with unlicensed medicines

1.3 Definitions and useful terms

Licensed medicines can be described as any medicines that have been tested through clinical trials and have been found to be safe and effective for a particular use. A drug company must have marketing authorisation (often referred to as a product licence) to promote and sell a medicine in the UK. The licence is granted by a government organisation called the Medicines and Healthcare products Regulatory Agency (MHRA[1]) after the efficacy, safety and quality of the medicine have been assessed.

The licence will include details of the illnesses or conditions the medicine can be used for, the age of the patients it can be given to, how much to give, how to give it, and how it should be stored.

Information about the use of a licensed medicine can be found in the Summary of Product Characteristics (SPC) available at: https://www.medicines.org.uk/emc or https://products.mhra.gov.uk/ It should be noted that despite being licensed, a medicine may not necessarily be available on an NHS prescription.

Unlicensed medicines for human use may include:

- products that are licensed in the UK but are being used outside the licence, for example for a different indication, patient type, dose or preparation. This is known as off-label use of products;
- products that are imported and licensed in the country of origin;

- 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;
- products that are made specially, individually or in bulk, to fulfil a specific need for a patient. These products are known as 'specials'.

According to the hierarchy published by the MHRA[2] on the use of unlicensed medicines, licensed medicines should be preferred when available and meet the patients needs, although each case should be considered separately. In certain circumstances unlicensed medicines may be required, for example when there is a medicine shortage of the UK licensed product and there are no licensed alternatives or the licensed alternatives cannot support the additional demand during the shortage period.

The General Medical Council (GMC) uses the term 'unlicensed medicine' as an umbrella term for **all** medicines that are used outside the terms of their UK licence or which have no licence for use in the UK (including 'specials' and off-label use). Therefore in this document, any **standalone mention** to 'unlicensed medicines' will **encompass** the GMC's definition[3].

Changing a medicine's **formulation** by for example crushing tablets[4] (refer to NEWT guidelines[5] or Handbook of drug administration via enteral feeding tubes[6]); or mixing preparations together (e.g. lidocaine and injectable steroids) may change the medicine's properties, have implications for patient safety, and is unlicensed use. This may have implications for prescribing and other processes through which supply of the medicine is being made such as PGD (see SPS guidance[7]). When considering changing a medicine's formulation, it may be helpful to discuss this with a pharmacist.

When removed from the **original packaging**, medicines can become unstable. Repackaging medicines in a monitored dosage system could represent unlicensed usage (Care Quality Commission guidance[8]). When considering the use of a monitored dosage system, alternative options should be fully explored first, and it may be helpful to discuss this with a pharmacist. Should a medicine be **stored incorrectly** (for example due to a temperature deviation), the manufacturer may state that it is still safe to use, but it is now an unlicensed use.

1.4 Who can prescribe unlicensed medicines?

The following healthcare professionals can prescribe unlicensed medicines: doctors, dentists, independent nurse and pharmacist prescribers and, providing it is in accordance with the patient's clinical management plan, supplementary prescribers (who can be a pharmacist, nurse, midwife, optometrist, physiotherapist, radiographer, or chiropodist/podiatrist). These healthcare professionals, as well as independant physiotherapist, chiropodist, podiatrist, therapeutic radiographer, optometrist and paramedic prescribers can prescribe medicines off-label[9].

The responsibility that falls on healthcare professionals when prescribing an unlicensed product may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label.

Patients should be reminded to report any unpleasant or unexpected effects whilst taking the medicine, to their prescriber or pharmacist. They can also report any suspected side effects to the Yellow Card Scheme at https://yellowcard.mhra.gov.uk/

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7. SPS. Mixing of medicines and Patient Group Directions. 2021. Available at: https://www.sps.nhs.uk/articles/mixing-of-medicines-and-patient-group-direction/. Accessed 06/09/2022.
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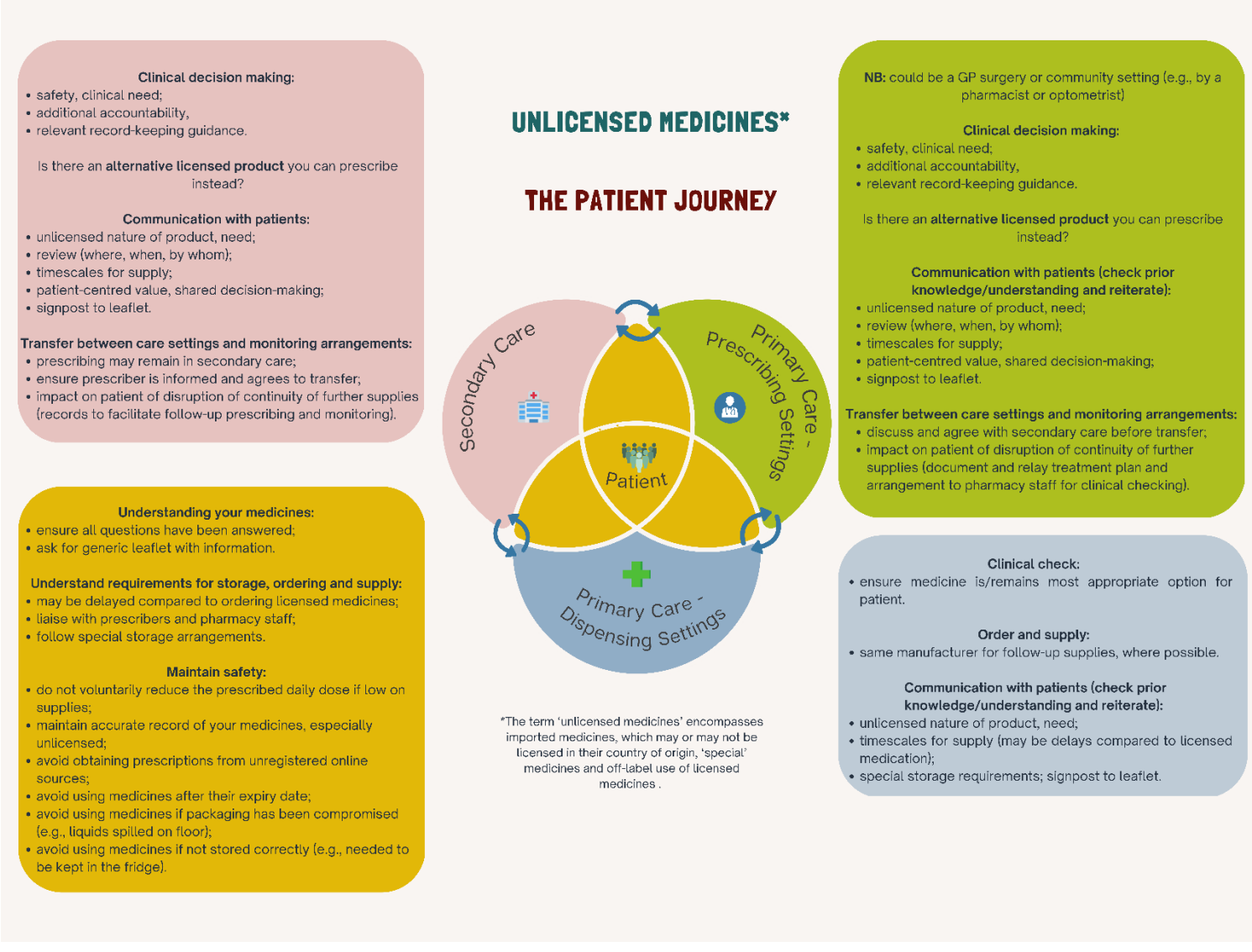
9. Pharmaceutical Services Negotiating Committee. Who can prescribe what? 2022. Available at: https://psnc.org.uk/dispensing-and-supply/prescription-processing/receiving-a-prescription/who-can-prescribe-what/. Accessed 24/11/2022.

2.0 Infographic: prescribing unlicensed medicines



3.0 Secondary care

3.1 Clinical decision making for prescribing an unlicensed medicine

Prescribers must consider **clinical need** and **safety** when issuing unlicensed medicines. The General Medical Council (GMC) has published guidance[1] relating to unlicensed medicines that should be used to support decision-making:

A key point in the GMC guidance states:
"You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient"[1]

To support prescribing decision making:

- review treatment options recommended in local medicines formularies and the British National Formulary (BNF) and British National Formulary for Children (BNFC) (which include information relating to commonly used unlicensed medicines), and other relevant sources;
- review prescribing information in the Summary of Product Characteristics (SPC) (licensed uses of the medicine);
- consider if there is an **alternative licensed product** (strength/formulation etc.) that you could prescribe instead;
- be aware that the drug salt and bioavailability of a licensed medicine may be different to that of an unlicensed alternative;
- if relevant, refer to specialist advisory group guidance, such as the British Association of Dermatology list[2], NHS Wales palliative care[3], Royal College of Paediatrics and Child Health[4] and NPPG standard strength of liquid medicines for children list[5];
- refer to your organisation's prescribing procedural pathways (which may include cold-chain breaches), formularies and any additional guidance that needs to be reviewed;
- where appropriate, prescribe unlicensed medicines included in part VIIIB of the Drug Tariff, as a specific price for the medicine is provided;
- in certain circumstances an unlicensed medicine may be more appropriate for the patient than a licensed one (e.g. licensed phenobarbital oral liquid contains alcohol but the unlicensed 50mg/5mL oral liquid is alcohol-free[6]).

If prescribing an unlicensed medicine, **the prescriber must**:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy and that there is no suitable licensed alternative that would meet the patient's needs;
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or make sure that arrangements are in place for another suitable healthcare professional to do so;
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine, utilising relevant professional or regulatory body guidance such as that provided by the GMC[1].

Some general information on additional responsibilities when prescribing unlicensed medicines can be found in MHRA guidance[7].

3.2 Communication with patients

Patients may be worried about terms such as 'unlicensed' and 'off-label', and may have questions. It is important to reassure them and provide all of the information they require in a way they will understand to enable them to make an informed decision. Ensure the following key points are covered:

- explain the nature of the product (licensed vs. unlicensed vs. off-label);
- explain the need for an unlicensed product and where relevant explain the unavailability or unsuitability of a licensed preparation;
- explain possible alternative therapeutic options;
- undertake a patient-centred value assessment to identify patient preferences;
- ensure the patient has made an informed choice and is consenting to the treatment (follow the organisation's guidelines, and document appropriately);
- explain the expected length of treatment and timescale for review.
- clarify the point of, and process for, obtaining an ongoing supply where appropriate (e.g., from community or hospital pharmacy);
- use the patient information leaflets included in these resources to support discussions.

3.3 Order, supply and administration of medicine

Unlicensed medicines may have **different processes** for ordering, supply and administration, and the following points should be considered by all healthcare professionals involved:

- refer to your organisation's guidelines for purchasing, risk assessment, recording batch numbers/patient names and any other relevant information;
- where possible source unlicensed medicines that are on a National Contract in the first instance, as the quality and cost will have been considered with the relevant suppliers;
- remember unlicensed medicine labelling and packaging must still meet the requirements of the MHRA[8];
- repackaging medicines in a monitored dosage system could represent unlicensed use (Care Quality Commission guidance[9]);
- any healthcare professional administering the unlicensed medicine should be competent to do so, and should have sufficient knowledge of the medicine to ensure that it is appropriate for the patient;
- where necessary, seek advice from the prescriber, pharmacy professional or senior colleague;
- understand that any action resulting in unlicensed administration (e.g., crushing tablet formulations, mixing medicines, refer to NEWT guidelines[10] or Handbook of drug administration via enteral feeding tubes[11]) may invalidate processes such as PGDs through which supplies of medicines are made.

3.4 Transfer between care settings and monitoring arrangements

The initiating healthcare professional should take responsibility for prescribing the unlicensed medicine and oversee the patient's care, monitoring and any follow up treatment **or** ensure that arrangements are in place for another suitably qualified prescriber to assume these responsibilities. Consider whether transfer of prescribing and monitoring responsibility is appropriate, or whether these need to be maintained within secondary care. Refer to the health board formulary for information relating to unlicensed medicines routinely available in primary care. The agreement of the

patient's **primary care prescriber** should be obtained **before prescribing is transferred** to ensure continuity of therapy. The GMC advises that the prescriber should have the necessary knowledge and experience of the patient and medicine in order to prescribe[12].

Unlicensed medicine use must be **accurately recorded** when transferring between care settings, and ongoing use **monitored**.

Ensure the prescribing team are fully informed about the use of the unlicensed medicine, and are provided with all necessary prescribing information or supporting evidence for use. Make sure the indication and rationale for the unlicensed medicine are recorded in the patient's record.

The initiating healthcare professional should **provide support** to prescribers in primary care to aid their decision making, as the latter have responsibility for any prescription that they sign:

- if inpatient and using MTeD, use "notes" section on eDAL to relay to prescriber: indication; expected length of treatment; timescales for review; supplier/manufacturer; any other important information;
- if inpatient and not using MTeD, include same information on separate note that accompanies discharge documentation or clinical summary;
- If outpatient, include same information on the clinical letter or clinical summary that will be sent to prescribers.

Contact details of the original prescriber and consultant should be **clearly recorded** to facilitate any follow-up discussion that is needed with primary care prescribers or community pharmacy staff (for example when conducting a Discharge Medicines Review).

Continuity of supply and the **risk to the patient** of disrupted or unreliable supply should be carefully considered. Where appropriate, inform the community pharmacy or practice dispensary where they can obtain the unlicensed medicine.

1. General Medical Council. Prescribing unlicensed medicines. 2021. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines Accessed 04/08/2022.
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3. NHS Wales. End of Life Care. 2022. Available at: https://collaborative.nhs.wales/implementation-groups/end-of-life-care/. Accessed 04/08/2022.
4. Royal College of Paediatrics and Child Heath. The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice. 2020. Available at: http://nppg.org.uk/wp-content/uploads/2020/09/The-use-of-unlicensed-medicines-or-licensed-medicines-for-unlicensed-applications-in-paediatric-practice.pdf. Accessed 24/11/2022.
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6. NHS Wales. Patient Safety Notice PSN061 Reducing the risk of patient harm – standardised strength of phenobarbital oral liquid. 2021. Available at: https://du.nhs.wales/files/notices/psno61-phenobarbital-oral-liquid-pdf/. Accessed 05/10/2022.

7. MHRA. Off-label or unlicensed use of medicines: prescribers' responsibilities. 2014. Available at: https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities. Accessed 04/08/2022.

8. MHRA. The supply of unlicensed medicinal products ("specials"). 2014. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/373505/The_supply_of_unlicensed_medicinal_products__specials_.pdf. Accessed 24/11/2022.

9. Care Quality Commission.Multi-compartment compliance aids (MCAs) in adult social care. 2022. Available at: https://www.cqc.org.uk/guidance-providers/adult-social-care/multi-compartment-compliance-aids-mcas-adult-social-care. Accessed 28/09/2022.

10. NEWT Guidelines. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. 2019. Available at: https://www.newtguidelines.com/method_of_administration.html. Accessed 11/08/2022.

11. Pharmaceutical Press - Handbook of Drug Administration via Enteral Feeding Tubes Third Edition. 2015. Available at: https://www.pharmpress.com/product/9780857111623/handbook-of-drug-administration-via-enteral-feeding-tubes. Accessed 06/09/2022.

12. GMC. Good practice in prescribing and managing medicines and devices content. 2021. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/shared-care#paragraph-76. Accessed 05/10/2022.

4.0 Primary care – Prescribing

4.1 Clinical decision making for prescribing an unlicensed medicine

Prescribers in primary care (e.g. GPs and non-medical prescribers) must consider **clinical need** and **safety** when issuing unlicensed medicines. Professional and regulatory bodies such as the General Medical Council (GMC) have published guidance[1] relating to unlicensed medicines that should be used to support decision-making:

A key point in the GMC guidance states:
"You should usually prescribe licensed medicines in accordance with the terms of their licence. However, you may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient"[1].

To support prescribing decision making:

- review treatment options recommended in local medicines formularies and the British National Formulary (BNF) and the British National Formulary for Children (BNFC) (which include information relating to commonly used unlicensed medicines), and other relevant sources (e.g. health board formulary);
- review prescribing information in the Summary of Product Characteristics (SPC) (licensed uses of the medicine);
- consider if there is an **alternative licensed product** (strength/formulation etc.) that you could prescribe instead;
- be aware that the drug salt and bioavailability of a licensed medicine may be different to that of an unlicensed alternative;
- if relevant, refer to specialist advisory group guidance, such as the British Association of Dermatology list[2], NHS Wales palliative care[3], Royal College of Paediatrics and Child Health[4] and NPPG standard strength of liquid medicines for children list[5];
- refer to your organisation's prescribing procedural pathways (which may include cold-chain breaches), and any additional guidance that needs to be reviewed;
- where appropriate, prescribe unlicensed medicines included in part VIIIB of the Drug Tariff, as a specific price for the medicine is provided;
- in certain circumstances an unlicensed medicine may be more appropriate for the patient than a licensed one (e.g. licensed phenobarbital oral liquid contains alcohol but the unlicensed 50mg/5mL oral liquid is alcohol-free[5]);
- advice relating to unlicensed medicines is available from pharmacy teams and medicines information services.

If prescribing an unlicensed medicine, **the prescriber must**:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy;
- take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or make sure that arrangements are in place for another suitable healthcare professional to do so;
- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an

unlicensed medicine, utilising relevant professional or regulatory body guidance such as that provided by the GMC[1].

Some general information on additional responsibilities when prescribing unlicensed medicines can be found in MHRA guidance[6].

4.2 Clinical decision making (if *continuing* supply of an unlicensed medicine initiated in secondary care)

The AWMSG prescribing dilemmas guidance[7] has advice when prescribing medicines initiated in secondary care.

The agreement of the patient's **primary care prescriber** should be obtained **before prescribing is transferred** to ensure continuity of therapy. When considering whether to continue the prescription of an unlicensed medicine initiated in secondary care, it is important to ensure that the prescription is **still appropriate**:

- review the discharge information from secondary care and ensure you are satisfied with the clinical need for the unlicensed medicine (use appropriate guidelines to support your decision-making);
- discuss with the consultant or prescriber who authorised the discharge advice letter if additional information or clarification is needed;
- contact pharmacy teams or medicines information services if extra support is needed;
- be aware that repackaging medicines in a monitored dosage system could represent unlicensed use;
- do not prescribe if you do not have the required competencies and are not prepared to accept clinical responsibility;
- check whether a different prescriber in your workplace has the required competencies and is prepared to accept clinical responsibility.

If you are happy to accept clinical responsibility and agree to prescribe :

- select the appropriate product from prescribing software (liaise with community or practice pharmacist if more information is needed);
- review the need for the unlicensed medicine regularly, and document in the patient record. Liaise with the secondary care team where necessary.

Consider the **impact on the patient** of not prescribing in primary care. Make alternative arrangements, in a timely manner, with secondary care if deciding not to prescribe, or where an unlicensed medicine that requires specialist prescribing has been transferred in error.

4.3 Communication with patients

Patients may be worried about terms such as 'unlicensed' and 'off-label', and may have questions. It is important to reassure them and provide all of the information they require, in a way they will understand to enable them to make an informed decision. Ensure the following key points are covered (check prior knowledge and understanding, and reiterate where needed):

- explain the nature of the product (licensed vs. unlicensed vs. off-label);
- explain the need for an unlicensed product and where relevant explain the unavailability or unsuitability of licensed preparation;
- explain possible alternative therapeutic options;
- undertake a patient-centred value assessment to identify patient preferences;

- ensure the patient has made an informed choice and is consenting to the treatment (follow the organisation's guidelines, and document appropriately);
- explain the expected length of treatment and timescale for review;
- clarify the point of, and process for, obtaining an ongoing supply where appropriate (e.g., from community or hospital pharmacy);
- use the patient information leaflets included in these resources to support discussions.

4.4 Transfer between care settings and monitoring arrangements

Unlicensed medicine use must be **accurately recorded** when transferring between care settings, and ongoing use **monitored**. Ensure the indication, rationale for the unlicensed medicine, and treatment plan are recorded in the patient's record. **Share** this with community pharmacists to support the clinical check before dispensing, as they have equal responsibility with the prescriber when supplying a medicine. This may also be needed by a different prescriber who is asked to authorise a further supply of the medicine.

Provide **notice** and enough time for the community pharmacist to source, order and receive the unlicensed medicine. (NB: timescales vary widely depending on the pharmacy and manufacturer, and some unlicensed medicines may need to be made up by the supplier):

- if available, share details of supplier/manufacturer of the product supplied in hospital;
- liaise with pharmacy staff regarding supply timelines of individual medicine manufacturers and ensure prescribing intervals are aligned.

1. General Medical Council. Prescribing unlicensed medicines. 2021. Available at: https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-practice-in-prescribing-and-managing-medicines-and-devices/prescribing-unlicensed-medicines. Accessed 04/08/2022.
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6. MHRA. Off-label or unlicensed use of medicines: prescribers' responsibilities. 2014. Available at: https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities. Accessed 04/08/2022.

7. AWMSG. Prescribing dilemmas: A guide for prescribers. 2021. Available at: https://awttc.nhs.wales/medicines-optimisation-and-safety/medicines-optimisation-guidance-resources-and-data/prescribing-guidance/prescribing-dilemmas-a-guide-for-prescribers/. Accessed 04/08/2022.

5.0 Primary Care – Dispensing

5.1 Clinical check

When dispensing takes place in a community pharmacy, the pharmacist shares accountability for supply with the prescriber. There are clinical checks that should be undertaken when dispensing an unlicensed medicine:

- ensure that the unlicensed medicine is (and remains) the most appropriate treatment for the patient. This might include discussing the indication and rationale for the medicine with the prescriber. It is good practice to record this information on the patient's medication record[1];
- discuss with the prescriber any potential licensed options that are available for the same indication (e.g., non-preservative free drops, melatonin 1mg/ml vs 10mg/5ml);
- ensure that any unlicensed medicine use is recorded appropriately;
- some general information outlining additional responsibilities when checking and dispensing unlicensed medicines and imports can be found at the PSNC website[2];
- advice relating to unlicensed medicines is available from hospital pharmacies and medicines information services.

Guidance for the procurement and supply of specials is available from the Royal Pharmaceutical Society[1].

5.2 Order and supply

The BNF maintains a list of NHS hospital manufacturing units[3] where unlicensed medicines can be sourced. When sourcing medicines:

- check whether company policy requires you to use a specific supplier. If not, the secondary care team may have provided a recommendation for a supplier;
- follow standard operating procedures for contacting manufacturers to source the product;
- for continuity of supply ensure the same manufacturer is used for follow-ups, as flavour, excipients etc. may vary between manufacturers. Contact hospital pharmacy teams or medicines information services if extra support is needed;
- record the manufacturer in the patient medication record; check standard operating procedures for guidelines on recording batch numbers etc.
- be aware that repackaging medicines in a monitored dosage system could represent unlicensed use (see Care Quality Commission guidance[4]);
- ensure patients are aware of the expected timescales for supply so that they can arrange for a prescription to be issued in plenty of time.

Please note this document does not provide advice relating to extemporaneous preparation. If you are preparing an unlicensed 'special' medicine in the pharmacy, review the GPhC guidance[5].

5.3 Communication with patients

Patients may be worried about terms such as 'unlicensed' and 'off-label', and may have questions. It is vital to reassure them and provide all the necessary information they require in a way they will understand to enable them to make an informed decision. Ensure the following key points are covered (check prior knowledge and understanding, and reiterate where needed):

- explain/reiterate the nature of the product (licensed vs. unlicensed);
- explain/reiterate the need for unlicensed product and where relevant explain the unavailability of licensed preparation;
- explain/reiterate the expected length of treatment and timescale for review, if provided on prescriber's notes;
- explain timescales for obtaining future supplies, including potential differences with other licensed medicines the patient may be using;
- discuss any special storage requirements;
- use the patient information leaflets included in these resources to support discussions.

The supplying pharmacist retains a duty of care towards the patient and must be able to demonstrate that they have taken all reasonable steps to ensure: procurement from an appropriate and cost-effective source; that the product is of appropriate quality; that relevant records are kept and adverse events are reported.

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6.0 Patient/carer

Patients and carers may be worried about terms such as ‘unlicensed’, ‘specials’ and ‘off-label’, and may have questions. As part of the prescribing or dispensing process, you should ensure they understand the reasons behind the prescription, how and where to re-supply their medicine, and any storage and safety requirements.

As a healthcare professional involved in the care of the patient, you should provide them with an overview of what unlicensed medicines are and why they have been given this type of medicine. You should also provide a generic patient information leaflet on unlicensed medicines with key points to consider and useful contacts (see 6.1).

6.1 Understanding medicines

Ensure the patient understands what is meant by ‘licensed’, ‘unlicensed’, ‘special’ or ‘off-label’ and the reason why this particular medicine has been prescribed. Remember this may be as simple as crushing a tablet to allow easy swallowing, for example.

During consultations with patients ensure you have answered all of their questions and that they are satisfied with your answers.

Provide a generic patient information leaflet on unlicensed medicines as this will answer many common questions and provide something the patient can refer back to for information. Example leaflets are provided in Appendices 1 and 2. Signpost to other relevant information sources (such as the NHS medicines information resources[1]) and give a point of contact in case of further questions.

6.2 Understand storage requirements, ordering and supply

Ensure patients and carers understand the processes for obtaining repeat prescriptions. Make patients aware of any differences between their repeat prescriptions for their other medicines and for their unlicensed medicine.

Unlicensed medicines may have differences in supply and reorder when compared to licensed medicines the patient may already be taking, or have taken previously. Expiry dates may be shorter, patients should be aware of this and check that the unlicensed medicine will not expire before the end of their treatment regime. Tell them to contact their prescriber or pharmacist if this occurs to check if it safe to continue taking the medicine.

Unlicensed medicines may have particular storage requirements (temperature, for example). Ensure these are fully explained to the patient.

6.3 Involving patients in decisions around their treatment

Patients should be encouraged to ask for a review of their unlicensed medicine at the recommended interval (this should be explained when prescribing the medicine).

6.4 Maintain safety

As with all medicines, safety is a number one priority when using unlicensed medicines. Encourage patients to follow these steps at all times:

- hold an accurate record of the unlicensed medicines they are prescribed;

- **do not** voluntarily reduce the prescribed daily dose of their unlicensed medicine if they are running low on supplies – request that they speak to their prescriber to request a prescription and pharmacist/dispensing practice to arrange a new supply or for advice on alternative options;
- **avoid** obtaining prescriptions for supplies of their unlicensed medicine via unregistered online sources:
    - the quality of medicine purchased from an unregistered online source cannot be guaranteed and could actually cause harm;
    - information does not get transferred automatically to their NHS record.
- if they obtain a private prescription, advise them to share this information with their prescribing team and GP surgery;
- **avoid** using unlicensed medicines after their expiry date (unless advised differently by their healthcare professional);
- **avoid** using unlicensed medicines whose packaging has been compromised (e.g., if liquids have been spilled on floor);
- **avoid** using unlicensed medicines that have not been stored correctly (e.g., if needed to be kept in the fridge) unless advised differently by their healthcare professional.

1. NHS. Medicines Information. 2020. Available at: https://www.nhs.uk/conditions/medicines-information/ Accessed 07/12/2022.

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.

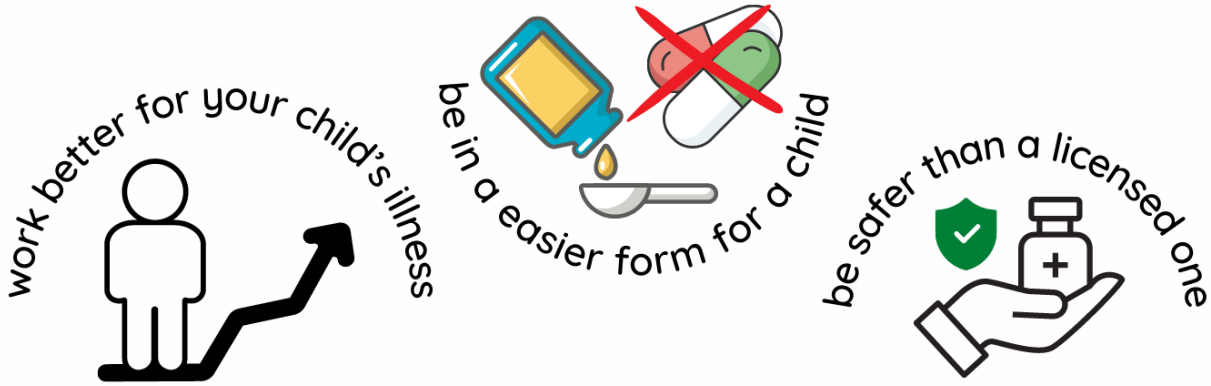
The medicine needs to be taken in a form that is not normally available (e.g. liquid), and must be specially made to order.

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:

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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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Appendix 3: MHRA Guidance on the hierarchy for the use of unlicensed medicines

Appendix 2 of the MHRA Guidance Note 14: “The supply of unlicensed medicinal products (“specials”)” provides the following guidance to inform the choice of medicinal product.

MHRA APPENDIX 2 - Guidance on the hierarchy for the use of unlicensed medicines

This hierarchy is provided for guidance only and each case should be considered on its individual merit.

1. An unlicensed product should not be used where a product available and licensed within the UK could be used to meet the patient's special need.

2. Although MHRA does not recommend "off label" (outside of the licensed indications) use of products, if the UK licensed product can meet the clinical need, even "off-label", it should be used instead of an unlicensed product. Licensed products available in the UK have been assessed for quality safety and efficacy. If used "off-label" some of this assessment may not apply, but much will still be valid. This is better than the use of an un-assessed, unlicensed product. The fact that the intended use is outside of the licensed indications is therefore not a reason to use an unlicensed product. It should be understood that the prescriber’s responsibility and potential liability are increased when prescribing off-label.

3. If the UK product cannot meet the special need, then another (imported) medicinal product should be considered, which is licensed in the country of origin.

4. If none of these options will suffice, then a completely unlicensed product may have to be used, for example, UK manufactured "specials", which are made in GMP inspected facilities, but which are otherwise un-assessed (GMP inspection of “specials” manufacturers is not product specific). There may also be other products available which are unlicensed in the country of origin.

5. The least acceptable products are those that are unlicensed in the country of origin, and which are not classed as medicines in the country of origin (but are in the UK). For example, the use of products from countries where they are classed as supplements, not pharmaceuticals, and may not be made to expected standards of pharmaceutical GMP. These should be avoided whenever possible.