NHS Grampian Guidance for processing requests to prescribe unlicensed, off-label or non-formulary medicines (including medicines awaiting consideration by, or not recommended for use by, the Scottish Medicines Consortium) in NHS Grampian

Approved by: Grampian Medicines Management Group

Last update: 20th March 2008  (F)

Review Date: February 2010

Review Group: Grampian Medicines Management Group
1 Background
The safety, effectiveness and cost-effectiveness of medicines are controlled by regulatory and advisory processes.

1.1 The regulatory process
The majority of medicines that are prescribed have a marketing authorisation (i.e. licensed medicines). Safety, quality, and efficacy (but not effectiveness in comparison to existing medicines) 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 (EMEA) and the expert advisory bodies to ensure that the sometimes difficult balance between safety and efficacy is achieved.

1.2 The advisory process
Most mature healthcare systems have in place processes of health technology assessment to advise local healthcare providers as to the effectiveness of medicines both independently and in comparison with other available treatments. Such assessment and provision of advice generally occur at two levels; national and local.

1.2.1 National
In NHS Scotland this assessment is provided at, or close to, the point of licensing by the Scottish Medicines Consortium (SMC). SMC considers the clinical and cost effectiveness of all newly licensed medicines and provides advice to NHS Scotland (NHSiS) as to whether the medicine is recommended for use, and if so its place in treatment.

1.2.2 Local
The implementation of national advice from the SMC and, in some circumstances the National Institute for Clinical Excellence (NICE), where ratified by Quality Improvement Scotland, is dealt with through the Grampian Formulary Group. There are also occasions where national advice from SMC or from NICE is not available e.g. consideration of using medicines that were licensed prior to SMC being established. In these instances local processes of decision making are in place to provide NHS Grampian with the relevant guidance and policies to support clinicians’ prescribing decisions and to manage the use of medicines in Grampian.

2 Purpose and scope
NHS Grampian recognises that there will be times when prescribers may wish to prescribe a medicine that either has not been licensed, is awaiting SMC advice, SMC has advised should not be used in NHSiS, or is contrary to NHS Grampian’s policy. The processes and associated guidance in this document describe NHS Grampian’s policies for the prescribing of medicines in such circumstances, specifically prescribing of:

- non-formulary licensed medicines
- unlicensed medicines
- off-label medicines initiated in the acute service
- medicines in exceptional clinical circumstances contrary to agreed local NHS Grampian policies
- medicines which are awaiting SMC guidance
- medicines which the SMC have recommended should not be used in NHSiS
3 Prescribing of non-formulary licensed medicines

It is recognised that no formulary can cover one hundred percent of prescribing but wherever possible and clinically appropriate prescribers in NHS Grampian are expected to prescribe within the Grampian Joint Formulary.

3.1 Continuation of non-formulary licensed medicines initiated in primary care

Where, in the acute service, there is a need to continue non-formulary licensed medicines initiated in primary care, Form A will be used to gain authorisation for such use.

The Chief Pharmacist, or his or her designated deputy, will authorise such requests. Once completed, Form A will be stored in the Pharmacy Office at Aberdeen Royal Infirmary to maintain a record of non-formulary medicine continuation.

4 Prescribing of unlicensed medicines

4.1 Background

The licensing of medicines 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 (EMEA).

Additional requirements are enshrined in European Law. A medicine holding a full Marketing Authorisation (MA) will do so after a full evaluation by the MHRA or EMEA of all data required for the medicine. 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 medicine in use when the terms of the licence are complied with.

The majority of medicines prescribed within NHS Grampian 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 medicine, and it can be proved that the product was prescribed and used in accordance with the terms of the Marketing Authorisation.

4.1.1 Liability

Prescribers of unlicensed medicines, or medicines prescribed outwith their marketing authorisation, have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine treatment. NHS Grampian carries a 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 that local policies and procedures are adhered to.

Where it is intended that such prescribing of an unlicensed medicine 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 Grampian Shared Care Policy. Retention of prescribing responsibility within secondary care should be considered as an option.

The clinical liability associated with the prescribing of unlicensed medicines or medicines prescribed outwith their marketing authorisation may be accepted by Grampian Health Board, provided that its employees have followed Grampian’s medicines management policies for the prescribing of such medicines.
The Grampian Medicines Management Group, through the work of its sub-groups, the NHS Grampian Formulary Group and the Grampian Medicine Guidelines and Policies Group, have the responsibility to define local policies to guide the prescribing of medicines within NHS Grampian. Where a licensed medicine is available, it should generally be prescribed in preference to any unlicensed equivalent alternative. The following criteria should be applied prior to the decision to prescribe, or request authorisation to prescribe a medicine that is not licensed, is off label, or is not recommended for use in NHS Grampian.

1. There is no suitable licensed alternative.
2. The risk-benefit assessment for the patient is in favour of prescription on the unlicensed medicine.
3. There is a clinical and economic evidence-base to support this usage.
4. Prescribing is supported by multi-professional opinion.
5. The patient/carer has been fully informed and has consented or will consent.

4.1.2 Non-medical prescribers
At this time, NHS Grampian does not support the prescription of unlicensed medicines or of medicines prescribed outwith their marketing authorisation by non-medical prescribers.

4.1.3 Specials
In NHSG policies for the use of unlicensed medicines exclude medicines manufactured by the Specials Suppliers. Use of licensed medicines off-label is dealt with later.

4.2 Requests to prescribe an unlicensed medicine for a single patient
Where a request is made to use an unlicensed medicine in a single patient, as opposed to a group of patients or the first of a group of patients, Form B should be used to request authorisation to prescribe such medicines. Prescribers should consider carefully whether the request is truly for single use or whether in fact the patient is the first of a group of patients likely to require treatment with the unlicensed medicine in which case the FG1 Form should be completed (Form B is not the appropriate route for such requests -see below).

Requests for use of an unlicensed medicine for a single patient using Form B will be considered and authorised by a panel consisting of the requesting clinician, Chief Pharmacist or their deputy, Unit Operations Manager and the Group Clinical Director.

Once completed, one copy of Form B will be added to the patient notes, one copy will be sent to the requesting clinician and the original will be stored in the Pharmacy Office at Aberdeen Royal Infirmary.

4.3 Requests to prescribe an unlicensed medicine for a group of patients
Where a request needs to be made to use an unlicensed medicine for a group of patients, or for the first patient amongst a group of patients (existing or anticipated), a request should be made to the Formulary Group using the existing Formulary Group application (the FG1). Requests for use of unlicensed medicines for a group of patients should not be seen as a mechanism to pre-empt SMC advice.

4.4 Requests for use of an unlicensed medicine as part of a clinical trial
Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied. Prescribers, lead clinicians / investigators and service managers are reminded of their responsibilities to advise the patient as to the exit strategy at the end of such trials and explain their impact on the individual patient. In particular patients should be advised that, unless specific arrangements have been made, at the end of the trial there is no ongoing commitment from NHS Grampian to provide the medicine made available through
the trial, regardless of individual response to treatment; i.e. their unlicensed medicine
provided during the trial will stop at the end of the trial. Patients need to be advised of how
their treatment will be managed at the end of the trial as part of their recruitment to such
studies. Prescribers, lead clinicians / investigators and service managers are reminded that
where medicine companies are offering open-label extensions to funding these do not
necessarily cover fully the costs of these medicines between licensing, the SMC guidance
and decision whether or not to use in NHS Grampian.

5 Use of off-label medicines initiated in the acute service

Where off-label use of a licensed medicine is fairly common prescribers should request such
use through an application to the Formulary Group using the appropriate forms (FG1). It is
unlikely that such use cannot be anticipated and it is appropriate that such use is supported
by advice from the Formulary Group. NB The Royal Aberdeen Children's Hospital and
Theatres are currently exempted from this process due to the high levels of use of
medication off-label. Liability for off-label prescribing is the same as for unlicensed
medicines as described in 4.1.1.

6 Requests to prescribe medicines in exceptional clinical circumstances
contrary to agreed local NHS Grampian policies

There may be occasions where a prescriber feels that his/her patient will benefit from a
medicine that has been recommended not to be used in NHSG. The most common example
will be for medicines either awaiting SMC guidance or for which the SMC has recommended
should not be used in NHS Grampian.

6.1 Requests to prescribe medicines which are awaiting SMC guidance

NHSG policy is that medicines awaiting SMC guidance should not be used until such
guidance has been published, the guidance discussed with local clinicians and the place of
the medicine in local treatment decided through the Formulary Group. This process is
managed by the NHSG Formulary Group. Where SMC recommends that a medicine be
made available for use in NHSIS the Formulary Group decides which of these drugs should
join the Grampian Joint Formulary, with input from local clinicians. This input is particularly
important where the medicine is a 'me-too', in other words one which is very similar to a
medicine NHSG already has on the joint formulary. Following discussion with local clinicians
the Formulary Group makes a decision as to whether the ‘me-too’ offers better clinical and
cost effectiveness than the medicines recommended for local use in the joint formulary. If it
does then a decision to add the new medicine to the formulary may be made; if it does not
the medicine may not join the formulary; i.e. it will not be recommended for use in NHSG.

6.1.1 SMC aims to provide its advice as close to licensing as possible. There are occasional
delays to this, generally where the medicine manufacturer fails to submit a timeous
application to the SMC. In addition there have been a number of occasions where medicine
manufacturers have submitted incomplete or insufficient information for the SMC to base a
decision on, often due to incomplete economic information. In these instances the SMC
generally advises that the medicine is not recommended for use in NHSIS and the company
manufacturing the medicine makes a further submission. In instances where the SMC then
goes on to recommend the medicine it is easy to criticise such delay as leading to individuals
missing out on using a particular medicine or delaying their access with resultant
deterioration of their condition.

6.1.2 Despite this, the NHSG position remains that medicines that are going through, or are
due to go through, the SMC process should not be used in NHSG. To do otherwise would
undermine the national SMC process, to which NHSG is committed. Some have argued that
where there is a delay in SMC decision-making NHSG should undertake review of these
medicines’ clinical and cost-effectiveness locally. In reality SMC has access to a wider set of data relating to the medicine than we would have locally (i.e. the manufacturer’s submission) and there would almost certainly be duplication of effort. The SMC was specifically established to avoid this, particularly as in many cases by the time NHSG undertakes the review and made decisions locally the SMC will have provided its guidance anyway.

6.2 Requests to prescribe medicines which the SMC have recommended should not be used in NHSiS

Where SMC recommends that a medicine is not used in NHSiS, NHSG follows this guidance, i.e. such medicines should not be prescribed. However, there may be occasional circumstances where a prescriber believes, following review of published evidence, that his/her patient will respond significantly differently to the medicines than the group of individuals upon which the SMC advice and NHSG policy is based, i.e. that they are more likely to respond to the medicine, that their response will be greater or that the cost effectiveness of treating that individual patient will be better than described in the SMC guidance.

6.2.1 In these circumstances a request to use a medicine in exceptional clinical circumstances should be made using Form C.

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

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

6.2.3 Only where requests to prescribe such medicines are deemed to meet the exceptional clinical circumstances criteria will the decision making panel move on to consider whether authorisation of the treatment should be provided. NB Exceptionality does not automatically result in authorisation.

6.2.4 Once completed by the requesting clinician a copy of Form C should be sent to the Chief Pharmacist who will provide a copy to the Chair of the GMMG who will initiate the process of decision making. Once completed, one copy of Form C will be added to the patient notes, one copy will be sent to the requesting clinician and the original will be stored in the Pharmacy Office at Aberdeen Royal Infirmary. These Forms should be updated once the decision making panel decision has been ratified.

6.2.4 The process to be followed in requesting use of a medicine in exceptional clinical circumstances is outlined in Appendix 6.
Appendix 1

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 treatment.

Unlicensed Medicines and ‘Off-label’ medicines
Prescribing practice involves the use of unlicensed medicines, (products which have not been licensed for human medical use) and off-label medicines (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 for the patient.
Appendix 2

Summary of request forms and their uses in relation to this guidance

Form A
- Requests for continuation of previously, primary care, initiated non-formulary licensed medicines in NHS Grampian acute service

Form B
- Requests for use of an unlicensed medicine for a single patient in the acute service
- Requests for use of an off-label medicine for a single patient in the acute service

Form C
- Requests for use of medicines which the SMC have recommended should not be used in NHSiS where a prescriber believes, following review of published evidence, that his/her patient will respond significantly differently to the medicine than the group of individuals upon which the SMC advice and NHSG policy is based

FG1
- Requests for use of an unlicensed or off-label medicine for a group of patients.
### REQUEST FOR MEDICINES SUPPLY

**FORM A**

**NON-FORMULARY LICENSED MEDICINES** *

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To be completed by requesting consultant or pharmacist  
Date ____________ / ____________ / ____________

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Patient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward</td>
<td>Unit No.</td>
</tr>
<tr>
<td>CONSULTANT</td>
<td>Address</td>
</tr>
<tr>
<td>Tel No.</td>
<td></td>
</tr>
<tr>
<td>Bleep No.</td>
<td>Date of Birth</td>
</tr>
</tbody>
</table>

Section A **must** be completed for ALL REQUESTS

In covering a **repeat hospital supply**, quote original reference no., and **complete Sections A and B**.

This form provides for supply to be made to the stated patient only

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**SECTION A – TO BE COMPLETED BY PHARMACIST**

<table>
<thead>
<tr>
<th>Approved Name of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name of Medicine</td>
</tr>
<tr>
<td>Strength</td>
</tr>
</tbody>
</table>

**Reason for Request:**

**Quantity required**

| Total Treatment Cost (this request) |

**Pharmacist’s Signature**

| Date: |

| Bleep No. | Supply directly to ward/dept on receipt | Y / N* | Supply to |

| Checked By | Date: |

**Note:** *If “Supply on Receipt” indicates ‘N’ – pharmacist to be contacted on receipt*

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**SECTION B - FOR PHARMACY PROCUREMENT SECTION ONLY**

<table>
<thead>
<tr>
<th>New Product Record No.</th>
<th>Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Therapeutic Classification</td>
<td>Order No.</td>
</tr>
<tr>
<td>Shelf Location</td>
<td>Expected Delivery Date</td>
</tr>
<tr>
<td>Unit Cost</td>
<td>Quantity Ordered</td>
</tr>
<tr>
<td>Ref No.</td>
<td>Issued</td>
</tr>
</tbody>
</table>

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Fax (01224-(5)54422

* Read notes on use of form A

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**UNCONTROLLED WHEN PRINTED**

NHSG/NF/proc/Guid/001  
Review date: February 2010  
- 9 -
REQUEST FOR MEDICINES SUPPLY
FORM A
NON-FORMULARY LICENSED MEDICINES

Notes on use of Form A

This form must be completed to request supply of a non-formulary medicine in hospital where:

- There is a need to continue a licensed non-formulary medicine initiated in primary care, where a change to a formulary medicine would or may be detrimental.
- The Chief Pharmacist, or their designated deputy, will authorise such requests.

This form is not appropriate in the following circumstances:

- Where a medicine is awaiting approval by the SMC. Current policy is that the medicine in question will not be available in hospital until the SMC has made a final decision and the funding is in place.
- Where the medicine is awaiting an imminent UK or European Licence and SMC guidance is expected. Current policy is that the medicine in question will not be available in hospital until the SMC has made a final decision and the funding is in place.
- Where there is a need to use an unlicensed medicine or off-label use of a licensed medicine in a single patient (Use Request for Medicines Supply Form B).
- Where a medicine has been approved by the SMC but funding has not been identified.
- Where a medicine has been turned down by the SMC. Current policy is that the medicine will not normally be available for prescription.
- Where a request needs to be made to use an unlicensed medicine for a group of patients, or for the first patient amongst a group of patients (existing or anticipated), where a UK licence application is unlikely to be made, a request should be made to the Formulary group using the existing Formulary Group application (FG1).
- Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied.
- Where off-label use of a licensed medicine is fairly common prescribers should request such use through an application to the Formulary Group using the appropriate forms (FG1).

Note: The Royal Aberdeen Children’s Hospital and Theatres are currently exempted from this process due to the high levels of use of medication off-label.
To be completed by requesting consultant or pharmacist

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Patient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward</td>
<td>Unit No.</td>
</tr>
<tr>
<td>CONSULTANT</td>
<td>Address</td>
</tr>
<tr>
<td>Tel No.</td>
<td></td>
</tr>
<tr>
<td>Bleep No.</td>
<td>Date of Birth</td>
</tr>
</tbody>
</table>

Section A must be completed for ALL REQUESTS

In covering a repeat hospital supply, quote original reference no., and complete Sections A and D

This form provides for supply to be made to the stated patient only

### SECTION A – TO BE COMPLETED BY PHARMACIST

<table>
<thead>
<tr>
<th>Approved Name of Medicine</th>
<th>Brand Name of Medicine</th>
<th>Strength</th>
<th>Formulation</th>
<th>Unit Cost</th>
<th>Manufacturer</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Quantity Required</th>
<th>Total Treatment Cost (this request)</th>
</tr>
</thead>
</table>

Pharmacist’s Signature  Date:  

Bleep No.  Supply directly to ward/dept. on receipt  Y / N*  Supply to

Note: *If “Supply on Receipt” indicates ‘N’ – pharmacist to be contacted on receipt

Checked by  Date:  

### SECTION B – TO BE COMPLETED BY PRESCRIBING CONSULTANT/PHARMACIST

Formulary Status  Has an application been submitted to the GRAMPIAN FORMULARY GROUP?  Y / N

Reason for request, include reasons for not using FORMULARY product

Treatment Plan, include frequency of administration and duration of treatment

Has medicine been reviewed by SMC?  Y / N*, if Y state outcome  APPROVED/REJECTED*  

Licence Status of Medicine treatment

Hospital Treatment ONLY  Y / N,*  If continuing into Primary Care, indicate duration

Is there an agreed treatment protocol?  If so, please include

Anticipated Total Cost of Treatment £

*delete as appropriate

I understand that the medicine treatment requested is an Unlicensed Medicine treatment(s)* and understand and accept the responsibility for the use of this medicine treatment in the treatment indicated for this patient.

Consultant’s Signature  Date:
SECTION C TO BE SIGNED BY THE DECISION MAKING PANEL

Following review of the above information the panel AGREE / DO NOT AGREE* that this treatment should be approved for use as described. STATE REASON IF NOT APPROVED

<table>
<thead>
<tr>
<th>Post</th>
<th>Name</th>
<th>Signature</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Requesting Clinician</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chief Pharmacist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unit Operations Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Group Clinical Director</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Can this expenditure be accommodated within budget? Y / N

If N state where extra resource is to be found

Can this expenditure be accommodated within budget? Y / N

If N state where extra resource is to be found

Notes/Reason for refusal

SECTION D- FOR PHARMACY PROCUREMENT SECTION ONLY

<table>
<thead>
<tr>
<th>DATE RECEIVED</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Product Record No.</td>
</tr>
<tr>
<td>Therapeutic Classification</td>
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<td>Shelf Location</td>
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<td>Unit Cost</td>
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<tr>
<td>Ref No.</td>
</tr>
</tbody>
</table>

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* Read notes on use of Form B
REQUEST FOR MEDICINES SUPPLY
FORM B
OFF-LABEL/UNLICENSED MEDICINES

Notes on use of Form B

This form must be completed to request supply of a non-formulary medicine in hospital where:

- There is a need to use an unlicensed medicine or for off-label use of a licensed medicine in a single patient, as opposed to a group of patients, or the first of a group of patients. **Note:** Prescribers should consider carefully whether their request is truly for single use or whether in fact the patient is the first of a group of patients likely to require treatment with the unlicensed medicine in which case Form B is not the appropriate route for requests.

- For the purpose of this documentation, products manufactured by Specials Houses under an MHRA manufacturing licence will not be classed as unlicensed.

- Requests for use of an unlicensed medicine for a single patient using Form B will be considered and authorised by a panel consisting of the requesting clinician, Chief Pharmacist or their deputy, Unit Operations Manager and the Group Clinical Director.

This form must be completed for all unlicensed medicines to be used in hospital to fulfil the requirements of MCA guidance note 14 (Feb 2001) which require retention of records of supply of unlicensed medicines for 5 years. Records are required to detail:
- the source of the product
- the person to whom the product was supplied
- date of supply
- quantity supplied
- batch number supplied.

This form is not appropriate in the following circumstances:

- Where the request is for a need to continue a licensed non-formulary medicine initiated in primary care, where a change to formulary medicine would or may be detrimental. (Use Request for Medicines Supply Form A)

- Where the medicine is awaiting an imminent UK or European Licence and SMC guidance is expected. Current policy is that the medicine treatment in question will not be available in hospital until the SMC has made a final decision and the funding is in place.

- Where a medicine is awaiting approval by the SMC. Current policy is that the medicine in question will not be available in hospital until the SMC has made a final decision and the funding is in place.

- Where a medicine has been approved by the SMC but funding has not been identified.

- Where a medicine has been turned down by the SMC. Current policy is that the medicine will not normally be available for prescription.

- Where a request needs to be made to use an unlicensed medicine for a group of patients, or for the first patient amongst a group of patients (existing or anticipated) where a UK licence application is unlikely to be made, a request should be made to the Formulary Group using the existing Formulary Group application (FG1).

- Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied.

- Where off-label use of a licensed medicine is fairly common prescribers should request such use through an application to the Formulary Group using the appropriate forms (FG1). **Note:** The Royal Aberdeen Children's Hospital and Theatres are currently exempted from this process due to the high levels of use of medicines off-label.
Appendix 5

REQUEST FOR MEDICINES SUPPLY
EXCEPTIONAL CLINICAL CIRCUMSTANCES
FORM C*

Request is for the use of medicines, which NHSG / SMC have not recommended for use in NHSG / NHSiS where a prescriber believes, following review of published evidence, that his/her patient will respond significantly differently to the medicines than the group of individuals upon which the SMC advice or NHSG policy is based *

Sections A, B, C & D to be completed by Prescribing Consultant Date __________ / __________ / __________

SECTION A

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Patient Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ward</td>
<td>Unit No.</td>
</tr>
<tr>
<td>Consultant</td>
<td>Address</td>
</tr>
<tr>
<td>Tel No.</td>
<td></td>
</tr>
<tr>
<td>Bleep No.</td>
<td>Date of Birth</td>
</tr>
</tbody>
</table>

All sections must be completed for all requests. This form provides for supply to the stated patient only.

SECTION B  - Product required

<table>
<thead>
<tr>
<th>Approved Name of Medicine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brand Name of Medicine</td>
</tr>
<tr>
<td>Strength</td>
</tr>
<tr>
<td>Formulation</td>
</tr>
<tr>
<td>Unit Cost</td>
</tr>
<tr>
<td>Manufacturer</td>
</tr>
<tr>
<td>Quantity Required</td>
</tr>
<tr>
<td>Anticipated Total Treatment Cost</td>
</tr>
</tbody>
</table>

SECTION C  - Exceptional Circumstances

(To be supported by full patient report & systematic review of published clinical evidence)

Summary of reason for request (specifying the clinical circumstances that make this patient exceptional to the standard NHS Grampian policy for the medicine)

Proposed Treatment Plan, include frequency of administration and duration of treatment

Date of SMC decision ________________

SMC decision
Hospital Treatment ONLY Y / N**, if continuing into Primary Care, indicate duration ______________

Summary of reason for request, *include reasons for not using FORMULARY product*

Proposed Treatment Plan, *include frequency of administration and duration of treatment*

Date of SMC decision __________________
SMC decision

Hospital Treatment ONLY Y / N** If continuing into Primary Care, indicate duration ______________

*Is there an agreed treatment protocol? If so, please include*

**delete as appropriate

*Read notes on use of Form C for further guidance*

| SECTION D - Declarations of Interest (personal/non-personal, specific/non-specific) |
| Please specify any interests both personal and non-personal in the product /manufacturer/supplier. (see guidance sheet for further information. Attach a separate sheet if required) |
| |
| Consultant Signature | Date: |
| |
| Form to be submitted to the Chief Pharmacist, Acute Services on completion of section A-D |

| SECTION E  | To be completed by Chief Pharmacist |
| Date request received: | Signature: |
| Medicines Information comments on systematic review |

| SECTION F  | - Decision making panel |
| Date of decision making panel meeting: |
| Decision panel members (job titles): |
| Decision of panel: |
### SECTION G - GMMG

<table>
<thead>
<tr>
<th>Date of GMMG meeting:</th>
<th>Ratification of decision YES/NO</th>
</tr>
</thead>
<tbody>
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</table>

<table>
<thead>
<tr>
<th>GMMG Chairman signature:</th>
<th>Date:</th>
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### SECTION H - To be completed by head of service/budget holder

I have reviewed the above information and **AGREE** that this treatment should be approved for use as described.

**Can this expenditure be accommodated within budget?**

<table>
<thead>
<tr>
<th>Y / N</th>
<th>If N state where extra resource is to be found</th>
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<table>
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Completed forms must be forwarded to PROCUREMENT SECTION, PHARMACY DEPT, A.R.I.

### SECTION J - For pharmacy procurement section only

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<table>
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REQUEST FOR MEDICINES SUPPLY
EXCEPTIONAL CLINICAL CIRCUMSTANCES
FORM C

Notes on use of Form C and additional documentation required

Form C must be completed to request supply of a non-formulary medicine treatment in hospital where the:

- Request is for the use of a medicine, which NHSG / SMC have not recommended for use in NHSG / NHSiS where a prescriber believes, following review of published evidence, that his/her patient will respond significantly differently to the medicine than the group of individuals upon which the SMC advice or NHSG policy is based i.e. greater cost effectiveness, better clinical response

- Request is for a single patient, as opposed to a group of patients or the first of a group of patients.

It will be for the treating clinician to make a request to prescribe the medicine through this process and demonstrate that the patient concerned does have exceptional clinical circumstances.

This form is not appropriate in the following circumstances:

- Where the request is for a need to continue a licensed non-formulary medicine initiated in primary care, where a change to formulary medicine would or may be detrimental. (Use Request for Medicines Supply Form A)

- Where there is a need to use an unlicensed medicine or off-label use of a licensed medicine in a single patient (Use Request for Medicines Supply Form B)

- Where a medicine has been approved by the SMC but funding has not been identified.

- Where a request needs to be made to use an unlicensed medicine for a group of patients, or for the first patient amongst a group of patients (existing or anticipated) where a UK licence application is unlikely to be made, a request should be made to the Formulary Group using the existing Formulary Group application (the FG1).

- Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied.

- Where off-label use of a licensed product is fairly common prescribers should request such use through an application to the Formulary Group using the appropriate forms (FG1). Note: The Royal Aberdeen Children’s Hospital and Theatres are currently exempted from this process due to the high levels of use of medication off-label.

Note: NHSG policy is that medicines awaiting SMC guidance should not be used until such guidance has been published, the guidance discussed with local clinicians and the place of the medicine in local treatment has been agreed through the Formulary Group unless exceptional.
Additional documentation

Decision making should be supported by robust scientific evidence. Therefore it is the responsibility of the requesting clinician, or specialty / service where appropriate, to provide such evidence. This evidence should be in the form of a systematic review of the published evidence undertaken to the standards used by UKMI.

Requesting prescribers should produce a patient report for a decision making panel outlining the patient's disease, treatment history and background to the decision to recommend the proposed treatment. This review should include an assessment by the clinician of the patient outcomes associated with a) continuation with current treatment (if available), b) the requested treatment and c) withdrawal of treatment (where this is an option).

- The completed request (Form C), declaration of interest, patient report and systematic review of published evidence should be submitted to the Chief Pharmacist, Acute Services.

- NHSG's Medicines Information Centre will support the Chief Pharmacist in undertaking 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.
DECLARATION OF INTERESTS

INTRODUCTION

Grampian Medicines Management Group has for some time operated a policy of requiring members to declare any interests relevant to the matters under consideration at its meetings. The committee recently agreed that this policy should be extended to include clinicians requesting new medicines.

This paper aims to provide a guide to different kinds of interests which should be declared.

DIFFERENT TYPES OF INTEREST

(a) Personal Interests

A personal interest involves payment to a clinician 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 clinician 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 clinician has no influence on financial management.

(b) Non-personal Interests

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

Fellowships: the holding of a fellowship endowed by the pharmaceutical industry

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 a clinician personally but which does benefit his/her position or department, e.g.

(i) a grant from a company for the running of a unit or department for which a clinician is responsible;

(ii) a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which a clinician is responsible. This does not include financial assistance for students;

(iii) the commissioning of research or other work by, or advice from, staff who work in a unit for which the clinician is responsible.

Clinicians are under no obligation to seek out knowledge of work done for or on behalf of the pharmaceutical industry within departments for which they are responsible if they would not normally expect to be informed.
Appendix 6

Requests for medicine use in exceptional clinical circumstances - Guidance

1 Initiation of the request

1.1 It will be for the treating clinician to make a request to prescribe a medicine through this process and demonstrate that the patient concerned does have exceptional clinical circumstances (using Form C).

1.2 Decision making should be supported by robust scientific evidence. Therefore it is the responsibility of the requesting clinician, or speciality / service where appropriate, to provide such evidence. This evidence should be in the form of a systematic review of the published evidence undertaken to the standards used by UKMI (separate guidance).

1.3 Requesting prescribers will produce a patient report for the decision making panel outlining the patient's disease, treatment history and background to the decision to recommend the proposed treatment. This review should include an assessment by the clinician of the patient outcomes associated with a) continuation with current treatment (if available), b) the requested treatment and c) withdrawal of treatment (where this is an option).

1.4 The completed request (Form C), patient report and systematic review of published evidence should be submitted to the Chief Pharmacist, Acute Services.

1.5 NHSG’s Medicines Information Centre will support the Chief Pharmacist in undertaking 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 Decision making

2.1 The first decision to be made by the panel is whether the individual patient’s clinical circumstances are exceptional, i.e. that 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 Grampian’s policy not to support / fund a particular treatment should not 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 Grampian 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 must go on to consider the second stage of decision making, i.e. whether the medicine should be authorized for this individual patient.

2.4 The second stage of decision making, for those patients deemed to have exceptional clinical circumstances, i.e. whether the medicine should be authorized for this individual patient, should be undertaken by the panel using a decision making framework to include 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 the implications of the request on the equity of service provision in Grampian.

3 Decision making panel

3.1 The decision making panel will consist of ten members of whom:

(a) five will be comprised of a senior medical representative, a specialist or Consultant in public health and a senior pharmacist, and single representatives from the Grampian Medicines Management Group and the Formulary Group;
(b) two will be comprised of a senior finance officer and a senior NHS manager;

(c) three will be comprised of single representatives from the Clinical Ethics Committee, Clinical Governance Committee and a public representative from the NHS Grampian Community Forum;

(d) one of the above panel 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) and one each from paragraphs (b) and (c) or their deputies are present.

4 Patient representation
There is no requirement on the patient to come before the decision making panel. However, it is accepted that some patients may wish to make representation to the decision making panel either in person or through a representative. Therefore, the patient will be offered the opportunity to make representation to the decision making panel, either in person or through his/her chosen representative (this representative should not be acting in a legal capacity during the panel meeting but may be the patient’s solicitor if the patient so wishes) regarding their case for receiving the requested treatment. This representation may be personal, through a recorded message, in writing or in any other suitable manner agreed with the coordinator of the process. NB The patient or their representative will not be permitted to be in attendance during the decision making panel’s deliberations / decision making. If the patient decides not to make representation to the panel this will have no negative / detrimental effect on the consideration of their case.

5 Reporting

5.1 The decision making panel to produce a report summarising their decision to be presented to the Grampian Medicines Management Group for ratification of the decision.

5.2 A report summarising the decision, including the reasons for the decision, to be communicated to the clinician and the patient within 14 days of the decision being ratified by the GMMG, by the individual coordinating the process.

5.3 Patient to be informed that they have the right of appeal.

6 Appeals of the panel decision

6.1 Appeals will only be allowed on the following grounds:

- Assertion or evidence relating to the improper application of the decision making process itself (procedural impropriety). In these instances it will be for the appeal panel to consider whether the deviation materially affected the decision made.
- Where the decision was so outrageous that no rational authority could possibly have reached it (sometimes referred to as the “Wednesbury reasonableness” principle)

6.2 Appellants wishing to appeal should write to the Chief Executive of NHS Grampian Board identifying the grounds of their appeal. Appellants should normally make such appeals within three calendar months of the original panel decision being communicated to them.

6.3 Appeals will normally be heard, subject to the availability of panel members, representatives and any reports / information within six working weeks of the appeal being received.

6.4 Appeal Group Membership
Appeal panel membership should not include individuals previously involved in the decision making panel.

They should include the following postholders or their representatives:
- Non-executive Board Member (Chair of the Appeal Group)
- Chair, Area Clinical Forum
- Senior Clinical Manager – Medical Director or Nursing Director
- NHSG Legal Advisor
- Director of Medicines Management

6.5 Patient representation

The patient / patient’s guardian will be offered the opportunity to make representation to the appeal group, either in person or through their chosen representative (this representative should not be acting in a legal capacity) regarding the grounds of their appeal.

6.6 Reporting

A report of the appeal panel will be made to the Operational Management Team (OMT) and will be made available to the patient within fourteen days of the appeal panel meeting.

6.6 Successful appeals will normally result in a direction that the decision should be made again.

6.7 Successful appeals will result in a new decision being made (NB Not necessarily a different outcome)

6.8 Decision making following a successful appeal will be coordinated by OMT.

6.9 An unsuccessful appeal means that options within NHS Grampian processes have been exhausted, with the medicine not being made available to the patient in NHS Grampian.

7 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.

7.1 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 Form C, initiating the decision making process again including review of the new evidence. NB If the SMC are timetabled to consider the medicine NHSG will wait for such advice to be made as this is NHSG policy; i.e. a decision making panel will not be set up locally.