Policy for prescribing and administering unlicensed and off-label medication

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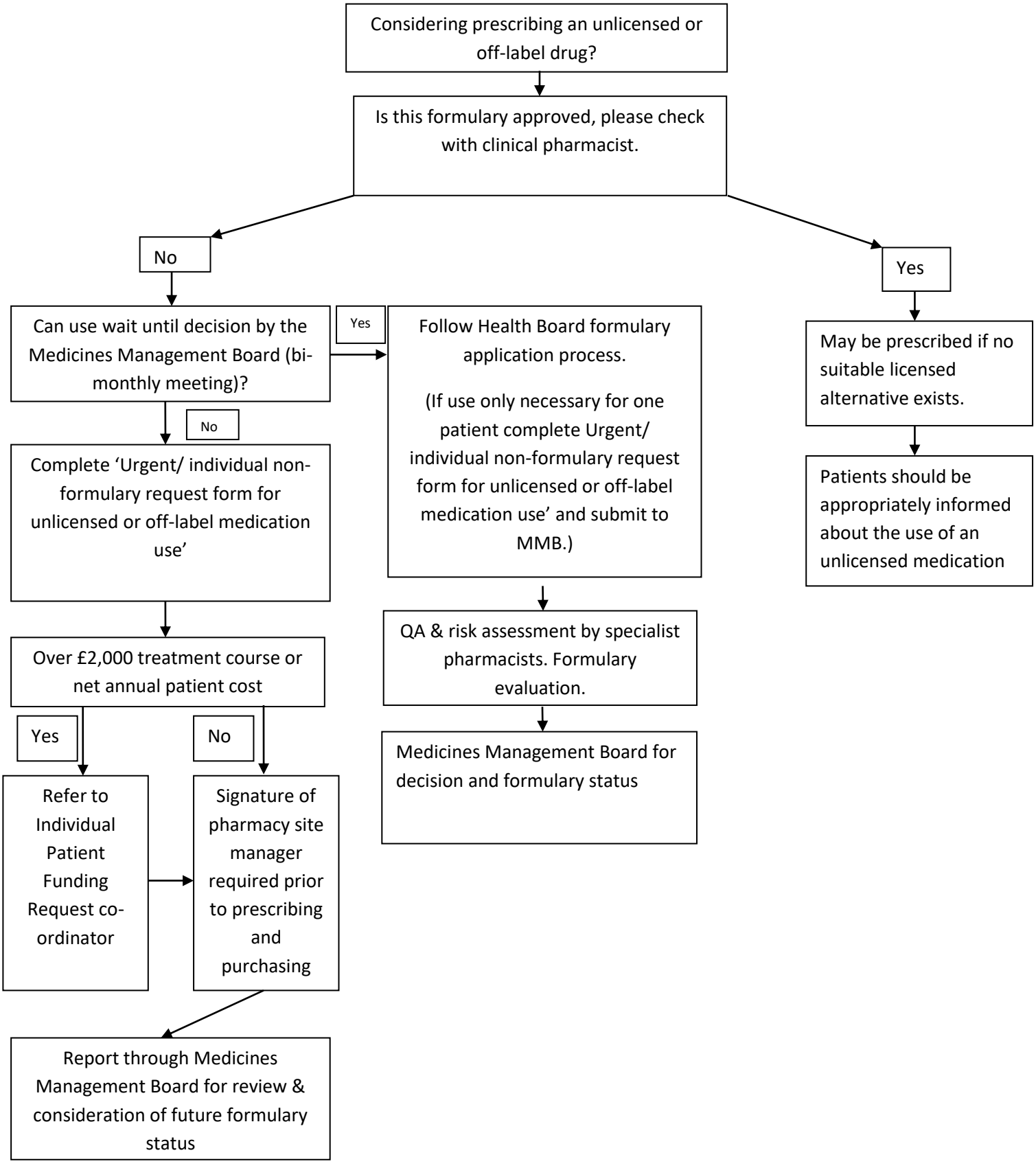
Flowchart for prescribing of unlicensed/off-label drug use



1. Important Definitions

1.1 For the purposes of this policy, important definitions are as follows:

- **UK Marketing Authorisation:** a license provided by the MHRA for drugs that have met stringent criteria to ensure the drug works well for its intended indication with minimal harm for most people.
- **Unlicensed medicines:** all medicines with no UK Marketing Authorisation.
- **Off label medicine use:** licensed medicines used outside of the terms of their Marketing Authorisation.
- **Special need:** this refers to the clinical need of an individual patient. It does not include reasons of cost, convenience or operational needs.

2. Introduction

2.1 Unless exempt, a medicinal product must be the subject of a marketing authorisation or product licence before being placed on the market. Regulation 167 of the Human Medicines Regulations 2012 provides an exemption from the need for a marketing authorisation for a medicinal product which is supplied in the UK:

- In response to an unsolicited order (e.g. a prescription).
- Manufactured and assembled in accordance with the specification of a person who is a doctor, dentist, nurse independent prescriber, pharmacist independent prescriber or supplementary prescriber.
- For use by a patient under their care in order to fulfil the **special needs** of that patient.

2.2 Unlicensed/ off-label medication should not be supplied where an equivalent licensed medicinal product exists, that would meet the special need of a patient.

2.3 Whilst licensed medicinal products are subject to stringent control by the Medicines and Healthcare products Regulatory Agency (MHRA), prescribers cannot make the same assumptions of quality, safety and efficacy about unlicensed products.

2.4 The use of unlicensed medicines and licensed medicines for unlicensed applications in clinical practice is accepted by the Welsh Risk Pool, which will indemnify participants against incidents arising out of these uses. This is subject to there being an appropriate in-house policy covering the use of drugs in such circumstances, which has been approved by the Health Board's Medicines Management Board (MMB).

3. Scope

3.1 This policy is intended for use by all healthcare professionals (HCPs) employed by SBU Health Board who are involved with prescribing and administering unlicensed/ off label medicines.

3.2 This policy does not cover the use of investigational products being used as part of a clinical trial.

3.3 This policy does not cover use of drugs on compassionate use, expanded access or named patient supply programmes (see Protocol for Making Decisions on Compassionate Use/ Expanded Access/ Named Patient Supply Programmes)

3.4 This policy does not cover procurement and dispensing of unlicensed medication (see SOP-DP27)

4. Prescribing unlicensed/ off-label medication.

4.1 No patient can be prescribed or administered an unlicensed medication unless the drug has the necessary Health Board formulary approvals. This can be checked via your clinical pharmacist.

4.2 If intended use is non-formulary it is necessary to acquire formulary approval. See policy for 'Managed Entry Process for SBU Health Board Joint Drug Formulary'.

4.3 For non-formulary use of unlicensed/ off-label medication required urgently see section 5.

4.4 For one-off non-formulary use of unlicensed medication for an individual patient see section 5.

4.5 The prescriber is professionally accountable for their judgment in prescribing an unlicensed medicine.

4.6 Prescribers should make an individual assessment of a patient to conclude a special need exists that requires the use of an unlicensed medication.

4.7 The special need and decision to initiate the unlicensed medication should be clearly documented e.g. in the patient's medical notes.

4.8 Patients should be appropriately informed about the use of an unlicensed medication, see section 7.

5. Urgent and one-off individual patient requests for non-formulary unlicensed/ off-label medication.

5.1 If the unlicensed medication request is a one-off for an individual patient a formulary decision is not required. The 'Urgent/ individual non-formulary request form for unlicensed or off-label medication use' (appendix 1) needs to be completed and submitted to MMB for approval.

5.2 Urgent requests can be made for non-formulary unlicensed medication use for an individual patient if a decision from the Medicines Management Board cannot be waited for.

5.3 Urgent unlicensed medication requires submission to pharmacy of an 'Urgent/ one-off individual patient non-formulary request form for unlicensed or off-label medication use' (appendix 1) which has been countersigned by the clinical director (or nominated deputy).

5.4 The clinical pharmacist is required to sign the urgent request form once satisfied the request is appropriate. Assistance is also available from senior clinical effectiveness pharmacists.

5.5 Urgent requests for unlicensed medication with a net cost <£2,000 per patient per year can be approved by an acute site pharmacy manager (or nominated deputy) for an individual patient in their managed unit.

5.6 Urgent requests for unlicensed medication with net costs >£2,000 per patient per year can be approved by an acute site pharmacy manager (or nominated deputy) with agreement of the Chair of the Individual Patient Funding Request panel (or nominated deputy) for an individual patient in their managed unit.

5.7 Approved urgent requests will be reviewed within 3 months at Medicines Management Board.

6. Pharmacist Role

6.1 Clinical pharmacist shares with the prescriber accountability for supplying an unlicensed or off-label medication to a patient. The clinical pharmacist has professional responsibility to liaise with the prescriber and the patient to ensure that unlicensed or off label medication is (and remains) the most appropriate choice.

6.2 The clinical pharmacist must be able to demonstrate due diligence in regards to the patient's safety and that the product meets the special need of a patient.

6.3 For urgent non-formulary requests for unlicensed medication the clinical pharmacist is required to sign the 'Urgent non-formulary request form for unlicensed or off-label medication use medication use'

6.4 Pharmacists should only clinically approve a prescription for an unlicensed or off-label medication when:
- A special need exists for that patient.
- No licensed medication exists that can meet that special need.
- The decision to initiate is appropriately documented.
- Is approved for use in the Health Board (as specified in section 4).
- Patient is appropriately informed.

7. Patient consent and provision of patient information.

7.1 When initiating any medication patients (or carers) must receive sufficient information about the medicines prescribed to allow them to make an informed decision about their use.

7.2 If patient is prescribed unlicensed or off-label medication they should be informed of this and explained why use is necessary. (There are exceptions to this, see statement 7.3)

7.3 For medicines routinely used off-label or medication used in emergencies or where there is no realistic alternative treatment and such information is likely to cause distress, it may not be practical or necessary to draw attention to the license.

7.4 Patients (or carers) must be given the likely timescale for supply of their medication, this is particularly important for unlicensed medication as these tend to have a longer ordering time.

7.5 Advise patients (or carers) where to order repeat prescription and obtain further supply of medication.

7.6 When available patients must be provided with appropriate written information of the unlicensed/ off-label medication they are prescribed.

8. Administration

8.1 A registered nurse may administer an unlicensed medication with informed consent against a patient specific direction and not a patient group direction.

8.2 A registered nurse may administer off-label medication against a patient specific direction or a patient group direction.

8.3 Any healthcare professional administering unlicensed/ off-label medication should be satisfied they have sufficient information to safely administer. Whenever possible be satisfied there is acceptable published evidence for the use of that product.

9. Adverse drug reaction reporting

9.1 Suspected adverse drug reactions to medication must be reported to the MHRA via the Yellow Card Scheme.

9.2 Yellow Card reports for unlicensed medication should state the manufacturer and that the product is unlicensed.

9.3 All healthcare professionals are responsible for completing Yellow Card reports.

10. Continuation of prescribing

10.1 Prescribers of unlicensed or off-label medication are responsible for overseeing the patients care, monitoring, follow up treatment and repeat prescriptions. Or ensuring that arrangements are made for another suitable doctor to do so.

10.2 See 'CID408 - Guidance for prescribing at the Primary / Secondary care interface across the Swansea Bay University Health Board'

10.3 Where prescribing responsibility for a patient is transferred it is required that sufficient information is provided to allow the new prescriber to identify the use of the drug as unlicensed/ off-label, the special need of the patient that requires such use. This information needs to contain full details of the drug regime to ensure safe prescribing.

10.4 When a general practitioner (GP) is asked to continue prescribing a product initiated in secondary care, prescribing responsibility rests with the GP signing the prescription.

10.5 A GP is under no obligation to accept prescribing recommended by secondary care and should only do so if they have full confidence in prescribing the drug.

10.6 If the GP does not wish to continue such treatment it will remain the responsibility of the initiating prescriber.

11. References

11.1. GMC: Good practice in prescribing and managing medicines and devices (2013)

11.2. The supply of unlicensed medicinal products 'specials', MHRA guidance note 14

11.3. RPS: Professional Guidance for the Procurement and Supply of Specials, December 2015

11.4. NMC: Standards for Medicines Management, 2007 (updated 2015)

Appendix 1: Urgent/ one-off individual patient non-formulary request form for unlicensed or off-label medication use'

Urgent/ one-off individual patient non-formulary request form for unlicensed or off-label medication use

Please note: If a formulary decision is required complete formulary application and submit to MMB.

Patient details

Name	Address
NHS No.	
Date of Birth	

Drug regime

Drug name:		
Strength	Form	Route
Dose	Frequency	Duration

Special Need

What is the indication for use?
What are the alternative treatment options and why can't they be used?
Please **detail** referenced evidence to support use of drug in proposed indication? (e.g. BNF advice, specialist guidelines, reference to literature)
Please detail the risks associated with the use of this drug in the proposed indication?
What are the implications of not receiving the requested medication?

Please return completed form to [redacted], Clinical Effectiveness Pharmacist, Pharmacy Department, POW Hospital.

Signatures of requesting consultant and clinical pharmacist

I have read the policy for prescribing and administering unlicensed drugs and accept full responsibility for its use.

Please select one of the following	For use by an individual consultant, for the above mentioned patient under their care.	
	For use by several consultants within a directorate for the above mentioned patient. Please state directorate:_____	
Consultant (name, signature and date)		
Counter signature by Clinical Director / nominated deputy (name, signature and date)		

I have read the policy for prescribing and administrating unlicensed drugs and understand my responsibilities.

Clinical Pharmacist (name, signature and date).

Approval

Urgent: Pharmacy Site Manager approval for individual patient use.
Urgent requests can be approved by pharmacy acute site managers or a nominated deputy providing:

- net cost <£2,000 per patient per year.
- net cost >£2000 per patient per year with agreement from the chair of the IPFR panel (or nominated deputy).
- for use in a managed unit for an individual patient.

Such approvals must be reviewed at MMB **within 3 months** after the date of signing.

Pharmacy site manager or nominated deputy (name, signature, date)

Non-Urgent: MMB approval for individual patient use.

Has approval been provided? (yes/ No)	Additional MMB comments
Signature of MMB Chair or nominated deputy (name, signature and date)	

Unlicensed products are not routinely stocked by the Pharmacy.

Please return completed form to [redacted], Clinical Effectiveness Pharmacist, Pharmacy Department, POW Hospital.