

SECTION 9: UNLICENSED MEDICINES POLICY

SECTION 9.1: UNLICENSED MEDICINES POLICY (ACUTE DIVISION)

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SECTION 9: UNLICENSED MEDICINES POLICY

POLICY SUMMARY

The purpose of this policy document is to provide guidance for staff of the acute services division of NHS Greater Glasgow and Clyde (NHSGG&C) in the use of medicines which are unlicensed for any use as well as those medicines which are licensed but being prescribed for a non-licensed indication (off label)

An appropriate clinical risk assessment should be carried out whenever a clinician wishes to use an unlicensed medicine / off label medicine, with consideration being given to the evidence base for the medicine, the risks / benefits to the patient or patient group in the proposed setting and peer group opinion. Suggested factors to be considered in this process are included in appendix 1.

Definitions

For the purposes of this policy the definitions are as follows:-

Unlicensed medicines are defined as all medicines with no Marketing Authorisation for ANY formulation or indication in the UK.

Off label medicines are defined as licensed medicines used out with the terms of their Marketing Authorisation. It includes all medicines used in paediatrics that have a Marketing Authorisation for use in adults, but not specifically in children.

General points

- The policy covers the prescribing of unlicensed and off label medicines in the **Acute Services Division** only.
- It does **NOT** apply to investigational medicinal products which are being prescribed as part of a clinical trial – these are covered by separate policies and procedures
- The principles and good practice described within the policy are equally applicable to adults and children.
- All healthcare professionals working within the acute services division of NHSGG&C have responsibility for ensuring that unlicensed/ off label medicines are prescribed, supplied and administered in a safe manner.
- The MHRA currently advises that when prescribing, a clinician should take into consideration the risks and benefits of each potential drug. Where there is a choice between a licensed agent and off label/ unlicensed agent, with no perceived difference in risks or benefits between the options, the licensed agent should be used to treat patients in preference to the unlicensed/ off label medicine.

Completion of an unlicensed medicine/ off label medicine request

- The decision to prescribe unlicensed and off label medicines is the responsibility of the consultant in charge of the patient's care.
- An unlicensed medicine request must be completed by the **consultant** looking after the patient in the following circumstances:
 - All medicines with no Marketing Authorisation for any formulation or indication in the UK
 - Off label medicines that fall into the high risk category (see appendix 1)
- The request for use of an unlicensed medicine / high risk off label medicine (see appendix 1) should be signed and approved by the appropriate clinical director. For high cost medicines (over £3000 per annum or per patient treatment), the supply should be approved by the associate medical director.
- The following do NOT require a request form
 - Extemporaneously prepared medicines e.g. suspensions, ointments, creams
 - Off label use of established, low or intermediate risk medicines (see appendix 1)
 - Unlicensed/ high risk off label medicines where approved protocols for the medicines are in place (see paragraph below)

Protocol development for an unlicensed or off label medicine

- When an unlicensed/ off label medicine will be used frequently, clinical specialists can draw up a protocol for use of the medicine for an indication or group of indications. Once approved by the clinical director, separate forms are no longer required for each individual patient. However, for unlicensed medicines the patient's name and CHI number must still be supplied to pharmacy.

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Addition of an off label medicines to the Formulary

- In a limited number of circumstances (see appendix 7) it may be appropriate to consider an application to the Area Drugs and Therapeutics Committee for addition of indication for the off label medicine to the Formulary.

Patient Consent

It is standard practice when starting a patient on any new form of therapy that benefits and significant side effects are discussed.

Unlicensed medicine - Prescribers MUST advise patients/ carers that they are being treated with an unlicensed medicine. Written consent MUST be obtained in this setting.

Off label medicines - It is appropriate in the context of a prescribing a *high risk off label medicine* to mention the off label status. For non-high risk off label medicines it is left to the discretion of the prescriber as to when it is appropriate to discuss this with the patient and/ or their carer. This discussion and patient/ guardian consent (verbal/ written) should be documented.

Unlicensed / off label medicines intended for long-term use

- For those unlicensed medicines prescribed in hospital and intended for use on a long-term basis, it is essential that arrangements are made for the continuing prescribing, monitoring and supply prior to the patient's discharge, including making contact with the community pharmacist, where appropriate.
- General practitioners should not be expected to prescribe unlicensed medicines, but may do so if they feel it appropriate for their patient, after discussion with the Consultant.
- General practitioners may be asked to prescribe off label medicines, but should be given sufficient information to do this safely.
- The consultant is responsible for ensuring that the relevant General Practitioner is given sufficient information about the product.

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UNLICENSED MEDICINES POLICY

1. SCOPE

This document is intended for use by all healthcare professionals employed within the acute services division of NHSGG&C engaged in the prescribing, supply and administration of unlicensed/ off label medicines.

There are separate specific policies for investigational medicinal products, which are being prescribed as part of a clinical trial.

2. AIM

This policy has been put in place to

- provide safe procurement and supply of unlicensed medicines (ULMs).
- Promote best practice when prescribing Unlicensed/ off label medicines for adults and children
- Ensure continuity of supply of medicines between the acute and primary care sectors.

3. BACKGROUND

The manufacture and sale or supply of medicines is controlled by national and EU legislation. This ensures that medicines are safe, effective and of the appropriate quality. In the UK this is regulated by the Medicines Act, 1968, which has been amended to comply with EEC directive 65/65/EC. No medicine can be placed on the market without a Marketing Authorisation (formerly known as a Product Licence) granted by the Medicines and Healthcare Products Regulatory Agency (MHRA). This Marketing Authorisation (MA) signifies that the medicine concerned meets the appropriate quality standards and is safe and efficacious for its designated use. The MA details the indications for which the product is licensed and can be marketed. It also defines the form, dose, route of administration for the medicine and the container in which it is supplied. The product information supplied with the agent will only apply to licensed indications and doses.

Unlicensed medicines have not been subject to the same stringent scrutiny by the MHRA and so the same assumptions regarding product quality, safety and efficacy that accompany licensed products cannot be made. "Guidance Note 14 – the supply of unlicensed relevant medicinal products for individual patients" - issued by the MHRA provides guidance on the prescribing, procurement, manufacture and distribution of unlicensed medicines. It states that unlicensed medicinal products may only be placed on the market (and by implication purchased) when no pharmaceutically equivalent licensed product is available for use. Products are considered pharmaceutically equivalent if they contain the same amount of the same active substance in the same dosage form and meet the same standards, when considered in the light of the clinical needs of the patient at the time of its use.

However, it is recognised that licensed indications for a product will not always meet the clinical needs of an individual patient in every situation. Therefore, to ensure that the patient's requirements for a medicine are met, and to preserve the prescriber's clinical freedom, the legislation provides an exemption to allow the manufacture, supply and administration of **unlicensed medicines** (i.e. medicines without a Marketing Authorisation) when necessary. In addition, provision is also made for **licensed medicines** (i.e. medicines with full Marketing Authorisation) to be prescribed for unlicensed indications or in unlicensed dosages i.e. "**off label**".

The MHRA[1] state that a prescriber must

- Before prescribing an unlicensed medicine, be satisfied that an alternative, licensed medicine would not meet the patient's needs
- Before prescribing a medicine off-label, be satisfied that such use would better serve the patient's needs than an appropriately licensed alternative
- Before prescribing an unlicensed medicine or using a medicine off-label:
 - Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to show its safety and efficacy

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- Take responsibility for prescribing the medicine and for overseeing the patient's care, including monitoring and follow-up
- Record the medicine prescribed and, where common practice is not being followed, the reasons for prescribing this medicine; you may wish to record that you have discussed the issue with the patient

4. POLICY STATEMENTS

4.1. GENERAL STATEMENTS

- Medicines with the appropriate Marketing Authorisation should be used to treat patients in preference to unlicensed or off label medicines whenever possible. However, use of unlicensed / off label medicines may be necessary in order to provide the optimum treatment for patients, but they should only be prescribed if their use can be clearly justified from a clinical / pharmaceutical perspective. In some specialties, such as paediatrics, many medicines are prescribed off label due to lack of MA in the paediatric setting.
- No ULM or off label medicine should be used routinely in preference to a licensed alternative solely because of cost.
- Risk assessment is an integral part of the approval process for the use of ULMs and off label medicines and is a fundamental part of the policy governance arrangements. Instruction is provided in Section 6 of this document.
- Evidence supporting the prescribing and contributing to the risk assessment should be made available as appropriate to those members of staff involved in the prescribing, distribution or administration of an unlicensed/ off label medicine to facilitate awareness of its unlicensed status and effective management of any risks identified.
- The **decision** to prescribe unlicensed and off label medicines is the responsibility of the consultant in charge of the patient's care.
- Subsequent **prescribing** may be carried out by the consultant or fully registered medical staff or a supplementary prescriber under the guidance of the initiating consultant.
- Independent prescribers may prescribe unlicensed and off label medicines, where it is accepted clinical practice or for high risk off label prescribing, within an approved protocol. Supplementary prescribers may prescribe unlicensed medicines within an approved clinical management plan.
- Purchasing is the responsibility of the pharmacy department and appropriate information surrounding clinical risk assessment and evidence supporting use of the drug must be provided by the consultant to the relevant pharmacist prior to procurement.
- Medication errors, adverse drug reactions etc should be reported in the same way as for all other medicines i.e. via Directorate clinical incident monitoring systems (Datix) or the Yellow Card scheme.

4.2 UNLICENSED MEDICINES

- Adequate records must be kept regarding the requisition, procurement, supply and administration of unlicensed medicines.
- Patients / guardians / carers must be made aware, whenever possible, that an unlicensed medicine has been prescribed. They must be given any relevant information and consent must be obtained prior to administration.
- Principles described in NHSGG&C "Safe and Secure Handling of Medicines" policy will apply to unlicensed medicines.
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4.3 OFF LABEL MEDICINES

- Off label use should be managed, where appropriate, with underpinning Directorate protocols. Within Paediatrics, it is recognised that the use of off label medicines is extensive but the same principles should hold true.
- High risk off label medicines (as defined in Appendix 1) with appropriate documentation should be submitted to the clinical director for consideration and, if required, to relevant directorate clinical governance structures.

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4.4 INCLUSION OF OFF LABEL MEDICINES IN THE NHS GG&C FORMULARY

Where the use of an off label medicine has become established practice within a defined patient group, who have been shown to benefit from the medicine, it may be appropriate for the Area Drugs and Therapeutics Committee to consider this medicine for inclusion in the NHS GG&C Formulary for this use (appendix 7).

NB This process will **not** be available for off label medicines given "not recommended for use in NHS Scotland" advice by the Scottish Medicines Consortium (SMC) for a licensed indication. Refer to Section 7.

5. LEGAL LIABILITY

5.1. HEALTH BOARD

It is the responsibility of the Health Board to ensure that medicines are prepared and administered correctly. While any liability associated with the use of unlicensed or off label medicines will be accepted by the employing authority. This policy describes best practice for employees of the acute division NHS GG&C.

5.2. PRESCRIBER

The prescriber is always responsible for the use of a medicine and the patient's welfare and in the event of adverse reactions may be called upon to justify the decisions that they have made. (see GMC advice, appendix 4). In the case of unlicensed/ off label medicine prescribing it is important to be aware that information regarding efficacy and safety may be less robust and this should be considered where there is a licensed alternative.

5.3. PHARMACIST

A pharmacist assumes professional responsibility as purchaser of the medicine, particularly if this involves specifying an unlicensed medicine to be purchased.

5.4. MANUFACTURER

If an untoward incident occurs with:-

- **a licensed medicine** prescribed and administered according to the Marketing Authorisation, liability rests with the manufacturer.
- **off label use of a licensed medicine** i.e. prescribed or administered out with Marketing Authorisation then the manufacturer is **unlikely** to be found liable for any harm caused by that medicine, unless harm is directly attributable to a defect in it, rather than the way it was prescribed.
- **an unlicensed medicine** with no Marketing Authorisation within the UK then the manufacturer is not liable (unless the medicine is shown to be defective).

N.B It should be noted in the event of an adverse event the manufacturer has no right to be supplied with the patient name. Indeed the divulgence of any information which can identify the patient would be a breach of confidentiality.

6. RISK MANAGEMENT AND CLINICAL GOVERNANCE ARRANGEMENTS

All medicines have side-effects which can vary dependent on the indication being treated and this should be considered when prescribing off label. If there is little data for use in a particular setting adverse events may occur which have not been previously described with possibly unforeseen consequences. In the case of ULMs, the level of knowledge about product quality, efficacy and side-effects will frequently be lower than for medicines used within a MA and knowledge may be minimal if the medicine is used early on in its development.

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It is important that systems are in place to show that when prescribing an unlicensed/ high risk off label medicine this was the most appropriate therapy for the patient.

A risk management programme with associated controls has been developed and implemented within NHSGG&C.

There are two aspects to risk management.

- **Prescribing / requesting – clinical risk management (unlicensed and off label medicines)**
- **Procurement / receipt – product risk management (unlicensed medicines)**

6.1 CLINICAL RISK MANAGEMENT

(See appendix 1 clinical risk assessment of off label medicines)

6.1.1 RISK ASSESSMENT

Prior to initiating therapy with an ULM / off label medicine, the clinician should:-

- Assess suitability of licensed alternative agents for the patient
- Be aware of current peer group opinion of treatment options for the patient
- Consider the evidence base for the ULM/ off label medicine
- Consider the risks of the ULM/ off label medicine including route of administration, possible side-effects, contraindications and precautions which may be required when using the medicine e.g. intrathecal and epidural routes are, by their very nature, higher risk and side-effects are more likely to be severely disabling / life threatening. (see below and appendix 1)
- Weigh up the risk / benefit to the patient or patient group in the proposed setting

Unlicensed Medicine (requires approval documentation)

From a **clinical** perspective **all unlicensed medicines** should be considered as “**high risk**” and treated accordingly. Products, which have had their marketing authorisation revoked due to concerns over product quality and/or safety must be considered as “**very high**” risk. An extensive assessment will be required in each individual case to weigh up risk versus patient benefit before use of the product.

Off label medicines

These should be risk assessed by the following criteria:-

High Risk (requires approval documentation)

- Only evidence for use is based on :-
 - Phase I clinical trial data
 - Case reports published in established journals
- Route of administration :-
 - Intrathecal
 - Epidural

Intermediate Risk

- Only evidence for use is based on :-
 - Phase II/ III clinical trial
- Reported incidence of significant damage due to side effects :-
 - High risk of life threatening or disabling side effects/ toxicity
 - Teratogenic
 - Carcinogenic
 - Requires on going monitoring e.g. full blood count, LFT etc.
- Type of Agent :-
 - Cytotoxic
 - Biological agent e.g. Antibody therapy, cytokine stimulator/ inhibitor

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For medicines falling within the **intermediate risk** category, it is **highly recommended** that an approved guideline or protocol be put in place that describes in detail the prescribing and monitoring requirements of the medicine. This is particularly important for those medicines that may be continued in Primary Care (see section 7)

6.1.2 COMPLETION OF REQUEST FORM (APPENDICES 2 AND 3 FOR AN OVERVIEW OF THE REQUEST PROCESS AND APPENDIX 9 FOR REQUEST FORM)

This is ONLY needed for unlicensed medicines and high risk off label medicines. It is NOT needed for off label medicines which fall into the established, low or intermediate risk categories.

ONLY Consultants are allowed to submit a request for unlicensed medicines and for high risk off label medicines. See appendices 2 and 3 for an overview of the request process and appendix 8 for request form.

The submission MUST include:-

- Name of the prescriber
- Name of patient & CHI number
- Clinical indication
- Published evidence supporting use in the setting
- Reason for prescribing for this patient as against alternative agents, particularly if licensed agent available
- Risk assessment outcome
- Fiscal information

Evidence of clinical efficacy MUST be provided. Failure to provide this information may result in the request being delayed / refused.

6.1.3 SUBMISSION OF UNLICENSED/ OFF LABEL MEDICINES REQUEST

The clinical director will consider, in a timely fashion, the use of an unlicensed or a high risk off label medicine following receipt of the fully completed request form. High cost medicines (over £3000 per annum or per patient treatment) must be submitted for consideration to the Associate Medical Director or equivalent.

If approved, the signed form will be returned to the requesting consultant who will forward the form to pharmacy together with supporting paperwork to facilitate supply. A copy of the form should also be filed in the patient's notes.

6.1.4 EMERGENCY REQUEST FOR AN UNLICENSED OR A HIGH RISK OFF- LABEL MEDICINE.

In an emergency, the medicine may be provided without the request form having been approved. However, the clinician requesting the medicine MUST be able to complete the following:

- Name of the prescriber
- Name of patient
- Clinical indication
- Supporting published evidence for use in the setting
- Reason for prescribing for this patient

The form will be reviewed retrospectively in a timely fashion by the Clinical Director or Associate Medical Director (as appropriate).

To ensure compliance with the policy in this situation, the pharmacy department has a set of documentation which must be completed.

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6.1.5 APPEALS PROCESS IN THE EVENT THAT A REQUEST TO PRESCRIBE AN UNLICENSED MEDICINE IS DECLINED

This will follow the Health Board appeals process for non-formulary medicines. However in the first instance any appeal will be heard by the associate medical director.

6.2 PRODUCT RISK MANAGEMENT (UNLICENSED MEDICINES)

The medicine must be deemed to meet minimum standards of safety. This aspect of risk management is primarily an assessment of product quality and includes knowledge and confidence in the manufacturer / supplier, certificate of analysis information and whether or not the product is licensed within its country of origin. This will be carried out by pharmacy.

The pharmacy department has produced a series of standard operating procedures which guide staff through the procurement and receipt process. A number of controls have been established to ensure that products sourced meet the required standard.

Particular attention is given to the safe and secure handling of products sourced from outside the UK which may not have packaging or product information in English. Specific instructions are provided to control this issue.

6.3 MANAGING RISK THROUGH CLINICAL STAFF ACCOUNTABILITY AND DEFINED RESPONSIBILITIES

All staff involved in the treatment of a patient with an unlicensed medicine / off label medicine should be:-

- Aware of its unlicensed / off label status
- Informed of any potential problems / risks and how to deal with them. Ideally this information should be included in the patient's notes and this should also be forwarded to the appropriate General Practitioner where appropriate.
- Given sufficient information to administer or use the medicine safely

All health care professionals must be aware of their own liability and responsibilities when prescribing, supplying and administering unlicensed or off label medicines. (see section 5)

6.3.1 PRESCRIBER

The Consultant initiating the use of the medicine must comply with the following.

- Ensure that unlicensed or off label medicines are only prescribed when licensed medicines for that indication would not meet the patient's needs.
- Be prepared to provide detailed written information to support the decision taken regarding the selection of the particular medicine. This should include benefit to the patient, evidence of efficacy, side-effects and why any alternative licensed medicine is inappropriate in this situation. In the case of unlicensed medicines, this will **ALWAYS** be required prior to drug purchase.
- Discuss with the relevant pharmacist where to obtain the medicine, what formulation and dose is required and duration of administration.
- Complete the relevant request form where appropriate (see flow chart, appendices 2 and 3)
- Discuss, where appropriate, with the patient/ carer the status of the medicine, side- effects, continuation of supply and document discussions.
- Ensure that all staff are aware of side effects/ dosing/ monitoring etc. that may be different from licensed indications
- Ensure that all staff are aware the medicine is being used is unlicensed and have appropriate access to information about side effects/ dosing/ monitoring etc.

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- Provide, in conjunction with pharmacy, information to staff involved in handling and administration about side-effects, repeat prescribing etc.
- The person who first prescribes an ULM or off label medicine **should** be the Consultant. However, this can be delegated to a registered medical practitioner working under the supervision of the Consultant.
- Provide written information about dosage, side-effects etc. at the time of discharge for primary care if the medicine is to be taken by the patient in the community setting
- Ensure continuity of supply on patient discharge, if this is required either via primary care or hospital out patients.

All prescribers should:-

- Ensure any adverse event related to the ULM or off label medicine is documented via the Yellow Card system or the directorate clinical incident reporting system e.g. Datix.
- Ensure the ULM / off label medicine continues to be appropriate for that patient
- Ensure they are aware of any potential side-effects and can arrange for the patient to be monitored appropriately as required

Non- Medical Prescribers

Supplementary prescribers can only prescribe unlicensed medicines within the confines of a Clinical Management Plan. Independent prescribers can prescribe unlicensed and off-label medicines, where it is accepted clinical practice or for high risk off label prescribing, within an approved protocol.

6.3.2 PHARMACY STAFF

Many pharmacy staff may be involved in the process of ULM procurement e.g. clinical pharmacists, technicians, medicines information, etc. Therefore, all members of the staff should be aware of this policy and the role they need to fulfil in order to comply with its requirements.

The pharmacist may be involved in the discussion as to whether to prescribe a ULM or off label medicine. However, if in the professional opinion of a pharmacist, the use of an unlicensed medicine would be unsafe for a given patient, it is their responsibility not to supply the product and to inform the prescriber of their reasons.

Such cases should be referred to the Clinical Director for the specialty for review / arbitration.

Responsibilities of pharmacy staff are described in detail in the Pharmacy Policy document and accompanying standard operating procedures.

6.3.3 NURSING STAFF

Nursing staff administering unlicensed medicines must be made aware of the unlicensed status of the medicine. It is the responsibility of the pharmacist and consultant to inform them of this.

Nursing staff should:-

- Ensure that they have information on the safe use of an unlicensed medicine before administration
- Follow safe and secure handling of medicines policies and practice
- Inform the pharmacy staff when transferring a patient to a different ward / department
- Inform the staff in the new ward /department of the status of the medicine and ensure that stocks are sent with the patient.

For Unlicensed Medicines held as stock items on the ward / in department it is the responsibility of the nurse in charge to ensure additional records are kept regarding administration e.g. stock control records. These **MUST** include drug batch numbers and each patient's name and CHI number

6.3.4 AREA DRUG AND THERAPEUTICS COMMITTEE

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The ADTC is responsible for the development of policy and ongoing review of the use of unlicensed and off label medicines within NHSGG&C.

6.4 PATIENT INFORMATION AND CONSENT

Patients and, where appropriate, carers have the right to participate in the making of properly informed decisions about their health care. Wherever possible, patients should be made aware that they are being prescribed an unlicensed or off label medicine and that this may increase the risks associated with treatment because there is less information available with regard to efficacy and side effects in the off label and unlicensed setting. In addition the quality of manufacture etc, of unlicensed medicines is more difficult to establish.

The MHRA recommends^[1] that prescribers should provide patients/ carers with the following

- Sufficient information about the proposed treatment, including known serious or common adverse reactions, to enable them to make an informed decision
- Where current practice supports the use of a medicine outside the terms of its licence, it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients or carers require or which they may see as relevant
- Explain the reasons for prescribing a medicine off-label or prescribing an unlicensed medicine where there is little evidence to support its use, or where the use of a medicine is innovative

There are patient information sheets for the adult and paediatric settings in appendices 4 and 5

Unlicensed medicine - Prescribers MUST advise patients/ carers that they are being treated with an unlicensed medicine. Written consent MUST ALWAYS be obtained in this setting.

Off label medicines –

It is good practice when starting a patient on any new form of therapy that benefits and significant side effects are discussed. In the 'high risk' setting this discussion should be documented and consent (verbal/ written) obtained.

7. PRIMARY CARE

Medicines are frequently used off label in all specialties in the acute services division and there are a large number of unlicensed medicines also in common usage. The dosage, side-effects, monitoring etc. of these drugs for each indication will be well known to Hospital staff and be documented in the patient's notes. However, the primary care team may not be familiar with the use of the agent at all, or not in the setting for which it is being used. Unless adequate information is supplied to the primary care team errors in dosing, response assessment etc can be made, particularly where drugs are used off label as, although information will be readily available from sources such as the BNF it may not be applicable to the current setting.

Where it is intended that either unlicensed or off label treatment will be continued after patient discharge, clear arrangements MUST be agreed between primary and secondary care regarding clinical, prescribing and dispensing responsibilities. A decision on final responsibility should depend primarily on the best interests of the patient in terms of safety and convenience. However, General Practitioners are at liberty to refuse to prescribe within primary care if they have not been given sufficient information to prescribe safely or that this is out with their level of expertise.

Where initiation of treatment with an off label medicine/ ULM occurs in hospital, the consultant recommending the medicine is responsible for ensuring that appropriate information is provided to the GP and arrangements are made, in conjunction with the acute sector pharmacy, for relevant information to be passed on to community pharmacists.

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7.1 UNLICENSED MEDICINES

In general, General Practitioners should **not be expected** to prescribe any unlicensed medicines as defined by the policy. However, there may be circumstances where this is considered by both clinicians to be in the patient's best interests. Pharmacy must be involved in this process to ensure continuity of supply.

7.2 OFF LABEL MEDICINES

General Practitioners can be asked to continue to prescribe off label medicines i.e. used out with their licence indications e.g. amitriptyline for neuropathic pain. However, within the intermediate and high risk categories, off label prescribing is best done where there is a written protocol for use. These instances are best discussed with the GP on a case by case basis.

7.3 INFORMATION REQUIRED

The hospital consultant who has initiated treatment with the unlicensed / off label medicine is responsible for ensuring that the relevant General Practitioner is given sufficient information about the product.

The following information should be provided:-

- Name of Drug
- Dose and formulation
- Licensed status of drug
- Reason for prescribing
- Monitoring requirements if any
- Duration of treatment
- Common side effects

7.4 MONITORING

In situations where there is expected to be a high incidence of side-effects, or special monitoring is required, the appropriate arrangements must be put in place for this.

This is the responsibility of the Consultant and Acute Division unless it falls within pre-existing agreements between Primary Care and the Acute Division i.e. in line with the 'near patient testing local enhanced scheme'.

For some individuals it may be possible to transfer monitoring to primary care but this requires the agreement of the patient's GP.

8. SAFE AND SECURE HANDLING OF UNLICENSED MEDICINES

It is a requirement of Guidance Note 14 (MHRA) that all patients receiving unlicensed medicines can be identified and that the use of that medicine can be accounted for.

In addition, compliance with good practice statements described in "Safe and Secure Handling of Medicines in Hospital Wards, Theatres and Departments" NHS GG&C should be demonstrated.

SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 1: SUGGESTED CRITERIA FOR CLINICAL RISK ASSESSMENT OF OFF-LABEL MEDICINES

Established Practice	Low Risk	Medium Risk	High Risk
<ul style="list-style-type: none"> ▪ Established generally e.g. BNF, SIGN guidelines ▪ BNF for Children 	<ul style="list-style-type: none"> ▪ Established use in speciality e.g. Specialist published guidelines ▪ Phase III / IV clinical trial data published in established Journals 	Phase II clinical trial data, abstracts of phase III/IV	<ul style="list-style-type: none"> ▪ Phase I clinical trials or case reports
<ul style="list-style-type: none"> ▪ Few significant side effects 		<ul style="list-style-type: none"> ▪ Teratogenic ▪ Carcinogenic ▪ Cytotoxic ▪ Biological Agent 	
<ul style="list-style-type: none"> ▪ Oral / external ▪ Subcutaneous / respiratory / nasal 		<ul style="list-style-type: none"> ▪ Intravenous or installation into cavity or bone 	<ul style="list-style-type: none"> ▪ Intrathecal ▪ epidural

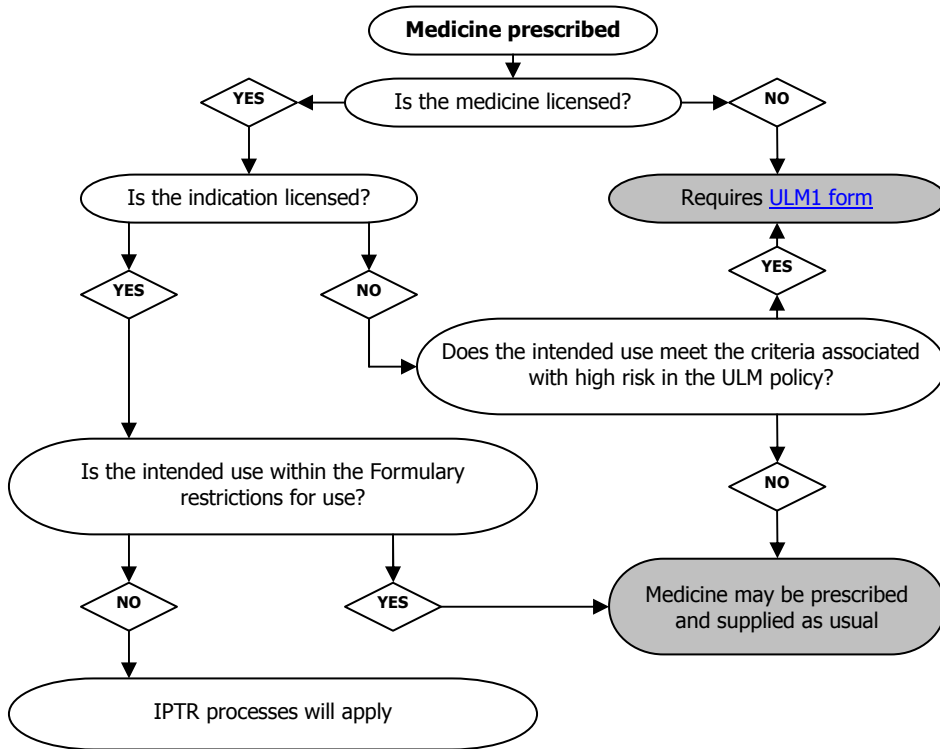
Any off label medicine fulfilling any of the criteria in the high risk column automatically requires an unlicensed medicines form.

Note – there is an element of subjectivity in assigning clinical risk category. The above table provides guidance only and should not be considered as an exhaustive list.

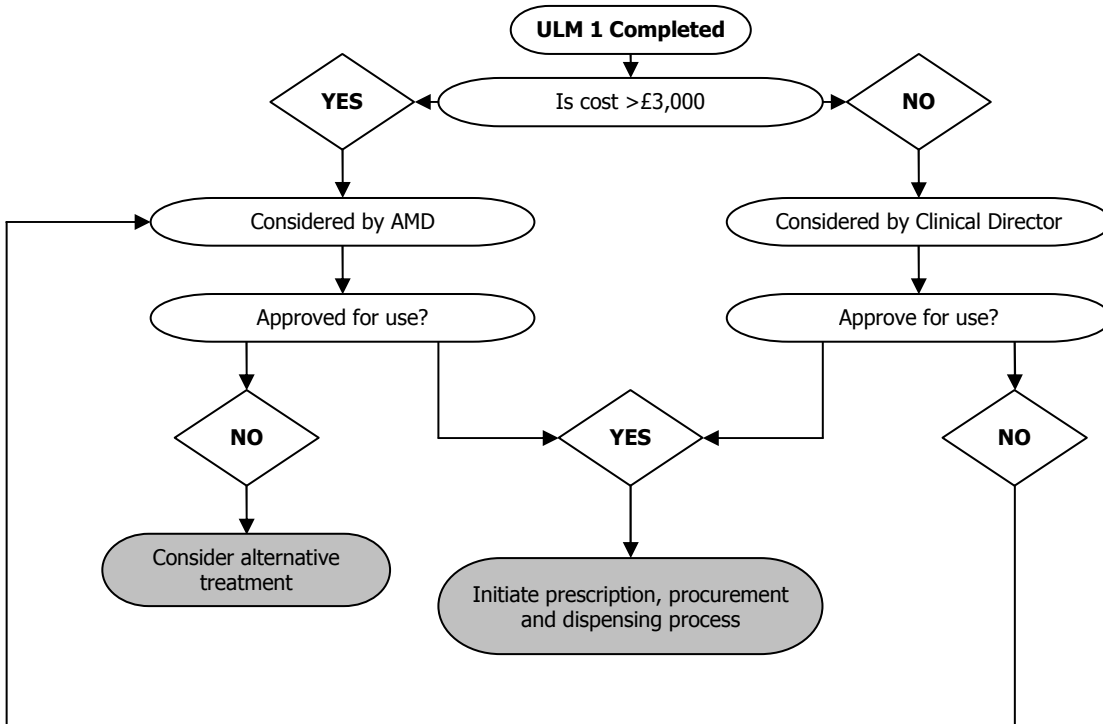
Discussion should take place with clinical peers, Medicines Information and clinical pharmacists as required to assign the risk

SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 2: WHEN IS AN ULM REQUEST FORM REQUIRED? (REVISED)



APPENDIX 3: HOW AN ULM REQUEST IS PROCESSED (REVISED)



SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 4: GMC GUIDANCE

http://www.gmc-uk.org/guidance/current/library/prescriptions_faqs.asp#5c

Prescribing unlicensed medicines

18. You can prescribe unlicensed medicines but, if you decide to do so, you must:
 - a. Be satisfied that an alternative, licensed medicine would not meet the patient's needs
 - b. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy
 - c. Take responsibility for prescribing the unlicensed medicine and for overseeing the patient's care, including monitoring and any follow up treatment (see also paragraphs 25-27 on prescribing for hospital outpatients)
 - d. Record the medicine prescribed and, where you are not following common practice, the reasons for choosing this medicine in the patient's notes.

Prescribing medicines for use outside the terms of their licence (off label)

19. You may prescribe medicines for purposes for which they are not licensed. Although there are a number of circumstances in which this may arise, it is likely to occur most frequently in prescribing for children. Currently pharmaceutical companies do not usually test their medicines on children and as a consequence, cannot apply to license their medicines for use in the treatment of children. The use of medicines that have been licensed for adults, but not for children, is often necessary in paediatric practice.
20. When prescribing a medicine for use outside the terms of its licence you must:
 - a. Be satisfied that it would better serve the patient's needs than an appropriately licensed alternative
 - b. Be satisfied that there is a sufficient evidence base and/or experience of using the medicine to demonstrate its safety and efficacy. The manufacturer's information may be of limited help in which case the necessary information must be sought from other sources
 - c. Take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring and any follow up treatment, or arrange for another doctor to do so (see also paragraphs 25-27 on prescribing for hospital outpatients)
 - d. Make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing the medicine.

Information for patients about the licence for their medicines

21. You must give patients, or those authorising treatment on their behalf, sufficient information about the proposed course of treatment including any known serious or common side effects or adverse reactions. This is to enable them to make an informed decision (for further advice, see [Consent: patients and doctors making decisions together](#)).
22. Some medicines are routinely used outside the scope of their licence, for example in treating children. Where current practice supports the use of a medicine in this way it may not be necessary to draw attention to the licence when seeking consent. However, it is good practice to give as much information as patients, or those authorising treatment on their behalf, require or which they may see as significant. Where patients, or their carers express concern you should also explain, in broad terms, the reasons why medicines are not licensed for their proposed use. Such explanations may be supported by written information, including the leaflets on the use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice produced by the [Royal College of Paediatrics and Child Health/Neonatal and Paediatric Pharmacists Group Standing Committee on Medicines](#).

SECTION 9: UNLICENSED MEDICINES POLICY

23. However, you must explain the reasons for prescribing a medicine that is unlicensed or being used outside the scope of its licence where there is little research or other evidence of current practice to support its use, or the use of the medicine is innovative.
24. For specific information on prescribing medicines for children see the websites of the [Royal College of Paediatrics and Child Health](#) and the [British National Formulary for Children](#).

Responsibility for prescribing medicines for hospital outpatients

25. Where a patient's care is shared between clinicians, the doctor with the responsibility for the continuing management of the patient must be fully competent to exercise their share of clinical responsibility. They also have a duty to keep themselves informed about the medicines that are prescribed for their patient. They should take account of appropriateness, effectiveness and cost when prescribing any medicine. They should also keep up to date with any relevant guidance on the use of the medicine and on the management of the patient's condition.
26. If you are the doctor signing and issuing the prescription you bear responsibility for that treatment; it is therefore important that, as the prescriber, you understand the patient's condition as well as the treatment prescribed and can recognise any adverse side effects of the medicine should they occur.
27. There should be full consultation and agreement between general practitioners and hospital doctors about the indications and need for particular therapies. The decision about who should take responsibility for continuing care or treatment after initial diagnosis or assessment should be based on the patient's best interests rather than on the healthcare professional's convenience or the cost of the medicine.

For specific information on prescribing medicines for children see the following websites: Royal College of Paediatrics and Child Health www.rcpch.ac.uk and the British National Formulary www.bnf.org.

APPENDIX 5: USE OF UNLICENSED MEDICINES IN PAEDIATRIC SERVICES

MEDICINES FOR CHILDREN
Information for parents and carers

What is this leaflet about?

In the UK most medicines are 'licensed' but some are not. This leaflet explains why medicines are licensed and why some useful medicines for children do not have licences.

You will have been given this leaflet by your doctor or pharmacist because the medicine prescribed for your child is not 'licensed' or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for your child and to answer any questions you may have.

Why are medicines 'licensed'?

The makers of medicines must ask the government for a 'Product Licence' if they want to sell their medicine in the UK. They show the government's Medicines Control Agency that their medicine works for the illnesses to be treated, does not have too many side effects or risks and has been made to a high standard.

How do the makers test medicines?

To be sure that a medicine works and is safe the maker has to try it first on a small number of people in what is called a 'clinical trial'. Information from clinical trials is given to the Medicines Control Agency when the maker asks for a Product Licence.

Why don't all medicines have a licence?

There are several reasons why some medicines are used for illnesses or conditions not covered by their original licence. Also, some medicines do not have a licence at all. Sometimes the clinical trial (and Product Licence) is for one illness but doctors find that the medicine works very well for another illness. Sometimes the patients in the clinical trial may have been adults but doctors find that the medicine works well for children too. These doctors use medicines for reasons or ages that are not written in the Product Licence.

Some medicines have no licence at all. These may be some liquid medicines that children can take easily or medicines used for rare illnesses. It may be too expensive or there may not be enough children with the illness to have a clinical trial. Sometimes it may not be worth their while for makers to test and produce specific medicines for children.

How do I know that these medicines are safe and will work?

This medicine will have been recommended by another doctor who is an expert or your own doctor will have read information that says it is the best one for your child.

Your pharmacist is trained to make medicines and if your child needs a special medicine will make sure that it is well made and will work properly.

SECTION 9: UNLICENSED MEDICINES POLICY

How will I know that my child's medicine is not licensed?

Your doctor or pharmacist may tell you. When you read the information leaflet with the medicine you may notice that the information is not quite 'right' or does not refer to children. The leaflet may not talk about your child's particular illness or condition or it may say that the medicine should not be used for your child's age.

Unlicensed medicines may be made specially or may be more difficult to get hold of or obtain. Your pharmacist may tell you this and make special arrangements for you to get your child's medicine.

Should I be worried about giving these medicines?

Doctors and pharmacists caring for children have a lot of experience with the medicines used for children whether the medicines are licensed or not. If you are still worried after reading this leaflet, please talk to your doctor or pharmacist. They are looking after your child and have carefully thought about the best medicine.

What if I don't want to use unlicensed medicines?

Talk it over with your doctor (or pharmacist) and tell them what you are worried about. They can tell you more about the information or advice that they have about the medicine. They can also tell you about any other treatments available and why they think this is the best one.

Can I get more information about this unlicensed medicine?

Your pharmacist may have made a special information leaflet about your child's medicine or illness. Please ask.

Often there are support groups for children with particular illnesses or conditions. If you are a member you could talk to someone from the group. If you are not a member or don't know if there is a group, ask your doctor, pharmacist or nurse for more information.

If I'm confused what should I do?

Talk to the person who gave you this leaflet (usually your doctor or pharmacist). Ask them to explain.

Doctors and pharmacists who work with children have written a book called 'Medicines for Children'. As well as talking about all the licensed medicines used for children it also talks about most of the unlicensed medicines. This may be one of the books that your doctor and pharmacist use when deciding the best medicine for your child.

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Date of preparation: August 2000

SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 6: ADULT INFORMATION LEAFLET

What is this leaflet about?

In the UK most medicines are 'licensed' but some are not. This leaflet explains why medicines are licensed and why some useful medicines do not have licences.

You will have been given this leaflet by your doctor or pharmacist because the medicine prescribed is not 'licensed' or is being used for a reason not covered by the licence. We want to reassure you that we have thought very carefully about the best medicine for you and to answer any questions you may have.

Why are medicines 'licensed'?

The makers of medicines must ask the government for a 'Product Licence' if they want to sell their medicine in the UK. They show the government's Medicines and Healthcare Products Regulatory Agency (MHRA) that their medicine works for the illnesses to be treated, does not have too many side effects or risks and has been made to a high standard.

How do the makers test medicines?

To be sure that a medicine works and is safe the maker has to try it first on a small number of people in what is called a 'clinical trial'. Information from clinical trials such as side effects and effectiveness is given to the MHRA when the maker asks for a Product Licence.

Why don't all medicines have a licence?

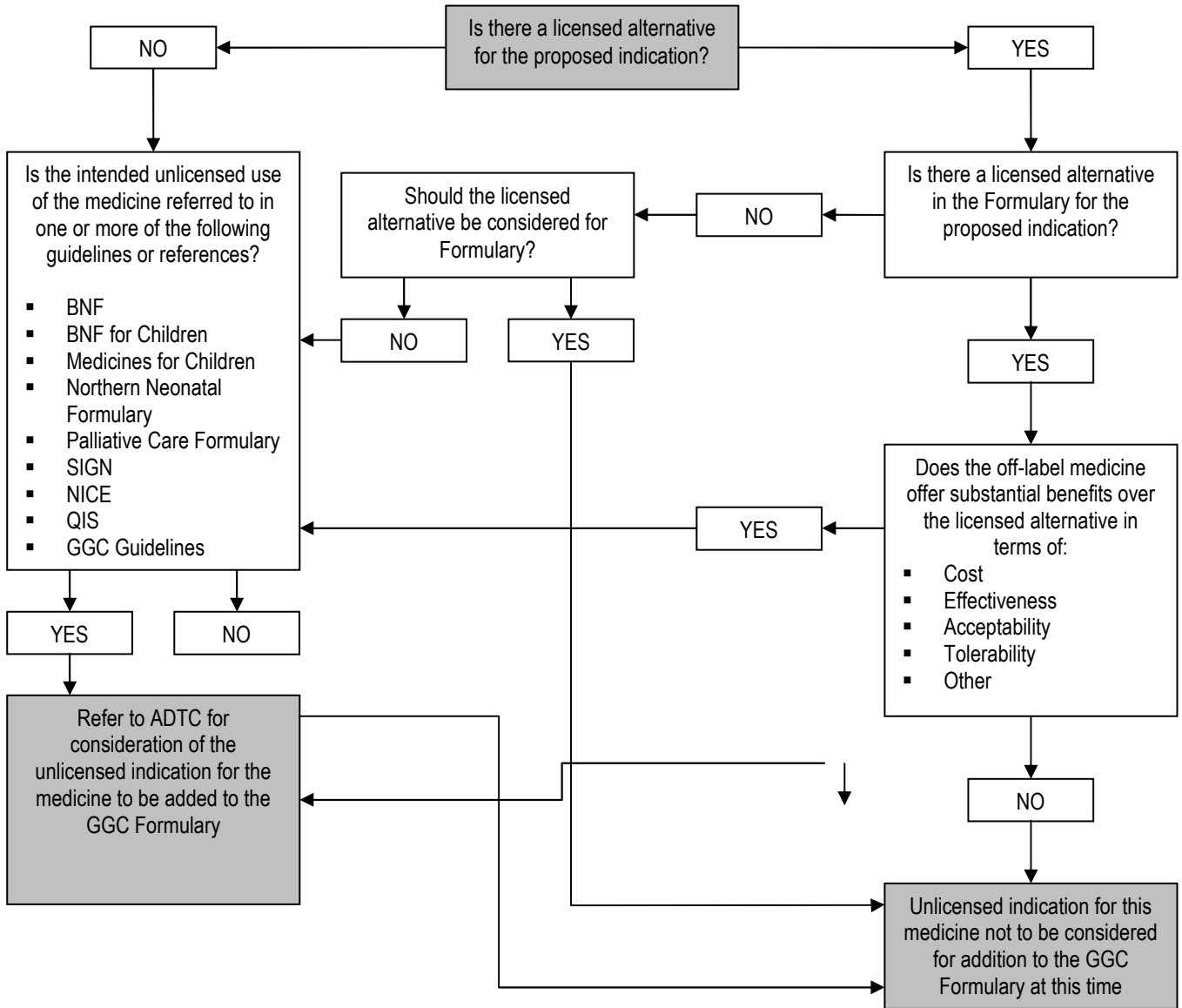
There are several reasons why some medicines are used for illnesses or conditions not covered by their original licence. Also, some medicines do not have a licence at all.

Sometimes the clinical trial (and Product Licence) is for one illness but doctors find that the medicine works very well for another illness for which it does not have a product licence. However, there will be clinical evidence to support the use of this medicine for your condition that your doctor will discuss with you.

Some medicines have no licence at all. This may be because it may be too expensive to have a clinical trial or too rare an illness to have a clinical trial. Sometimes it is because the medicine has not yet been given a product licence and is still being tested or waiting to be given a product licence. In this setting your doctor will discuss the information about the drug and discuss with you why this drug is more suitable for you than a medicine with a product licence.

SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 7: TEMPLATE FOR ASSESSING MEDICINES USE FOR INDICATIONS OUT WITH THE MARKETING AUTHORISATION FOR INCLUSION INTO THE FORMULARY



SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 8: UNLICENSED MEDICINES SHORT-LIFE WORKING GROUP

Acute Services Representatives

Anne Parker, Lead Clinician Haemato-oncology

Prof David Wray, Oral Health Directorate

Karen McGugan, Head Nurse for Diagnostics Directorate

Tim Cooke, Associate Medical Director Surgery & Anaesthetics Directorate

Stuart Rodger, Clinical Director Renal, Transplant and Homeopathy, Regional Services Directorate

Barbara Holland, Consultant Neonatologist, Women and Children's Services Directorate

Bibhas Ray, Consultant Obstetrician, Women and Children's Services

David Stewart, Associate Medical Director Emergency Care and Medical Services

Keith Beard, Consultant physician, Hospital Prescribing Adviser

Lynn Morrison, Regional Quality Assurance Pharmacist

Roy Foot, Lead Pharmacist, Formulary and Prescribing Interface

Colette Byrne, Lead pharmacist Clinical Governance,

Janice Watt, Principal Pharmacist Medicines Information,

Gordon Craig, Deputy Pharmacy Manager, Vale of Leven Hospital

Eleanor Sweeney, Senior Pharmacist, Yorkhill

Primary Care Representatives

John Nugent, Clinical Director CHP Chair

Barbara West, Local medical committee

Derek Brown, Consultant Psychiatrist

Andrew Power, Medicines Management in primary care

Robert Jamieson, Local medical Committee

Richard Groden, CD Chair of Primary Care Medicines Resource Management Group

SECTION 9: UNLICENSED MEDICINES POLICY

APPENDIX 9: ULM REQUEST FORM

**NHS GREATER GLASGOW AND CLYDE HEALTH BOARD
REQUEST FOR AN UNLICENSED MEDICINE OR HIGH-RISK USE OF A LICENSED
MEDICINE**



WHAT TO DO WITH THIS FORM

- This form should be completed by the requesting consultant when unlicensed medicines of high-risk off-label use of licensed medicine are considered for use
- If the medicine requested costs in excess of £3,000 per patient treatment, the requesting consultant should send the original form to the relevant Associate Medical Director (AMD) and General Manager (GM) (or their nominated deputy) for directorate approval.
- If the request is for an unlicensed medicine costing <£3,000, approval by the relevant clinical director will suffice
- Once a decision about the use of the medicine has been made by the relevant person(s), the form will be returned to the requesting consultant.
- All sections must be completed by all relevant persons prior to prescribing/requesting medicine to ensure that delays in treatment are minimised.
- The requesting consultant should then send the completed form accompanied by the prescription/medicine request to the relevant pharmacy department prior to supply being made. Acute pharmacy departments will have a designated pharmacist who deals with unlicensed medicines that can be contacted for advice and who will authorise the supply from a pharmacy perspective.
- This form is not intended to be used for specialist oncology services, which have their own process and documentation.

SECTION 1: CONSULTANT, DIRECTORATE PATIENT & MEDICINE DETAILS

<p>Patient Details: Attach addressograph or use patient CHI number and postcode CHI Number: <input type="text"/></p> <p>Postcode: <input type="text"/></p>	<p>Ward or department: <input type="text"/></p> <p>Hospital: (please tick)</p> <table border="0"> <tr> <td>GGH: <input type="checkbox"/></td> <td>GRH: <input type="checkbox"/></td> <td>GRI: <input type="checkbox"/></td> </tr> <tr> <td>INV: <input type="checkbox"/></td> <td>LEV: <input type="checkbox"/></td> <td>RAH: <input type="checkbox"/></td> </tr> <tr> <td>SGH: <input type="checkbox"/></td> <td>STO: <input type="checkbox"/></td> <td>VIC: <input type="checkbox"/></td> </tr> <tr> <td>VOL: <input type="checkbox"/></td> <td>WIG: <input type="checkbox"/></td> <td>YOR: <input type="checkbox"/></td> </tr> </table> <p>Other(specify): <input type="text"/></p>	GGH: <input type="checkbox"/>	GRH: <input type="checkbox"/>	GRI: <input type="checkbox"/>	INV: <input type="checkbox"/>	LEV: <input type="checkbox"/>	RAH: <input type="checkbox"/>	SGH: <input type="checkbox"/>	STO: <input type="checkbox"/>	VIC: <input type="checkbox"/>	VOL: <input type="checkbox"/>	WIG: <input type="checkbox"/>	YOR: <input type="checkbox"/>
GGH: <input type="checkbox"/>	GRH: <input type="checkbox"/>	GRI: <input type="checkbox"/>											
INV: <input type="checkbox"/>	LEV: <input type="checkbox"/>	RAH: <input type="checkbox"/>											
SGH: <input type="checkbox"/>	STO: <input type="checkbox"/>	VIC: <input type="checkbox"/>											
VOL: <input type="checkbox"/>	WIG: <input type="checkbox"/>	YOR: <input type="checkbox"/>											

Patient's Health Board: (Please indicate the Health Board that the patient currently resides in)

NHS Greater Glasgow & Clyde: <input type="checkbox"/>	NHS Lanarkshire: <input type="checkbox"/>	NHS Forth Valley: <input type="checkbox"/>
NHS Highland: <input type="checkbox"/>	NHS Ayrshire & Arran: <input type="checkbox"/>	Other: <input type="text"/>

Name of Consultant: (print clearly in capitals)

Page/contact number:

Directorate: (please tick)

Diagnostics: <input type="checkbox"/>	Emergency Care & Medical services: <input type="checkbox"/>	Surgery & Anaesthetics: <input type="checkbox"/>	Other: <input type="checkbox"/>
Rehabilitation & Assessment: <input type="checkbox"/>	Women's & Children's: <input type="checkbox"/>	Regional Services: <input type="checkbox"/>	(please specify below)

Medicine name and formulation requested:

Indication:

The request is for an UNLICENSED MEDICINE: The request is for an UNLICENSED INDICATION of a LICENSED MEDICINE:

NB: If the medicine is a licensed medicine that is being used out with its marketing authorisation, or the medicine is unlicensed, the prescriber carries the responsibility of the patient's welfare and may be called to justify his/her actions in the event of an adverse reaction.

SECTION 9: UNLICENSED MEDICINES POLICY

Supporting guidance:
(please tick all that apply
and provide further details
in the space below)

This particular use of this medicine is recommended in a relevant SIGN Guideline:

This particular use of this medicine is recommended in a relevant NICE Guideline:

This particular use of this medicine is recommended in other guidance (please specify):

Please provide further
details:

**Clinical rationale for
use in this patient,
including expected
outcome:**

(please submit any clinical
papers referenced with this
form)

Continue on a separate sheet if necessary

SECTION 9: UNLICENSED MEDICINES POLICY

Previous treatment for this indication:
(Including duration)

--

Expected duration of treatment:

--

Estimate of expected cost:
(indicate what cost is for e.g. treatment period or per year)

FOR AN UNLICENSED MEDICINE, IF THE ESTIMATED COST OF PRESCRIBING THIS MEDICINE IS IN EXCESS OF £3,000 PER PATIENT EPISODE, THEN DIRECTORATE APPROVAL IS REQUIRED.

Are there any supportive treatments needed for this treatment?

--

Reason why a licensed drug (or drug licensed for this indication) not selected:

--

SECTION 9: UNLICENSED MEDICINES POLICY

What are the risks to the patient if they DO receive this treatment?

(include any side effects or toxic effects that may be expected)

What will be used if this drug is not authorised?

Planned review:

(please state when and how response to treatment will be measured)

Where is the treatment to be delivered and does it impact on other areas?

(e.g. within acute sector or intended to be continued in primary care) indicate whether the use of this medicine will impact on other directorates or on Primary Care)

SECTION 9: UNLICENSED MEDICINES POLICY

SIGNATURE OF THE REQUESTING CONSULTANT AND DECLARATION OF INTERESTS:

NOTE TO REQUESTING CLINICIAN: IF THE REQUEST IS FOR AN UNLICENSED MEDICINE, OR THE OFF LABEL USE OF A LICENSED MEDICINE, PLEASE ENSURE THAT YOU HAVE READ THE NHSGGC USE OF UNLICENSED MEDICINES POLICY BEFORE SIGNING BELOW:

Consultant signature: Date:

You are required to declare any current interests you have in the pharmaceutical company who market the medicine you are requesting on this form. Tick one of the four boxes below that best describe the interests you have in the pharmaceutical company who make the requested medicine (e.g. personal, and specific). Current interests are those that have you have received within the last 12 months. If you have no declared interests, please write "NO INTERESTS" in the details box below.

	SPECIFIC INTERESTS These are interests relate directly to the medicine you are requesting	NON-SPECIFIC INTERESTS These are interests that relate to the company, but not directly to the drug you are requesting
PERSONAL INTERESTS Payments/fees/resources etc that you have received personally from the company		
NON-PERSONAL INTERESTS Payments/fees/resources etc that your department has received from the company		

DETAILS OF INTERESTS:
 Give details of your interests in this section:

SECTION 9: UNLICENSED MEDICINES POLICY

SECTION 2: AUTHORISATION PROCESS

NOTES:

1. Requests for treatment costing <£3,000 per patient treatment can be authorised by the relevant Clinical Director for the speciality. However, all requests costing in excess of £3,000 per patient treatment must be authorised at directorate level by the relevant Associate Medical Director and General Manager
2. If the use of this medicine will have an impact on any other directorates or on Primary Care, then this should be discussed with the relevant person(s) prior to the medicine being prescribed.

Approved for use: Yes: No:

If YES, conditions of use:
(e.g. authorised for use for a specific time period)

If NO, reason:
(Continue on a separate sheet if necessary)

Clinical Director authorisation (or nominated deputy):
(For requests <£3,000 per patient treatment)

Name:
(If nominee, please also state position)

Signature:

Date:

Associate Medical Director authorisation (or nominated deputy)
(For requests >£3,000 per patient treatment)

Name:
(If nominee, please also state position)

Signature:

Date:

Directorate General Manager authorisation (or nominated deputy) for pharmacy to purchase
(For requests >£3,000 per patient treatment)

Name:
(if nominee, please also state position)

Signature:

Date:

IMPORTANT NOTICE FOR CLINICAL DIRECTORS, ASSOCIATE MEDICAL DIRECTORS AND GENERAL MANAGERS

Once the authorisation section of this form is complete (regardless of whether the request has been accepted or not), the original form should be returned to the consultant who requested the medicine.
You may choose to retain a photocopy for your own records

The relevant pharmacy department will retain the original form once the supply has been made