



NHS TAYSIDE

**PRINCIPAL POLICY AREA
CLINICAL**

**Policy on the Prescribing of Medicines that
are Non-Formulary
(including Individual Patient Treatment Requests)**

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1. PURPOSE AND SCOPE

The safety, effectiveness and cost-effectiveness of medicines are controlled by regulatory and advisory processes. The two main processes are:

- The regulatory process - the majority of medicines that are prescribed have a marketing authorisation (i.e. licensed medicines). Safety, quality and efficacy are the criteria on which legislation to control human medicines licensing is founded. It is the responsibility of the Medicines and Healthcare Regulatory Authority (MHRA) or the European Medicines Evaluation Agency (EMA) and the expert advisory bodies to ensure that the sometimes difficult balance between safety and effectiveness is achieved.
- The advisory process – the Scottish Medicines Consortium (SMC) issues advice on the use of newly licensed medicines and new licensed indications, based on the cost-effectiveness of the medicine.

NHS Tayside has had for some time a robust procedure in place for the timely introduction of SMC guidance into the Tayside Area Formulary and clinical use. Newly SMC approved medicines prompt a Local Introduction Form to be completed by a clinician and Principal Pharmacist which is then reviewed by the Medicines Advisory Group, a subgroup of ADTC for inclusion on the formulary/specialist list.

Further to this CEL 17 (2010) outlines the need for NHS Boards to have a clear process for introduction of new medicines and consistency of process, as well as outlining NHS Boards responsibilities regarding openness and transparency of process and decisions with the public. Key aspects of considering Individual Patient Treatment Requests are also covered.

The scope of this policy extends to the prescription of:

Unlicensed

- unlicensed medicines (*category 1, which includes special formulations*)

Licensed

- “off-label” medicines, i.e. use out with their licensed indications (*category 2*)
- prior to Scottish Medicines Consortium (SMC) advice (*category 3*)
- outwith Scottish Medicines Consortium (SMC) (*category 4*). This includes SMC not recommended and SMC non-submissions
- outwith NHS Tayside Drug and Therapeutics Committee advice. (*category 5*). This includes medicines that are accepted by SMC but are not listed in the formulary/specialist list or local protocols.

Where the prescriber wishes to prescribe in any of the above circumstances, a proforma should be completed (Appendix 1).

2. OUTLINE GLOSSARY

Marketing Authorisation

Previously medicines were described as having a “*product licence*”. Under the new arrangements, medicines are now more correctly described as having a marketing authorisation. A marketing authorisation defines the clinical conditions, routes of administration, dosages and precautions for which the licensing authority has approved a medicine.

Unlicensed Medicines and 'Off-label' medicines

Prescribing practice involves the use of unlicensed drugs, (products which have not been licensed for human medical use) and off-label drugs (licensed medicines prescribed outside the terms of their marketing authorisation).

Specials

Special formulations of medicines are produced for clinical reasons where an existing formulation of an available licensed product is not suitable or available for the patient.

3. BACKGROUND INFORMATION

The Licensing of Medicinal Products is covered by Parts One and Two of the Medicines Act 1968, as amended. The Licensing Body in the UK is the Medicines and Healthcare Products Regulatory Agency (MHRA), but in many cases, the relevant Licensing Body is now the European Medicines Evaluation Agency (EMA). Additional requirements are enshrined in European Law. A product holding a full Marketing Authorisation (MA) will do so after a full evaluation by the MHRA or EMA of all data required for the product. The MA holder is required to ensure that full Product Information is supplied to both the prescriber and dispenser of the product. The MA confers liability upon the Holder for the product in use when the terms of the licence are complied with.

The majority of medicines prescribed within NHS Tayside are covered by marketing authorisations and the manufacturer is held liable for any harm caused where the cause can be solely attributed to a defect in the product, and it can be proved that the product was prescribed and used in accordance with the terms of the Marketing Authorisation. For good clinical reasons, a number of medicines that either do not have a marketing authorisation (Unlicensed medicines) or are prescribed for indications out with their marketing authorisation (Off-label use), are used within NHS Tayside. Were this practice to be curtailed, the treatment of patients would be impeded.

Prescribers of unlicensed medicines have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine. NHS Tayside carries a liability for the actions of its employees and may accept liability for the prescription of unlicensed medicines provided that this Policy on the Prescribing of Medicines that are Non-Formulary is adhered to.

Where it is intended that treatment will be continued after patient discharge, clear arrangements require to be agreed between primary and secondary care regarding clinical and prescribing responsibilities, using appropriate processes such as shared care arrangements. Prescribers are referred to the NHS Tayside Shared Care Policy. Retention of prescribing responsibility within secondary care should be considered as an option.

4. STATEMENT OF POLICY

The clinical liability associated with the prescribing of unlicensed medicines or medicines prescribed out with their marketing authorisation may be accepted by Tayside Health Board, provided that its employees have followed this policy for the prescribing of such medicines. The NHS Tayside Drug and Therapeutics Committee have the responsibility to define local policies to guide the prescribing

of unlicensed medicines within NHS Tayside. Where a licensed medicine is available, it should be prescribed in preference to any unlicensed equivalent alternative. The following criteria should be applied, at all levels of the decision making process, prior to the decision to prescribe a non-formulary/non specialist list medicine.

1. There is no suitable licensed alternative, if unlicensed, out with licence or pre SMC or out with SMC.
2. The risk-benefit assessment for the patient is in favour of prescription.
3. There is a clinical and economic evidence-base to support this usage.
4. The patient is an exceptional case.
5. Prescribing is supported by multi-professional opinion.
6. The patient/carer has been fully informed and has consented or will consent.
7. There is a risk associated with waiting for treatment. (Consider when products are about to be licensed or SMC advice is about to be issued.)

Prescribers should only commence a prescription medicine for a non-formulary medicine when the appropriate approval outlined in Appendix 1 is granted. In an effort to ensure a consistent approach across NHS Tayside, completion of the proforma detailed in Appendix 1 is essential. Secondary care prescribers should only request that primary care continues the prescribing of a medicine that is non-formulary when the appropriate approval is granted through this policy, an adequate secondary care trial of medication has established tolerability and benefit of treatment, a shared care agreement/individual patient treatment plan is in place where appropriate and the arrangement has been agreed by the patient's GP.

At this time, NHS Tayside does not support the prescription of unlicensed medicines by non-medical prescribers. In exceptional circumstances, where this is deemed to be necessary, prescribers should seek a supporting decision from the appropriate non-formulary/IPTR Panel. Again, this requires the completion of the proforma detailed in Appendix 1. Whilst Patient Group Directions may be developed for the supply of medicines prescribed out with their marketing authorisation, such cases are likely to be exceptional and it is expected that a clear justification for the use made. Non-medical prescribers are referred to the Tayside Non-Medical Prescribing Policy.

5. POLICY PROCESS

NHS Tayside makes a distinction between prescribing for groups of patients which should be done via submission to the Medicines Advisory Group for inclusion on the Tayside Area Formulary (TAF)/Specialist List and that for Individual Patients.

5.1 Prescriptions for Unlicensed Medicines (category 1), including Special formulations

5.1.1 Unlicensed Medicines (category 1)

The NHS Tayside Drug and Therapeutics Committee expects that all **prescriptions for a new unlicensed medicine** should be brought to attention of the prescribers Clinical Group and approval granted via the appropriate non-formulary/IPTR panel. The proforma outlined in Appendix 1 should be used to seek this approval. The decision to prescribe or otherwise

should be documented in the patients notes and the non-formulary/IPTR data-base should be completed.

5.1.2 Special formulations

The prescription of unlicensed special formulations or "Specials" is uncommon within NHS Tayside. A "Special Formulation" is defined by the Medicines and Healthcare Products Regulatory Agency (MHRA) as an "unlicensed relevant medicinal product placed on the market". These are prescribed in both secondary and primary care. A "Special" should only be prescribed where no licensed formulation is available to meet a prescription presented by a patient for:

- Unusual strengths of existing licensed products
- Unusual presentations of existing active principles
- Imported products (not otherwise available in the United Kingdom)
- Preservative-free alternatives to licensed formulations
- Other products not otherwise commercially available.

Where an unlicensed special formulation is prescribed and dispensed, the following additional conditions are noted:

- The prescriber must be appraised by the pharmacist that he or she bears clinical responsibility for prescribing an unlicensed product, and that full prescribing information about the product is probably unavailable. This approach should be made when the first prescription or order is received.
- The pharmacist supplying the product shares clinical responsibility for the suitability of the product for the individual patient. He or she also bears responsibility for the quality of the product, and is also obliged to be certain that the product is fit for safe use by the patient. Community pharmacists should be aware of and follow the NHS Tayside policy on permission to supply specials.

The prescribing of a special formulation of a Tayside formulary medicine does not require submission of a non-formulary request form.

5.2 Licensed Medicines

- **Out with their Marketing Authorisation (off – label) (category 2)**
- **Prior to Scottish Medicines Consortium (SMC) advice (IPTR) (category 3)**
- **Out with SMC advice (category 4)**
- **SMC accepted but NHS Tayside Non-Formulary (IPTR) (category 5)**

The prescription of medicines, **outside their marketing authorisation**, is not common within NHS Tayside, however patients may require medicines for conditions not specified or at dosages not recognised by current licences. On occasion, a clinician may be unaware that the intended use is not a licensed use. This can occur where medicines within the same class do not have the same range of licensed indications. Many medicines prescribed in paediatrics are not licensed for prescription in neonates or children. (See Section 5.3 – Prescribing in Paediatrics).

- For **routinely prescribed licensed medicines in an unlicensed context or routinely prescribed unlicensed medicines**, it is acknowledged that it is very difficult to maintain a comprehensive approach and to secure approval via the application form in Appendix 1 in a timely and efficient manner. The risk assessment process is reflected only in the commonality of approach adopted by a wide range of clinicians. In any case of liability assessment, this would be the basis of defence i.e. that peer group practice clearly supported the prescriber. A list of such medicines should be held within each Clinical Group, under the specialist list process.
- The Drug and Therapeutics Committee expects that **all unusual and not well-understood unlicensed prescription of licensed medicines (category 2)** should be brought to attention of the prescribers Clinical Group and Lead Clinician for that speciality. Such medicines and prescribing practice should be formalised on the specialist list for that area. A prescription for an item not on the formulary/specialist list should not be produced until approval is granted through the application form in Appendix 1. The decision to prescribe or otherwise should be documented in the patient's medical notes and an entry included in the non-formulary/IPTR database.

If clinicians wish to prescribe a new medicine that has been licensed in the United Kingdom for the particular indication of interest, but has **not** gone through SMC (**category 3**) or is out with SMC (**category 4**), they should make a case for an Individual patient treatment request (IPTR) and complete the proforma in Appendix 1. The decision to prescribe or otherwise should be documented in the patient's medical notes and an entry included in the non-formulary/IPTR database.

If clinicians wish to prescribe a medicine that has been licensed for the indication of interest, has been accepted by SMC but has not been added to the formulary/specialist list or local protocol for that clinical area (**category 5**) they should complete the proforma in Appendix 1. This includes situations where a protocol is pending update. The decision to prescribe or otherwise should be documented in the patient notes and an entry included in the non-formulary/IPTR database.

- The Drug and Therapeutics Committee expects that, in exceptional circumstances, when a **non-medical prescriber wishes to prescribe a medicine for an unlicensed purpose**, a supporting decision is gained under the non-formulary/PTR process using the proforma in Appendix 1. The decision to prescribe or otherwise should be documented in the patient's medical notes.

To reiterate, in all of the above situations, it is expected that approval for prescription is granted via the application form in Appendix 1 which is considered in the first instance by the Lead Pharmacist for the Clinical Group or Community Health Partnership. The Lead Pharmacist is expected to give advice on the appropriateness of the request and to identify realistic alternatives, to progress the application to the non-formulary/IPTR panel as appropriate and also ensure completion of the non-formulary/IPTR database.

5.3 Prescribing in Paediatrics

Due to the number of medicines that are not licensed for paediatric use, it is recognised that the routine obtaining of consent for unlicensed prescribing in **paediatric practice** is not usual. Prescribers in paediatric practice must be able to provide justification for their actions if they do not provide suitable information to the patient and carer and gain their consent. It is therefore recommended that prescribing follows nationally accepted practice and reflects the advice given in the British National Formulary for Children (BNFC). It is also recommended that routine prescribing practice out with BNFC guidance be held on specialist list for paediatric prescribing. However, if the medicine is unlicensed or off-label and not prescribed routinely (an unusual and not well understood unlicensed prescription) within paediatrics, then prescribing should only follow approval via the proforma in Appendix 1. The final decision to prescribe or otherwise should be documented in the patient's medical notes and an entry included in the non-formulary/IPTR database.

6. Individual Patient Treatment Requests (IPTR's)

There may be occasions where a prescriber feels that his/her patient will benefit from a licensed medicine that has been recommended not to be used in NHS Scotland. i.e. medicines either awaiting SMC guidance or for which the SMC has recommended should not be used in NHS Scotland. Requests for such non-formulary medicines are termed IPTRs and can only be progressed if the clinician responsible for the patients care supports this action. At this point the patient or their carer should be given the leaflet '[New medicines in Scotland – who decides what the NHS can provide?](#)' as well as explaining the timeframes for decision making and that they are the patients point of contact in NHS Tayside for this process.

IPTR's for category 3 and category 4 medicines can only be progressed if the clinician demonstrates:

- The individual for whom the treatment is being sought presents with a clinical condition or patient clinical characteristics which are significantly different to the general population of patients who have the condition in question;

and

- The individual for whom the treatment is being sought is likely to gain significantly more benefit from the intervention than might normally be expected from the general population of patients with the condition in question.

Decision-making takes place in two stages to answer the following:

1. Are significantly different clinical circumstances demonstrated?
2. If significantly different clinical circumstances are demonstrated should the request for treatment be supported and funded?

Only where requests to prescribe such medicines are deemed to meet criteria 1 above will the decision-making panel move on to consider whether authorisation of the treatment should be provided. NB: Meeting clinical criteria in 1 above does not automatically result in authorisation to use the medicine.

Once completed by the requesting clinician, the non-formulary/IPTR request form (Appendix 1) should be forwarded to the appropriate Lead Pharmacist/ Principal Clinical Pharmacist for the clinical area.

It is important that the clinically relevant timescale needed for a decision is supplied on the request form by the requesting clinician. The panel will require this to process the form in a timeframe that does not impede patient care. These timeframes should also be shared with the patient/carer.

Where a request is successful, agreement will be made with the treating clinician and patient as to how success of individual treatment will be defined, i.e. what clinical outcomes would need to be achieved for continuation of treatment to be allowed and in what timescale those outcomes should be achieved. These outcomes will be a written part of the authorisation. Where these outcomes are not achieved, or the patient is not achieving clinical benefit from the medicine, the agreement should explicitly state that treatment with the medicine will cease.

The decision-making Panel will either approve or not approve the request providing a statement of their decision on the request form. A copy of the request form stating the decision and signed by the Chair of the panel along with the agreed note of the meeting will be provided to the requesting clinician following the decision. A further copy of the request form will be held on a central secure database. An entry will also be included in the non-formulary/IPTR database.

6.1 Panel Constitution

In order for panel membership to be appropriate to the different hierarchal structures of directorates and primary and secondary care, non-formulary/IPTR panel constitution cannot be too proscriptive. However any panel decision must include at least one doctor and one pharmacist, being chaired by the most senior doctor. Panels are expected to include a practising medical consultant with (or access to) specialist knowledge of the relevant clinical area as appropriate. Also in order for decision making to be timely to meet clinical need, such panels may have to work in a virtual environment via secure e-mail communication. Each panel member will have to submit any declaration of interest regarding the decision in question and may then be excluded from this particular decision.

Examples of panel members should include:

- Associate Medical Director
- Lead Speciality Consultant
- Lead GP
- Lead/Principal Clinical Pharmacist
- Clinical Service Manager
- Head of Patient Care & Nursing

6.2 Patient Representation

There is no requirement for patient or carer involvement in the decision process; however a patient or their representative may wish to submit a statement in support

of the request. The patients point of contact (requesting clinician) with NHS Tayside should facilitate and support this should the patient wish it. **A lack of supporting statement will have no detrimental effect on the outcome. The patient or carer may attend the panel meeting, prior to the hearing, to deliver their statement. This attendance is at the discretion of the chairman.**

7. APPEALS PROCESS

An Appeals Process has been set up to allow any prescriber to appeal against the decision made by the Clinical or CHP Group. An Appeal may be requested where it is considered that:

1. The Clinical/CHP Group or non-formulary/IPTR panel has failed to act fairly and in accordance with its procedures.
2. The Clinical/CHP Group or non-formulary/IPTR panel has prepared advice that is perverse in light of the evidence submitted.
3. The Clinical/CHP Group or non-formulary/IPTR panel has exceeded its powers.

Appeals against rejected non-formulary/ IPTR requests will be heard by the NHS Tayside executive Appeals Panel, which should be made up of the following personnel:

NHS Tayside Chief Executive or executive director deputy
 Chair of the Drug and Therapeutics Committee
 NHS Tayside Medical Director
 Director of Pharmacy
 Non-Executive Director
 Chair of the relevant Clinical/CHP Group where decision was turned down
 Appellant

The appeal should be submitted in writing to the Medical Director and heard by the Appeals Panel within 20 working days (Monday to Friday) of receipt, unless it is clinically essential to be earlier as stated on the request form.

The decision of the Appeals Panel should be forwarded to the Appellant verbally immediately after the meeting and, in writing, within 48 hours (Monday to Friday). Decisions should be documented in the patient's notes by the Appellant. An entry should also be included in the non-formulary/IPTR database.

8. RESPONSIBILITIES AND ORGANISATIONAL ARRANGEMENTS

	Responsibility	Organisational Arrangement
Individual Prescriber	<p>To gain peer support for the prescribing decision from Lead Clinician or other consultant in the field if this is not possible before application:</p> <p>Unlicensed</p> <ul style="list-style-type: none"> • unlicensed medicines (<i>category 1, which includes special formulations</i>) <p>Licensed</p> <ul style="list-style-type: none"> • “off-label” medicines (<i>category 2</i>) prior to Scottish Medicines Consortium (SMC) advice (<i>category 3</i>) out with SMC advice (<i>category 4</i>) SMC accepted but Tayside non-formulary (<i>category 5</i>) 	See Appendix 1: Request to prescribe a non-formulary medicine.

Lead/ Principal Clinical Pharmacists	To review the evidence that supports individual requests to prescribe non-formulary medicines and suggest alternatives, approve request or escalate to non-formulary/IPTR panel. Provide advice and support to clinical group/CHP and/or non-formulary/IPTR panel.	Clinical Group/CHP
Clinical Groups and CHPs	To establish and maintain processes that enable the transparent review of significant non-formulary requests (including IPTRs).	Clinical Group/CHP
NHS Tayside Drug and Therapeutics Committee	To monitor the implementation of the Policy on the Prescribing of Medicines that are Non-Formulary. To review situations in which medicines are requested by secondary care for use in primary care which require a shared care protocol.	DTC

9. PATIENTS RECEIVING CONCURRENT TREATMENT FROM NHS AND PRIVATE PROVIDERS.

The following guidance was issued from the Scottish Executive (SEHD/CMO(2007)3) in February 2007.

1. Clinicians may receive requests from patients to supplement NHS treatments with drugs or other treatments not currently available from the NHS following SMC and/or NHS Quality Improvement Scotland advice. This guidance sets out the legal position and the process that should be followed in such circumstances.
2. If a patient seeks to pay for one or other part of a possible treatment episode or total package of care not currently available from the NHS whilst at the same time continuing with the rest of that episode or total package of care within the NHS Scotland, NHS Boards will wish to be aware that:
 - There is no legislation that allows NHS Boards to require the patient to pay for all aspects of their treatment if they opt to pay for a particular drug or other treatment not currently available from the NHS
 - There should be protocols and processes already in place within NHS Boards for consideration of such non-NHS Formulary treatment requests. (This policy covers such prescribing for exceptional use).
 - If, in the opinion of the prescribing clinician there is a case to be made, non-NHS formulary protocols and processes should be followed in all such cases in line with local guidance. (This policy covers such exceptional use prescribing).
 - Each request for non-NHS formulary treatments (prescribing for exceptional use) should, therefore, be considered on its individual merit.
 - NHS Consultants cannot treat a patient both as a private patient and as an NHS patient for the treatment of one condition during a single visit to an NHS organisation (section 2.2 of the Consultants Contract).

If a patient who has been offered a treatment or total package of care from the NHS chooses to reject this in favour of an alternative option not currently available from the NHS (see paragraph 1) and where non-formulary (prescribing for exceptional use) request process(es) have been exercised and exhausted, they should be advised of alternative options that may be available, for example, provision via the independent sector of the treatment in question and/or total package of care as appropriate to the individual case.

3. A patient cannot be both a private and an NHS patient for the treatment of one episode of care (see paragraph 2). For patient safety reasons and good clinical governance, protocols should be in place to ensure safe and effective handover of the patient to the lead independent sector clinician or to ensure the safe provision of concurrent treatment where appropriate. NHS Boards should seek to establish such protocols with independent sector providers.
4. This guidance does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

10. KEY CONTACTS

	Location	Contact Number
For GP prescribing	Lead Pharmacists: Angus CHP Dundee CHP Perth and Kinross CHP	01307 474846 01382 424151 01738 473967
For secondary care prescribing	Principal Pharmacist in Speciality	

Sources of information

- (1) MHRA Guidance Note 14: The supply of unlicensed relevant medicinal products for individual patients. Medicines and Healthcare Products Regulatory Agency, May 2005.
- (2) BNF for Children 2005. BMJ Publishing Group Ltd. London 2005.
- (3) Page D. *Special formulations in primary care: A guide for pharmacists*. Information and Statistics Division, Edinburgh. 2002.
- (4) Royal College of Paediatrics and Child Health. The use of unlicensed medicines or licensed medicines for unlicensed applications in paediatric practice. Policy statement produced by the joint RCPCH/NPPG Standing Committee on medicines. www.rcpch.ac.uk/publications (accessed May 2006).
- (5) Faculty of Family Planning and reproductive health care Clinical Effectiveness Unit Guidance (2005). The use of contraception outside the terms of the product licence. *J. Fam Plann Reprod Health care* 2005; 31(3); 225-241

REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE

This form (guidance on completing this form is available in Appendix 2) should be completed by the clinician* who wishes the patient to receive a non-formulary medicine in any of the following circumstances:

Unlicensed

- unlicensed medicines (*category 1*)

Licensed

- “off-label” medicines (*category 2*)
- prior to Scottish Medicines Consortium (SMC) advice (*category 3*)
- outwith SMC advice (*category 4*)
- within SMC advice but outwith formulary/specialist list or protocols (*category 5*)

* note that a specialist recommending treatment from an outpatient clinic should complete this form and submit to the relevant Principal Clinical Pharmacist/Lead Pharmacist

1	Clinical group/CHP:
2	Clinical team/speciality:
3	Requesting clinician:
4	Patient CHI:
5	Requested medicine:
6	Indication the medicine is to be used for:
7	Dose: (including strength, form and frequency)
8	Anticipated duration of treatment:
9	Treatment cost: Annual Cost:
10	<p>Exception category <i>(please tick)</i></p> <p><input type="checkbox"/> Unlicensed for any indication (CATEGORY 1) NB: Read Policy Section 3 I have read and understood section 3. Signed:</p> <p><input type="checkbox"/> Off-label i.e. licensed for other indications (CATEGORY 2)</p> <p><input type="checkbox"/> Licensed and prior to SMC advice (CATEGORY 3)</p> <p><input type="checkbox"/> Licensed and outwith SMC (CATEGORY 4)</p> <p><input type="checkbox"/> Licenced and within SMC advice but outwith formulary/specialist list/protocols (CATEGORY 5)</p>

11 Reason for Request:

Continuation of medicine initiated in primary care **Go to section 22**
(If previous authorisation not granted: supply may be refused)

Continuation of previous hospital supply **Go to section 22**
(If previous authorisation not granted: supply may be refused)

Continuation of medicine approved in other health board

New treatment decision

12 Will treatment continue:

Only in hospital **Hospital and then primary care**

If to be continued in primary care:

Individual Patient Treatment Plan written*

***Seek advice from Principal Pharmacist.**

13 Previous treatments that the patient has received:

14 Explain why available licensed and formulary medicines are not appropriate in this case:

15 Summary of peer reviewed evidence for use in this indication in terms of safety, clinical and cost effectiveness if available. (attach relevant references):

NB: If for category 1 or 2 then safety evidence is necessary to enable a risk/benefit assessment.

Evidence Quality *Please tick*

<input type="checkbox"/>	I RCTs
<input type="checkbox"/>	II Case control or cohort studies
<input type="checkbox"/>	III Non-analytic studies e.g. case reports, case series
<input type="checkbox"/>	IV Expert opinion

16 Treatment outcomes and timescales:

Please note that treatment will only be authorised if agreed outcomes and timescales are clear. If approved, circumstances in which treatment may cease should be explained to the patient or carer by the prescriber. Please indicate clearly circumstances in which treatment will be stopped.

17 Service implications (if any):

18 Exceptionality (exception categories 1, 3 & 4):

E.g. Explain how the patient is expected to gain significantly greater benefit from this drug than the normal treatment group considered by SMC or NHS Tayside policy for this drug.

19 Monitoring requirements for treatment:

If required of primary care, an individual patient treatment plan is needed (seek advice from pharmacy)

20 Details of all discussions relevant to this case:

E.g. Advised by national experts, second opinions, colleagues etc.

21 Timeliness:

Please indicate timeframe, if relevant, in which decision is needed.
This must be realistic and clinically relevant.

22 Declaration:

I declare I have completed a conflict of interest form, that I have explained this process to the patient or carer and that approval is not guaranteed.

For Exception categories 3 & 4 I have given the patient the leaflet ['New medicines in Scotland – who decides what the NHS can provide?'](#)

Signed:

BLOCK CAPITALS:

E-Mail Address:

Page:

Clinician in support of application:

Name/Signature

BLOCK CAPITALS:

Date:

AUTHORISATION:

To be completed by the Principal Clinical Pharmacist/Lead Pharmacist

I have reviewed the request and the evidence for safety, clinical and cost effectiveness.

Request Approved Clinical Service Manager notified Yes N/A

Request referred to Clinical Group/CHP level

Request referred to non-formulary/IPTR panel

Request rejected

Name:

Signature:

Date:

NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.

Rationale behind decision:

AUTHORISATION:

To be completed by Chair of the decision-making panel

Decision and supporting statement:

(Including any conditions such as duration, evidence of outcomes etc)

NB: Ensure original is returned to medical notes and a copy forwarded to patients GP.

Name:

Signature:

Date:

REQUEST TO PRESCRIBE A NON-FORMULARY MEDICINE GUIDANCE NOTES

Requests to prescribe a non-formulary medicine should be considered by the relevant group as follows:

- Secondary Care – relevant Clinical Group
- Oncology and Haematology requests – Oncology & Haematology Medicines Management Group (OHMMG)
- Mental health, Care of the elderly, General practice requests – CHP panel

The Clinical Group/OHMMG/ CHP panel must consider whether there are overriding factors that make the decision not to prescribe unreasonable in the particular circumstances.

Please note:

- Secondary care clinicians who wish a patient to receive a medicine that is unlicensed or prior to/outwith SMC advice should make a case to their Clinical Group, as well as complete the proforma in Appendix 1. Prescribing approved by the Clinical Group and/or non-formulary/IPTR panel remains the clinical and financial responsibility of secondary care ie such medicines should normally be supplied from hospital. Primary care should only be asked to continue prescribing if: This is the best care delivery method for the patient AND an adequate secondary care trial of medication has established tolerability and benefit of treatment AND a shared care agreement/ Individual Patient Treatment Plan is in place where appropriate AND the arrangement has been agreed by the patient's GP.
- A separate form should be completed for each case, this process is not to be utilised for treatment of groups of patients where it is known at the time a group exists. For groups of patients a submission should be made to the Medicines Advisory Group after approval of the appropriate clinical group if in secondary care.
- Following discussion by the Clinical Group/OHMMG/ CHP panel, completed forms should be forwarded to the relevant Principal or CHP Lead Pharmacist and copied to the Tayside Medicines Governance Unit fao Mrs Karen Law. The non-formulary/IPTR database should also be completed.
- Appeals should be submitted as outlined in section 7 of the policy, seek early advice from the appropriate Principal/Lead Pharmacist if required.

Guidance on specific questions:

Requested medicine (Q.5)

The approved (generic) and brand name should be entered

Anticipated duration of treatment (Q.8)

Length of treatment should the unlicensed/new medicine be approved for use in this patient e.g. one course of 7 days; life-long; or duration of trial period, if that is what is intended.

Cost (Q.9)

The NHS cost for a relevant treatment period e.g. per course or per 28 day treatment period.

Reason for request (Q.11)

If the medicine is continued from another health board then details of that approval would be helpful to the application but NHS Tayside will make an independent decision.

Treatment continuation (Q.12)

If secondary care wishes to transfer the liability of prescribing to primary care on the basis that this is necessary for the patients optimal care, the appropriate approval of primary care must be sought, see notes above.

Previous treatment options and alternatives (Q.13 & 14)

Provide details of previous treatment options the patient has received. State any alternative medicines also licensed for the indication and reasons why they are not being used in this case.

Clinical evidence (Q.15)

Provide details of clinical outcomes associated with this unlicensed/new medicine in this patient group eg increase in disease free survival, overall survival and quality of life. Indicate the quality of evidence to support use, attach relevant references. For category 1, unlicensed medicines, evidence of safety is vital to construct a risk: benefit argument supporting use. If the medicine represents a financial liability then evidence of cost effectiveness will usually be required, such as alternative costs saved, hospital admissions reduced etc.

Treatment outcomes and timescales (Q.16)

In order to ensure financial governance clear timescales for treatment trial, duration and exit strategies will need described. Objective measures of treatment success and failure resulting in treatment stopping will usually need described, it is also desirable for this to be explained to the patient if clinically appropriate.

Service Implications (Q.17)

Describe any service pressure that will result, such as additional expensive tests/monitoring. Describe any service savings if not previously described.

Exceptionality (Q.18)

In this section you must explain why this patient's clinical circumstances and potential response to treatment with this medicine would be significantly different from the patient group/population considered by SMC/NHS QIS or NHS Tayside. The significant benefit you expect this patient to gain must be clearly explained and how you expect to measure/demonstrate this.

Timeliness (Q. 21)

Please describe the timescale within which a decision is needed. It is very difficult to hold frequent panels, NHS Tayside will endeavour to hold in-person panels for these requests. Should an urgent decision be clinically necessary please indicate this and why. A decision will be taken via the most appropriate communication means to meet the clinical deadline.

Declaration (Q.22)

It is important to describe this process to the patient/carer, and to explain that the request may be rejected so as not to raise false hope/expectation if this is clinically appropriate. Ensure also you provide the patient/carer with the described leaflet, the hyperlink to which is on the electronic form. See Appendix 3 & 4.

STANDARD EXPLANATION OF DECLARATIONS OF INTEREST

Personal Interests

A personal interest involves personal payment to the individual personally. The main examples are:

- Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind.
- Fee-Paid Work: any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind.
- Shareholdings: any shareholding in or other beneficial interest in shares of the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence or financial management.

Non-Personal Interests

A non-personal interest involves payment which benefits a department for which an individual is responsible, but is not received by the individual personally. The main examples are:

- a. Fellowships: the holding of a fellowship endowed by the pharmaceutical industry.
- b. Support by the pharmaceutical industry: any payment, other support or sponsorship by the pharmaceutical industry which does not convey any pecuniary or material benefit to an individual personally but which does benefit his/her position or department e.g.
 - A grant from a company for the running of a unit or department for which an individual is responsible;
 - A grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which the individual is responsible. This does not include financial assistance for students;
 - The commissioning of research or other work by, or advice from, staff who work in a unit for which the individual is responsible.

Interests are considered to have lapsed after 2 years.



DECLARATION OF INTERESTS

It is important that any interests in pharmaceutical companies that may be relevant to this submission are declared.
 Please complete this section regardless of whether you have any declared interests or not. (See Appendix 3).

Clinician Declaration of Interest	
I have an interest in the following pharmaceutical companies that are relevant to this application –	
Current Personal Interests (consultancy fees, fee-paid work, shareholdings etc.):	
Non-Personal Interests (Fellowships, Department grants/fellowships, sponsorship etc):	
Clinician's Signature	
Date	