

**POLICY FOR PROCESSING UNLICENSED, OFF LABEL OR INDIVIDUAL  
PATIENT TREATMENT REQUESTS (IPTR)**

<b>Title</b>	<b>NHS Borders Policy for Processing Unlicensed, Off label or Individual Patient Treatment Requests (medicines awaiting consideration or not recommended by the Scottish Medicines Consortium)</b>
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<b>Approved by</b>	<b>Area Drug and Therapeutics Committee; Clinical executive; BET</b>

## **Policy Statement**

NHS Borders has a duty to spend wisely the finite financial resources allocated to it by prioritising between competing demands. The Board must ensure that it does not spend scarce resources on procedures and interventions that are not considered to be clinically effective or cost effective in meeting the health needs of patients.

The implementation of advice from the Scottish Medicines Consortium (SMC) and National Institute for Clinical Excellence (NICE), where ratified by NHS Quality Improvement Scotland (QIS), is dealt with through the Borders Formulary Committee (BFC). The Area Drug and Therapeutics Committee (ADTC) provide guidance and policies to support clinicians' prescribing decisions and to manage the use of medicines in NHS Borders. The Medicines Resource Group (MRG) is accountable for the management of the medicines budget and provides advice on the financial aspects of managing new medicines and prescribing decisions to NHS Borders Clinical Executive (CE). Requests to prescribe licensed drugs will be approved through the BFC, for unlicensed / off-label through the ADTC and exceptional (individual patient) requests through the Exceptional Treatments Panel.

## **Purpose of this Guidance**

At times prescribers may wish to prescribe a medicine that is not on the Borders Joint Formulary. The guidance, based on CEL 17 (2010)<sup>1</sup>, in this document describes NHS Border's policy for the prescribing of medicines in such circumstances, specifically

- Unlicensed medicines
- Off-label medicines
- Medicines which are awaiting consideration by SMC
- Medicines which have not been approved by SMC for use in Scotland
- Medicines contrary to agreed NHS Border's policy

## **Review**

Every two years or sooner if recommendations change.

## **1. Background**

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

### **The Regulatory Process**

The majority of medicines prescribed are licensed products i.e. they have a marketing authorisation. Legislation to control human medicines licensing is based on safety, quality and efficacy (effectiveness in comparison to placebo not existing medicines). This process is regulated by the Medicines and Healthcare Regulatory Authority (MHRA) or the European Medicines Evaluation Agency (EMA).

The manufacture and sale or supply of medicinal products was first brought under legal control by The Medicines Act 1968. This was subsequently incorporated into European law by EEC Directive 65/65.

This directive states that no relevant medicinal product may be placed on the market unless a marketing authorisation (formerly called a product licence) has been issued. The directive also ensures that full control of manufacturing and marketing applies to relevant medicinal products on the market but allows for exemptions in relation to medicinal products to fulfil special needs - "specials", which are supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised health care professional, and for use by his/her individual patients on his/her direct personal responsibility.

Legislation only applies to relevant medicinal products, which includes all licensed medicines and "specials". Products extemporaneously prepared in the pharmacy in response to a prescription are not defined as relevant medicinal products. (2, 3)

UK manufacturers of relevant medicinal products (licensed and unlicensed) are required to hold a manufacturer's licence (ML).

A marketing authorisation defines the clinical indications for which a licensed medicinal product can be marketed and also defines the form, dose, route of administration and the patient age group which the medicine can be used in and the container in which the product is supplied.

A pharmaceutical company cannot promote an unlicensed medicine or a licensed medicine for an unlicensed indication.

Additional guidance which should be used in conjunction with this policy is contained within MCA guidance note 14 (3)

### **The Advisory Process**

In NHS Scotland the SMC considers and provides advice on the clinical and costs effectiveness of newly licensed medicines at, or close to, the point of licensing. The medicines will be recommended, recommended for restricted use or not recommended for use in NHS Scotland.

The implementation of advice from the Scottish Medicines Consortium (SMC) and National Institute for Clinical Excellence (NICE), where ratified by NHS Quality Improvement Scotland (QIS), is dealt with through the Borders Formulary Committee (BFC). There are occasions where advice from SMC or NICE is not available e.g. for medicines licensed prior to SMC being established. In these instances, NHS Borders has local decision making

processes in place to provide guidance and policies to support clinicians' prescribing decisions and to manage the use of medicines.

### Categories of Medicines in NHS Borders

Unlicensed /off-label and exceptional medicines will be assigned to one of three categories: green, amber or red

*The drug categorisation decisions will be made by the ADTC, who should be notified about any proposed or existing unlicensed /off-label medication used in NHS Borders.*

In general, only new medicines or new indications for existing medicines will be assigned to one of the three categories for unlicensed/off label use. However medicines in current use may be considered if a specific request is made or concerns are raised (i.e. if a GP practice is asked to prescribe an existing unlicensed / off-label medicine for the first time).

<b>Green</b>	<p><b>Unrestricted General Use</b></p> <p>Used widely and in accordance with a respectable, responsible body of professional opinion (e.g. Medicines for Children; SIGN/NICE recommendation)</p>
<b>Amber</b>	<p><b>General Use with Restrictions</b></p> <p>Use has been evaluated by the ADTC and has been authorised as being "acceptable". May require "shared care protocol". Local use has peer group support. Specific consent not normally required.</p>
<b>Red</b>	<p><b>Specialist Use Only</b></p> <p>Limited evidence of efficacy available. Rarely used or may have serious potential side effects requiring close supervision.</p> <p>Specific consent may be advisable.</p>
<b>Black</b>	Not Approved for use

## **2. Unlicensed / Off-label Medicines**

Unlicensed / off-label medicines can be prescribed by doctors, dentists and in some cases, independent and supplementary prescribers. Pharmacists can dispense such medicines and nurses and midwives can administer them to patients.

Current legislation allows nurse independent prescribers, pharmacist independent prescribers and optometrist independent prescribers and supplementary prescribers to prescribe for off-label use. Nurse and pharmacist independent prescribers can prescribe unlicensed medications.

If an untoward incident occurs with a licensed medicine that is the result of a product defect, or a problem with its use in an approved clinical situation (as defined in the marketing authorisation) any liability arising may in part or whole be transferred to the marketing authorisation holders. Should a patient suffer harm as a result of the effects of an unlicensed / off-label medicine then the manufacturer is not liable (unless the medicine was shown to be defective) and a claim against either the prescriber or the pharmacist is less easy to defend. Any legal action would also involve the relevant operating division (if applicable) as a result of employer's vicarious liability.

NHS Borders carries liability for the actions of its employees and may accept liability for the prescription of unlicensed medicines where such use has been authorised and agreed, provided local policies and procedures are adhered to.

### **2.1 Requests to Prescribe Unlicensed / Off-label Medicines**

2.1.1 Where possible, licensed products will be used to treat patients. A risk-benefit assessment and clinical and economic evidence should support the use of an unlicensed medicine.

2.1.2 It is recognised that the use of an unlicensed / off-label medicine is sometimes necessary in order to provide the optimum treatment for a patient. Any liability associated with the use of approved unlicensed medicines (or medicines used off-label) will be accepted by the employing authority provided that best practice, as outlined in this policy has been followed.

2.1.3 Adverse drug reactions and medication incidents involving unlicensed medicines should be reported in the same manner as for licensed medicines.

2.1.4 Requests to prescribe an off-label/unlicensed product should be made using the normal formulary submission form. Where off-label/unlicensed use is fairly common a local protocol to provide guidance will be required.

Requests to initiate new treatments using unlicensed / off-label medicines should be submitted by the responsible hospital clinician, supported by the relevant clinical pharmacist to the ADTC. The submission should include:

- The medicine to be used
- The clinical indication
- The licence status of the medicine and availability
- Whether treatment is for an individual patient or group of patients
- Likely benefit(s) over existing / licensed therapy
- The supporting evidence of efficacy and safety.
- Associated treatment costs.

## **2. 2 Responsibilities**

### **Prescribers**

2.2.1. Unlicensed / off-label medicines should only be used where their use is clearly justified and the clinical / pharmaceutical benefits are considered to outweigh the risks involved. The prescriber is professionally accountable for this judgement, and may be called upon to justify their actions. Consultant medical staff should initiate unlicensed / off-label prescribing of medicines in the red and amber categories.

2.2.2. Prescribers have a responsibility to advise the patient/carer that they are being treated with an unlicensed / off-label medicine and should document that this has happened and notify appropriate parties. They should also obtain consent to the level required for the appropriate category. In addition, they should provide the patient/carer with accurate and clear information that meets their needs, including information on side effects.

2.2.3. Other clinical staff involved in the treatment of a patient with an unlicensed / off-label medicine should, where appropriate (and particularly for unlicensed medicines in the red category) be:

- a. Made aware of it's unlicensed / off-label status
- b. Informed of any problems and risks and how to deal with them
- c. Given sufficient information to use the product safely and correctly

In clinical areas where there is a requirement for high levels of usage of such medicines (i.e. neonatal units, critical care etc) staff should be aware of the issues surrounding unlicensed drugs.

2.2.4. Recommendations for General Practice. The Consultant recommending the unlicensed medicine use is responsible for ensuring that the G.P is given sufficient information about the product and it's availability to allow safe and effective prescribing.

2.2.5. Whilst the decision to prescribe an unlicensed / off-label medicine will always rest with the individual prescriber, it is anticipated that GPs will prescribe medicines assigned to the green category. A shared care approach to prescribing and the explicit agreement of the prescribing GP is required for medicines assigned to the amber category. Specialists are expected to prescribe medicines assigned to the red category.

### **Pharmacy**

1. Pharmacy will promote implementation of this policy.

*The remaining points for pharmacy relate to Unlicensed medicines only (as defined earlier) and do not cover off-label medicine usage.*

2. Unlicensed medicines should be procured, received, assessed for quality and issued in accordance with the Code of Practice for the Control of Medicines policy and following any additional guidance from the NHS Pharmaceutical Quality Assurance Committee (1) and the MCA guidance note no 14 (2).
3. Pharmacy should ensure, as far as is practicable, that the prescriber is aware that a medicine they have requested is only available on an unlicensed basis and that advice is given on alternative licensed products.

4. Pharmacy will keep purchasing and general issue records of all unlicensed medicines for a period of at least 5 years, on the pharmacy computer system.
5. All unlicensed medicines should be issued to a patient rather than a stock issue wherever possible.
6. Pharmacy staff should:
  - a. Notify prescribers of licensed alternative products becoming available
  - b. Notify clinicians of any serious problems that they are alerted to with individual unlicensed medicines.
  - c. Ensure, where relevant, that individual patients are given information to pass on to the community pharmacist to support continuity of supply.

### **3. Individual Patient Treatment Requests (Requests to Prescribe Medicines in Exceptional Circumstances)**

Exceptionality is difficult to define, therefore pragmatism and flexibility are necessary. It may be summed up by asking the question “on what grounds can the Health Board justify funding treatment for this patient when others from the same patient group are not being funded” (NHS Confederation 2008).

There may be occasions where a prescriber feels that their patient will benefit from a medicine that has not been recommended for use in NHS Borders. The most common reasons will be the medicine is awaiting SMC review or that SMC has recommended the medicine should not be used in NHS Scotland.

Exceptional or individual patient treatment requests (IPTR) generally arise if:

- The patient has a rare condition (i.e. referrals for treatment are too low / unpredictable to have been considered by SMC/NHS Borders)
- The patient has a specific condition where the usual care pathway or treatment threshold is deemed inappropriate for that individual on clinical grounds (this may involve a tertiary referral).

In making a case for special consideration in relation to restricted treatment on grounds of exceptionality, it needs to be demonstrated that:

- The patient is significantly different from the general population of patients with the condition in question and
- The patient is likely to gain significantly more benefit from the intervention than might normally be expected for patients with that condition.

Requests for solid tumour cancer treatments should be referred to the oncology medicines management committee (OMMC) within SCAN.

#### **3.1 Requests to Prescribe Medicines Awaiting SMC Guidance**

Medicines awaiting SMC guidance should not be used until such guidance is available and the place of the medicine decided through BFC. When SMC recommends that a medicine be made available BFC, together with local clinicians, will decide whether to add to the Joint Formulary for use in NHS Borders. Where the new product is similar to an existing formulary product, the BFC will discuss with local clinicians whether it offers

better clinical and cost-effectiveness compared with current formulary options. If it does not the medicine will be non-formulary and not recommended for use in NHS Borders.

The SMC aims to provide advice as close to licensing as possible. Occasionally there may be delays and in these instances the SMC generally advises that the medicine is not recommended for use in NHS Scotland. NHS Borders is committed to the SMC process and the position remains that the medicine must go through the SMC process prior to being accepted for use in NHS Borders.

### **3.2 Requests to Prescribe Medicines Not Recommended by SMC**

Where SMC recommends that a medicine is not used in NHS Scotland, NHS Borders also recommends that the medicines should not be prescribed locally. There may be occasions where a prescriber, following review of published evidence, believes their patient will benefit from the medicine. In these circumstances a request should be submitted using the form in Appendix 1 (available on request and the intranet).

Decision making will be based on answers to the following questions:

1. Are exceptional circumstances demonstrated
2. If exceptional clinical circumstances are demonstrated should the request for NHS funded treatment be supported?

Where the request is deemed to meet the criteria for exceptional clinical circumstances the decision making panel will consider whether authorisation of the treatment should be provided. Exceptionality does not automatically result in authorisation.

The completed form should be returned to the Formulary pharmacist (or Chair, ADTC in their absence) who will retain the original and agree a timescale with the referring clinician. The form will be updated once the outcome of the decision making panel has been ratified and a copy returned to the requesting clinician.

The process to be followed when requesting the use of a medicine in exceptional clinical circumstance is outlined in Appendix 2.

### **3.3 Completion of Individual Patient Treatment Request Form**

The form must be completed to request a supply of:

- A medicine, which SMC have not recommended for use in NHS Scotland and a prescriber, following review of published evidence, believes their patient will benefit from the medicine.
- Request is for a single patient, as opposed to a group of patients or the first of a group of patients.

This form is not appropriate in the following circumstances:

- The request is to initiate or continue a licensed non-formulary medicine, unlicensed medicine or off-label use of a licensed medicine (a request should be made to the Formulary Committee using the existing BFC application).

The referring clinician is responsible for providing relevant supporting evidence with the referral (using the standard hierarchy of evidence criteria), in sufficient detail, to assist in

the decision making process, reduce delays and demonstrate exceptional clinical circumstances.

#### **4. Ethical Framework**

- All decisions will be taken on an individual patient basis and their prognosis should be considered. NHS Borders will aim to provide equal access to treatments/services for their residents based on patient need.
- NHS Borders has a statutory duty to achieve financial balance and decisions to limit access to treatments/services legitimately include aspects of financial cost. Decisions to treat inevitably divert resources from other health care options.
- Both cost effectiveness and the individual cost of treatment will be considered in NHS Borders decisions about which treatments to limit and in reaching decisions on individual patient needs.
- In some cases, the needs of a community for a range of treatments may outweigh the needs of an individual for a highly expensive treatment.
- Where an alternative, more cost effective solution can be found, it is appropriate for NHS Borders to consider alternative options.

#### **5. Patient Focus, Public Involvement (PFPI)**

Through the development and implementation of this policy we will encourage patients and members of the public to engage with the policy. We hope that by engaging with the existing PFPI structures we will:

- Make our services more efficient and responsive to local needs
- Help prioritise services and make best use of limited resources
- Demonstrate our commitment to be open and accountable
- Promote a greater sense of ownership and responsibility

NHS Borders manages a public involvement network. The Public Partnership Forum (PPF) is a key part of this network. The PPF is a group that can be engaged in the development and implementation of this policy. Although the PPF will not be privy to sensitive information, for example Individual Patient Treatment Requests, they can be engaged in broader issues in relation to NHS Borders decisions making on the introduction of new medicines. In undertaking the PFPI engagement we will comply with NHS Borders Process for Co-ordinating Public / Patient Engagement and the Scottish Government Guidance on Informing, Engaging and Consulting the Public in Developing Health and Community Care Policies and Services (2010).

In addition to engaging with the PFPI structures the Individual Patient Treatment Request panel will continue to support the involvement of a public member. Their involvement in this process will be supported through timely information, briefings, support and appropriate training.

#### **6. Equality Impact Assessment**

On the.....we (names here) completed the Scottish Borders Council & NHS Borders Equality Impact Assessment (EIA) and concluded that the policy was....

## **References**

1. CEL 17 (2010) Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland.
2. NHS Pharmaceutical Quality Assurance Committee. Guidance for the purchase and supply of Unlicensed medicinal products notes for prescribers and pharmacists. June 2004: Third edition.
3. MCA / MHRA Guidance Note no. 14 (Previously MAL 14). The supply of unlicensed relevant medicinal products for individual patients – revised. February 2000:

## **Appendices**

1. Exceptional Clinical Circumstances – Request for Medicine Supply
2. Process for requesting medicines for use in exceptional clinical circumstances

## Definitions and Glossary of Terms

**Licensed medicines** are medicines with a UK marketing authorisation. When prescribed within the terms of the marketing authorisation the manufacturer is likely to be found liable for any harm caused by that medicine.

**Off-label medicines** are medicines with a UK marketing authorisation, which are prescribed for an unlicensed indication or via a different route etc (i.e. outwith the terms of the marketing authorisation). If a patient is harmed by such use of a medicine then the manufacturer is unlikely to be found liable, unless the harm is directly attributable to a defect in the medicine, rather than the way in which it was prescribed. *Examples: Sodium valproate as a mood stabiliser; Use of some medicines in children which are only licensed for adult use.*

**Unlicensed medicines** are medicines without a UK marketing authorisation and include:

- Medicines prepared by a UK manufacturer but not for sale in the UK and may include medicines undergoing clinical trial, medicines awaiting a UK marketing authorisation, medicines withdrawn from the UK market, or medicines manufactured for export. Such medicines are usually available on an “individual patient basis”. *Examples: Pyrazinamide tablets; Naproxen suspension.*
- Medicines prepared outwith the UK with a marketing authorisation from the country of origin. Such medicines are imported into the UK. *Examples: Melatonin; Cisapride; Thalidomide*
- “Specials” obtained from a hospital or commercial supplier with a manufacturer’s “specials” licence. Such medicines can be supplied against an unsolicited order or prescription (1, 2). *Examples: Phenytoin 90mg/5ml (concentrated product results in use of much smaller volumes of medicine for use in stroke patients and paediatric patients); 50/50 Liquid Paraffin/White Soft Paraffin*
- Extemporaneously dispensed medicines prepared for a specific patient under the supervision of a pharmacist in accordance with a practitioner’s prescription, including TPN compounding, IV additive & cytotoxic reconstitutions.
- Re-packed medicines. These are medicines which are removed from their original containers and re-packed during dispensing or ward stock “pack down” procedures. *Example: Starter packs for some specialist units (mainly analgesic / antibiotics)*
- Chemicals used to treat rare metabolic disorders. (Mainly tertiary referrals)

Some of the above examples are common practice (e.g repackaged medicines) and raise little concern for prescribers or patients, provided that a patient information leaflet is made available, whereas others, though sometimes accompanied by published evidence of efficacy, raise concerns over unfamiliarity with prescribing, quality assurance and liability.

ADTC	Area Drug and Therapeutics Committee
BFC	Borders Formulary Committee
CE	Clinical Executive
EIA	Equality Impact Assessment
EMA	European Medicines Evaluation Agency
IPTR	individual patient treatment requests
MHRA	Medicines and Healthcare Regulatory Authority
MRG	Medicines Resource Group
NICE	National Institute for Clinical Excellence
OMMC	Oncology Medicines Management Committee
PFPI	Patient Focus, Public Involvement
PPF	Public Partnership Forum
QIS	NHS Quality Improvement Scotland
SMC	Scottish Medicines Consortium

**Appendix 1  
AREA DRUGS AND THERAPEUTICS COMMITTEE**



**Individual Patient Treatment Request Form**

**Completing this request form:** Request is for the use of medicines which NHS Borders/SMC have not recommended for use and a prescriber following review of published evidence, believes their patient will benefit. If possible request forms should be completed electronically or printed in black ink (*applications that are not legible will be returned*).

**Please return completed form to Liz Leitch, Formulary Pharmacist, NHS Borders.**  
Please supply evidence if available from a National body such as NICE/HTBS or SMC.

Generic Name:	Brand Name:
Formulation Strength:	Manufacturer:
Does your speciality/department support the implications of implementing this treatment	
	Yes/No
Indication for use:	
Dosage:	
Cost of 1 month's treatment or 1 treatment course of requested product.	
Anticipated number of month's treatment / treatment courses?	
What are the likely treatment outcomes of this product over existing therapy	
What are the likely outcomes if the treatment is not provided?	
Does it replace or augment current therapy?	
State what are comparable treatments and their monthly cost.	



What evidence is available to support these claims? If available, how does this differ from national guidance from SMC/NICE/NHS QIS?

Evidence available from a National body such as NICE/HTBS or the Scottish Medicines Consortium should be supplied in full with your request form. Include numbers needed to treat or cost effectiveness data (**applications should be submitted with non sponsored information wherever possible**).

What is the reason that this patient's clinical circumstances are exceptional i.e. how are they / and their anticipated response to treatment different from that referred to in SMC/NHS borders guidance not to use the medicine?

Is special funding available or required?

What is the impact on prescribing/healthcare in the community?

Consultant		Ward	
Tel. No.		CHI No	
Bleep No.		Date of Birth	
Date of Request			

**Declarations of Interest**

Please specify any interests both personal and non-personal in the product/manufacture/supplier

**Patient Report**

(please use space provided or append as additional sheets a patient report detailing the background of the patient's progress including relevant clinical data, interventions, responses to interventions etc)

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**To be completed by Formulary Pharmacist or ADTC Chair**

Date request received	
Date sent to exceptional treatments administrator	

**To be completed by exceptional process administrator**

Date received by administrator	
Exceptional process reference number	

**To be completed by exceptional treatment panel chair**

Outcome of decision making panel	
Details of funding if necessary	
Signature	Date

If you require assistance in compiling this information contact your Pharmacist.

Ratified by Medicines Resource Group

\_\_\_\_\_ Chairman/Vice Chairman (Sign)      Date: \_\_\_\_\_

## **APPENDIX 2 – Individual Patient Treatment Requests**

### **1.0 Initiation of the request**

- 1.1** It will be for the treating clinician to make a request to prescribe a medicine through this process, demonstrate that the patient concerned does have exceptional clinical circumstances and provide supporting evidence.
- 1.2** Requesting prescribers will be required to produce a patient report for the decision making panel.
- 1.3** The completed request form, patient report and systematic review of published evidence should be submitted to the Formulary pharmacist. The Formulary Pharmacist will liaise with the exceptional treatments administrator to co-ordinate a review by the Panel. The administrator will log the application onto the database and collate all information for consideration by the panel.
- 1.4** The relevant clinical pharmacist/formulary pharmacist will undertake an initial assessment of the evidence provided identifying any deficiencies in the systematic review undertaken. Such deficiencies will be relayed to the requesting prescriber for rectification before decision-making (i.e. the process) can continue.

### **2.0 Decision Making**

- 2.1** The decision-making panel will determine whether there is acceptable evidence that the clinical circumstances of the patient under consideration are exceptional in some way that would improve either the clinical or cost-effectiveness of the treatment to such an extent that Border policy not to support / fund a particular treatment should apply to him/her as an individual case.
- 2.2** If the panel concludes that exceptional clinical circumstances haven't been shown then the NHS Borders policy for that medicine applies, e.g. if SMC has recommended that the medicine should not be used the patient and his/her prescriber would be advised that treatment will not be made available.
- 2.3** If the panel concludes that exceptional clinical circumstances have been shown then the panel will consider whether the medicine should be authorised for this individual patient. The panel will use a decision-making framework which includes:
  - consideration of health benefit (including response rate, timing of benefits and likely benefit to the individual patient),
  - value for money (including cost-effectiveness and the relative opportunity cost of supporting treatment) and
  - implications of the request on the equity of service provision in the Borders.

### **3.0 Decision Making Panel**

- 3.1** The decision making panel will consist of 3 members from the following:

**(a)** Director of Public Health (or consultant in Public Health), Associate Medical Director, a senior pharmacist (e.g. Clinical Pharmacy Development Manager, medicine management, formulary pharmacist or specialist pharmacist from relevant clinical area), Senior Finance Officer, Director of Integrated Healthcare Services

(clinical board general manager) and public representative (from ADTC where possible).

**(b)** The Director of Public Health (or deputy) or Associate Medical Director will be Chairman.

- 3.2 Quorum:** No business will be transacted unless the Chairman, or in his absence the person acting as Chairman, and two persons appointed under paragraph (a) or their deputies are present.
- 3.3** Patients will **not** be invited to attend the Panel but may be able to submit a statement.
- 3.4** Requesting clinicians may be invited to attend the Panel to present evidence. They must not be present when the decision is being made.
- 3.5** Administrative support to the Panel will be provided by a dedicated exceptional treatments administrator, who will be the point of contact for the process.
- 3.6** If there is any circumstance where any panel member may have a conflict of interest in a case put before the panel, they shall acknowledge this at the outset and will remove themselves from the proceedings for the time required.

#### **4.0 Reporting**

- 4.1** In most instances the decision of the panel will be communicated to the referring clinician within 48hrs of the decision being made. Where communication is made by telephone or face to face meeting this will be followed by a letter from the exceptional treatments administrator within 5 working days. Where there is a delay contact will be made with the patient to explain the reasons for such delays and the revised timescale of reporting.
- 4.2** Following the meeting the formulary pharmacist will liaise with the Director of Pharmacy / Head of service / requesting clinician to communicate the decision and make the medicine available if approved.
- 4.3** The report summarising the decision-making panel's decision will be presented to the Medicines Resource Group for recording of the decision.
- 4.4** In the event of the decision-making panel turning down a request to use a medicine the clinician will inform the patient/carer about the appeals process.
- 4.5** The exceptional treatment administrator will coordinate any appeal lodged by the patient or the requesting clinician.

#### **5.0 The Process for Appeals**

**5.1** Should the referring clinician or patient be unhappy with the decision taken by the exceptional treatments Panel, they have the right to challenge the decision within 28 days of the letter being received by the clinician. Should a third party, other than the referrer, wish to appeal against the decision on behalf of the patient, written confirmation and authority must be gained from the patient by the third party, stating that they are acting on the patient's behalf.

- 5.2** The referring clinician or patient/third party representative should write to the Chief Executive, clearly detailing the reason/s for their dissatisfaction. The letter can also provide additional/supporting information available, should it support the patient's case of appeal.
- 5.3** On receipt of this correspondence, the Chief Executive will then identify an appropriate Director (not one involved in the original Panel decision) to review the case to ensure that NHS Borders process has been fully implemented and followed.
- 5.4** The review of the case must be completed within 28 days of the receipt by NHS Borders of the request for review of the case. Should it be anticipated that the review will require longer than 28 days, NHS Borders must inform the referring clinician/patient giving an indication of the amount of time that will be required to complete the review.
- 5.5** On completion of the review of the case, the outcome will be forwarded to the referring clinician/patient/third party representative within 5 working days of the review being complete.
- 5.6**
- 5.7** Successful appeals will normally result in a direction that the decision should be made again and will result in a new decision being made (NB not necessarily a different outcome).

## **6.0 Review of the decision in the light of new evidence**

It is accepted that new evidence may well be published that may mean that a decision may need to be reviewed.

Where a clinician or patient believes that the weight of the new evidence is such that it may affect a new decision they should reapply using the form, initiating the decision making process again including review of the new evidence. NB If the SMC are timetabled to consider the medicine NHS Borders will wait for such advice to be made as this is NHS Borders policy.

## **7. 0 Declaration of Interest**

See NHS Borders declaration of interest policy.

## **8.0 Inter-Board Arrangements**

Where a decision has been made by an NHS Board to approve an IPTR for a Borders patient a copy of the request and outcome of the decision should be submitted to the Formulary Pharmacist. The request will be ratified at the next ADTC.