Policy for requests to prescribe medicines, which are not normally recommended for use, for individual patients in NHS Highland

NHS Highland

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Method

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1. Purpose and Scope

1.1 This guidance outlines the process to be followed when clinicians in NHS Highland wish to prescribe medicines for **individual patients**, not groups of patients or the first of a potential group of patients, out with normal NHS Highland policy and where the anticipated cost per cycle/annum exceeds £2000.

This process will be co-ordinated by the Exceptional Medicines Use Subgroup (EMUS) of the NHS Highland (NHSH) Area Drugs and Therapeutics Committee (ADTC).

Requests for medicines costing less than £2,000 per cycle/annum should be dealt with at directorate/CHP level using a similar process of governance involving lead clinician, lead pharmacist and manager.

1.2. NHS Highland recognises that there will be times when prescribers may wish to prescribe a medicine in exceptional clinical circumstances contrary to agreed local NHSH policies that either is awaiting Scottish Medicines Consortium (SMC) advice, SMC has advised should not be used in NHS Scotland (NHSS), or is contrary to NHS Highland's policy.

This policy aims to:

- ensure medicines for patients in NHS Highland are as safe and effective as possible
- promote consistency, fairness and equity
- ensure effective use of resources
- improve the rigour of the process ensuring that decisions are rational, reasonable and transparent.

The policy and associated guidance in this document describe NHS Highland's processes for the prescribing of medicines in such circumstances, specifically prescribing of:

- medicines which are awaiting SMC guidance
- medicines which the SMC has not recommended for use in NHS Scotland.

2. Background to national and local processes for recommending medicines

2.1 The regulatory process

The safety, effectiveness and cost-effectiveness of medicines are controlled by regulatory and advisory processes. 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 Agency (MHRA) or the European Medicines Agency (EMA) and the expert advisory bodies to ensure that the sometimes difficult balance between safety and efficacy is achieved.

2.2 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.

2.2.1 National

In NHSS this assessment is provided at, or close to, the point of licensing by the SMC. The SMC considers the clinical and cost effectiveness of all newly licensed medicines and provides advice to NHSS as to whether the medicine is accepted for use, and if so its place in treatment.

2.2.2 Local

The implementation of national advice from the SMC and, in some circumstances the National Institute for Health and Clinical Excellence (NICE), where ratified by NHS Quality Improvement Scotland (NHSQIS), is dealt with through the Formulary Subgroup (FS) of the Area Drugs and Therapeutics Committee (ADTC). 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 Highland with the relevant guidance and policies to support clinicians' prescribing decisions and to manage the use of medicines in Highland.

3. Requests to prescribe medicines for a patient who's clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal, contrary to agreed local NHS Highland policies

There may be occasions where a prescriber feels that his/her patient will benefit from a medicine that has not been recommended for use in NHSH i.e. medicines either awaiting SMC guidance or for which the SMC has recommended that it should not be used in NHSS.

3.1 Requests to prescribe medicines which are awaiting SMC guidance - NHSH policy is that medicines should only be used once SMC guidance has been published, the guidance discussed with local clinicians and the place of the medicine in local treatment decided through the Formulary Subgroup of the ADTC. This process is managed by the NHSH Formulary Subgroup of the ADTC. Where SMC has accepted that a medicine should be made available for use in NHSS the Formulary Subgroup decides which of these drugs should join the Highland Formulary, with input from local clinicians. **3.1.1** 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 NHSS and the company manufacturing the medicine makes a further submission. In instances where the SMC then goes on to accept 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. **3.1.2** Despite this, the NHSH position remains, that medicines which are going through, or are due to go through, the SMC process should not be used in NHSH. To do otherwise would undermine the national SMC process, to which NHSH is committed. Some have argued that where there is a delay in SMC decision-making NHSH 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 NHSH undertakes the review and made decisions locally the SMC will have provided its guidance anyway.

3.2. Requests to prescribe a medicine which the SMC has not recommended for use in NHS Scotland

Where SMC recommends that a medicine is not used in NHSS, NHSH 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 is significantly different to the group of individuals upon which the SMC advice and NHSH policy is based and 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.

In order to demonstrate this, the patient:

- Must be *significantly different* to the population of interest
  AND
- Be more likely to benefit from this intervention than might be expected than other patients with the condition **OR** have a contraindication to the established therapy.

Only evidence of clinical need should be taken into consideration. Factors such as demographic, lifestyle or other social factors such as employment or parenthood will not be considered on grounds of equality.

The fact that the treatment might be efficacious for the patient is not, in itself, grounds for them being significantly different clinically. Neither is the fact that a patient's clinical picture matches "accepted indications" for a treatment which is not normally provided.

Responsibility for demonstrating significantly difference clinically rests with the requesting clinician. In considering whether a patient's case is significantly different clinically or not, the group of patients against which the patient must be considered is the group of patients who are suffering from that particular condition and not the general population. The fact that someone has an "exceptional medical condition" does not, in itself, justify treatment which is significantly different from the normal treatment.

3.2.1 In these circumstances a request to use a medicine in significantly different clinical circumstances should be made using Form A (Appendix 1) and the accompanying process guidance (Appendix 2).

3.2.2 Once completed by the requesting clinician a copy of Form A should be sent to the Professional Secretary of the Exceptional Medicine Use Subgroup of the ADTC who will provide a copy to the Chair of the EMUS of the ADTC and process co-ordinator. One copy of Form A will be added to the patient notes, one copy will be sent to the requesting clinician and the original will be retained by EMUS. These forms should be updated once the decision making panel decision has been ratified.

3.2.3 The aim is to have a decision on the request within 15 working days of receiving a fully completed request using Form A. If a patient's clinical circumstances mean that this timescale is unsuitable the process co-ordinator will work with the requesting prescriber in conjunction with the Medical Director and Director of Pharmacy to facilitate a more timely decision.

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

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

3.2.5 Only where requests to prescribe such medicines are deemed to meet the significantly different clinical circumstances criteria will the decision making panel move on to consider whether authorisation of the treatment should be provided. **NB** meeting significantly different clinical circumstances criteria does not automatically result in authorisation of the request.

3.2.6 The process to be followed in requesting use of a medicine in significantly different clinical circumstances is outlined in section 4.

4. Process for a request to use a medicine in significantly different clinical circumstances

4.1 Initiation of the request

4.1.1 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 significantly different clinical circumstances (using Form A).

4.1.2 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). The process co-ordinator and NHSH Medicines Management and Information Department at Raigmore Hospital can work with the requesting clinician to do this.

4.1.3 Requesting prescribers will produce a patient report (to be incorporated onto Form A) for the decision making panel.

4.1.4 The completed request (Form A) should be submitted to the Professional Secretary of the EMUS (in due course, as the new process is implemented, co-ordinators will be assigned to individual requests and the information forwarded to them).

4.1.5 The decision making process will commence upon satisfactory completion and receipt of Form A and the systematic review of evidence.

4.2 Decision making

4.2.1 The first decision to be made by the panel is whether the individual patient's clinical circumstances are significantly different, i.e. that there is acceptable evidence that the clinical circumstances of the patient under consideration are significantly different in some way that would improve either the clinical or cost-effectiveness of the treatment to such an extent that NHS Highland's policy not to support/fund a particular treatment should not apply to him/her as an individual case.

4.2.2 If the panel concludes that significantly different clinical circumstances haven't been shown then the NHSH 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.

4.2.3 If the panel concludes that significantly different 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 for this individual patient.

4.2.4 The second stage of decision making, for those patients deemed to have significantly different clinical circumstances, i.e. whether the medicine should be authorised 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 opportunity cost of supporting treatment) and the implications of the request on the equity of service provision in Highland.

5. Decision making panel

5.1 The decision making panel will consist of up to 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 representatives from the NHS Highland Exceptional Medicines Use Subgroup of the ADTC and/or the Formulary Subgroup;

(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 patient public participant.

(d) One of the above panel will be Chairman.

5.2 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. In addition the quorum should be made up of at least two medical representatives as part of the criteria mentioned.

5.3 A decision will be made within 15 working days whenever possible pending availability of the patient, and/or the patient's representative and panel members.

5.4 There may be occasions when a decision on treatment is required more quickly. The requesting clinician is asked to highlight before completing the form by contacting the Professional Secretary of the EMUS of the ADTC and facilitate prompt decision making.

6. Patient and prescriber attendance at the meeting

6.1 Patient attendance

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. If the patient decides not to make representation to the panel this will have no negative/detrimental effect on the consideration of their case. The patient would not normally be in attendance for the decision making itself.

6.2 Prescriber attendance

The prescriber who has made the request will be asked to attend the meeting to present the request and also to answer questions from the panel during the decision making.

7. Reporting

7.1 The decision, including the reasons for the decision, will be communicated to the patient within 24 hours. Who communicates the decision will be confirmed at the meeting with the patient's choice being the priority.

7.2 The patient will be informed that they have the right of appeal.

7.3 The decision making panel will produce a report within 3 days summarising the decision.

8. Appeals of the panel decision

8.1 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).

8.2 Anyone (patient, their representative or the requesting clinician) wishing to appeal should write to the Chief Executive of NHSH identifying the grounds of their appeal. Such appeals should normally be made within two calendar months of the original panel decision having been communicated to the patient and clinician.

8.3 Appeals will normally be heard, subject to the availability of panel members, representatives and any reports/information within 28 days of the appeal being received.

8.4 Appeal Group Membership

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

They should include the following post holders or their representatives:

- Non-executive Board Member (Chair of the Appeal Group)
- Chair, Area Clinical Forum
- Senior Clinical Manager – Medical Director or Nursing Director
- Director of Pharmacy

8.5 Patient and clinician representation

The patient or their carer/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.

The requesting clinician will be offered the opportunity to make representation to the appeal group regarding the grounds of their appeal.

8.6 Reporting

A decision of the appeal panel will be communicated to the Chairman of the EMUS of the ADTC and the patient within 24 hours. A report will be made available to the patient within 5 working days of the appeal panel meeting.

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

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

8.9 Decision making following a successful appeal will be undertaken within 15 working days.

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

9 Review of the decision in the light of new evidence

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

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

10 Governance

10.1 The EMUS reports to NHSH ADTC which in turn reports to NHSH Board. An annual report of decision making will also be presented to NHSH Clinical Governance and Risk Management Committee.

REQUEST TO PRESCRIBE A MEDICINE FOR A SINGLE PATIENT IN SIGNIFICANTLY DIFFERENT CLINICAL CIRCUMSTANCES (>£2000 per cycle/annum)
FORM A

This form should be used to request a medicine, which NHS Highland (NHSH)/Scottish Medicines Consortium (SMC) has not recommended for use in NHS Highland (NHSH)/NHS Scotland (NHSS) 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 current NHSH policy is based *

FOR ADVICE ON YOUR REQUEST PLEASE CONTACT THE PROCESS CO-ORDINATOR (details at end of form)

Sections A, B, C & D to be completed in BLOCK CAPITALS (preferably electronically/typed) by the Prescriber in collaboration with a Pharmacist

Date _____

SECTION A

Hospital/CHP		Patient Name			
Ward (if applicable)		CHI number			
Doctor		Address			
Tel No.		Tel No.			
Mobile/Bleep No.		Date of Birth		Sex	

All sections must be completed for all requests. This form is for a request for the stated patient only.

SECTION B - Product required			
Approved Name of Medicine			
Brand Name of Medicine			
Strength	Formulation	Unit Cost	Manufacturer
Quantity Required (please specify doses, dosing frequency, number of cycles, length of treatment etc)		Anticipated Total Treatment Cost = cost of medicine **plus** additional costs (scans, tests, inpatient stays etc) **minus** any cost savings if any (e.g. cost of alternative drug)	

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

Date and reference number of SMC decision (if applicable):

Is there a treatment protocol available? E.g. NICE guidance which does not apply in Scotland, from other UK countries or abroad Y/N ** If so, please attach a copy.

Please state whether the medicine is for use in hospital or primary care or whether there will be shared care.

SECTION C - Significantly Different Circumstances and Patient Report (Please use Plain English where possible)

(To be supported by a systematic review of published clinical evidence in association with medicines management staff - contact process co-ordinator for details)

What is the clinical condition being treated?

What is the goal of treatment/anticipated outcome?

Are the patient's clinical circumstances unique or representative of a wider group of patients?

What is the reason that this patient's clinical circumstances are significantly different i.e. how are they/ and their anticipated response to treatment significantly different to the clinical circumstances of the group of patients referred to in the NHSH/SMC policy not to use this medicine?

What are the anticipated treatment outcomes associated with:

a) **providing the requested treatment?**

b) **not providing the requested treatment?**

What are the criteria for continuation/discontinuation of treatment?

What is the treatment option should the proposed treatment fail or not be tolerated?

Proposed date treatment to begin

The aim is to make a decision on this request within 15 working days after a fully completed request is received by the process co-ordinator. If a patient's clinical situation means that this timescale is unsuitable please state why and describe the urgency required (it is suggested that you contact the process co-ordinator directly by telephone).

Patient Report (*Please use this space or append as additional sheets a patient report detailing the background of the patient's progress from diagnosis to the request to use the medicine including relevant clinical data, interventions, responses etc)*

**delete as appropriate

*Read notes on use of Form A 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/patient (see guidance sheet for further information. Attach a separate sheet if required).	
Prescriber's Signature	Date:

Section E to be completed by Head of Service/Clinical Director/CHP Clinical Lead

SECTION E	
This request to use the above specified medicine in significantly different circumstances has been discussed at Directorate level. I/we** as Head of Service/Clinical Director/CHP Clinical Lead ** are aware of the submission of this request to the Exceptional Medicines Use Subgroup (EMUS) of the Area Drug and Therapeutics Committee (ADTC).	
Head of Service/Clinical Director/CHP Clinical Lead Signature	Date:

Form to be submitted to the Professional Secretary (Process Co-ordinator) of the EMUS of the ADTC on completion of section A-E.

Sharon Pfleger, Professional Secretary to EMUS (Process Co-ordinator), Consultant in Pharmaceutical Public Health, NHS Highland, Public Health Department, Assynt House, Beechwood Business Park, Inverness, IV2 3HG. Tel 01463 704950, fax 01463 717666, email: *sharon.pfleger@nhs.net*

SECTION F To be completed by Prof Sec EMUS/Request Co-ordinator			
Date request received:		Name, Designation and Signature:	
Request completed correctly YES/NO** (if NO, outline steps taken and dates) Date systematic review initiated Date systematic review completed Medicines Management and Information comments on systematic review			

SECTION G - Decision making panel		
Date of decision making panel meeting:		
Decision panel members (names and designations):		

Decision of panel:

Are the patient's clinical circumstances significantly different? Yes/No**

Has the proposed treatment been approved? Yes/No**

Comments:

SECTION H - For pharmacy procurement section only if medicine has to be ordered in a hospital					**Date received**
New Product Record No.		Supplier			
Therapeutic Classification		Order No.		Ordered By	
Shelf Location		Expected Delivery Date			
Unit Cost		Quantity Ordered			
Ref No.		Issued		Date:	

Appendix 2

REQUEST FOR MEDICINES SUPPLY FOR SINGLE PATIENT IN SIGNIFICANTLY DIFFERENT CLINICAL CIRCUMSTANCES (>£2000 cycle/annum)

Notes on use of Form A and additional documentation required

Form A must be completed to request supply of a medicine where the:

- Request is for a **single** patient, as opposed to a group of patients or the first of a group of patients in which case a formulary application should be made. *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 medicine.*

- Request is for the use of a medicine, which NHSH/SMC has not recommended for use in NHS Highland (NHSH)/NHS Scotland (NHSS) 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 Scottish Medicines Consortium (SMC) advice or NHSH policy is based i.e. better clinical response, greater cost effectiveness.

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 significantly different 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 or another health board (costing < £2000 per cycle/annum), where a change to formulary medicine would or may be detrimental (Use Non-formulary request form available at http://intranet.nhsh.scot.nhs.uk/Clinical/Formulary/Pages/Default.aspx under the non-formulary request section).
- 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 marketing authorisation (licence) application is unlikely to be made.
- Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied.
- *Note: NHSH 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 Subgroup.*

Please note that the decision making panel may be made up of non clinicians and lay representatives so Plain English, where possible, should be used.

All patient details will be removed for the members of the decision making panel.

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 clinicians are asked to work with the Exceptional Medicine Use Subgroup (EMUS) Professional Secretary (process co-ordinator) and the Medicines Management and Information staff to design and review the systematic review.

- The completed request (Form A) including a full patient report, declaration of interest and separate details of published evidence should be submitted to the process co-ordinator.

  Sharon Pfleger, Professional Secretary to the Exceptional Medicine Use Subgroup of the ADTC, NHS Highland, Public Health Department, Assynt House, Beechwood Business Park, Inverness, IV2 3HG, Tel 01463 704950, Fax 01463 717666, sharon.pfleger@nhs.net

- NHSH's Medicines Management and Information Department will support the co-ordinator and requesting clinician in undertaking the systematic review.

The decision making process will commence upon satisfactory receipt of Form A and agreement on the search strategy for the literature review.

DECLARATION OF INTERESTS

INTRODUCTION

NHS Highland Area Drug and Therapeutics Committee has for some time operated a policy of requiring members to declare any interests relevant to the matters under consideration at any of its meetings and for clinicians completing formulary applications. The committee recently agreed that this policy should be extended to include clinicians requesting medicines in significantly different circumstances.

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.

Initial letter to the patient

Dear (patient)

REQUEST FOR THE MEDICINE XXXXXXXXXXXXXXXXXXX

Dr xxxx, who is treating you, has made a request to treat you with the medicine xxxxx. The evidence for using this medicine has been considered by NHS Scotland's expert medicine group, the Scottish Medicines Consortium and it decided that the medicine should not be accepted for use in NHS Scotland.

However, Dr xxxxx believes that you might be expected to respond better to the drug than those patients that were in the clinical trials on which the SMC made its decision. Therefore he/she wishes to use xxxx as part of your treatment.

In NHS Highland our first priority is to ensure that patients are prescribed medicines which are safe and effective, and therefore, we have a process to consider requests such as yours. We put together a group of local experts and patient participants to consider the evidence and decide if NHS Highland should make the medicine available for your treatment.

I enclose information explaining the process, and a more detailed document that explains NHS Highland policy in full.

I have been appointed to co-ordinate the process. I will be your main point of contact for any questions you might have about the process. As co-ordinator I will not be part of the decision making panel.

We wish to arrange a meeting of the decision making panel as soon as possible. The dates we are looking at are xxxx, xxxx or xxxx. The meeting is likely to last between 1.5 and 2 hours and will be held in (town).

As you will see in the enclosed information, you may attend the meeting if you wish, either to observe or make representation to the panel. But you will leave the meeting when the panel makes its decision. If you wish to attend then obviously we will have the meeting when you are available to attend. If you wish to present supporting information to the panel and feel the timescale is too short, then please let me know. If travelling to the meeting would be difficult we may be able to arrange video or teleconference facilities.

Please contact me or my secretary, xxxxx, to let me know if you wish to be present and to confirm whether any of these dates are convenient and acceptable to you.

I am happy to answer any questions you have about the process by telephone, letter, e-mail or in a meeting, whichever you would prefer, and to offer any support I can, to make the process as easy and straightforward as possible for you.

A copy of this letter and information will also be sent to you by post.

Yours Sincerely

Patient information: requests to use medicines that are not accepted for use in NHS Highland

Background

When a new medicine is licensed the licensing process tells us that a new medicine works better than placebo (nothing), is safe and that the medicine can be manufactured to certain standards. What licensing doesn't tell us is how well a drug works (clinical effectiveness), or what value it delivers (cost effectiveness).

Therefore, the decision to use the medicine in NHS Scotland (NHSS) is separate to the process of licensing. In Scotland information about all newly licensed medicines is considered to decide whether they should be used by the NHS in Scotland to treat patients. This decision is made by a group of experts called the Scottish Medicines Consortium (SMC). SMC looks at all newly licensed medicines on behalf of all the NHS Boards in Scotland. Before a medicine is accepted for use in the NHS in Scotland the SMC looks at whether the medicine is clinically effective and cost effective and what it offers over the medicines we are already using in the NHS.

The clinical effectiveness of the drug will include the proportion of people who get a good response to the medicine once given it and the effects (both the good effects and the side effects) of the medicine. The cost effectiveness of the medicine will include what it costs to buy and use.

How do we decide which medicines should be used in Highland?

The medicines that are accepted for use in NHS Highland (NHSH) make up a list which is called the Highland Formulary. The Highland Formulary accounts for about 90% of the drugs that are commonly used in NHSH. It helps doctors to decide which drug will be the best to treat their patient. Like most other NHS Boards NHSH has a Formulary Subgroup made up of doctors, pharmacists, nurses and patient/public participants. The Formulary Subgroup, in partnership with local doctors, decides how to put advice from the SMC into practice in Highland.

Our policy in Highland is that medicines waiting for the SMC to make its decision should not be used until the decision has been published as SMC guidance, the guidance discussed with local doctors and the place of the medicine in local treatment has been decided through our Formulary Subgroup.

Where SMC approves a medicine for use in Scotland the Formulary Subgroup decides which of these drugs should join the Highland Formulary, with input from local doctors. Where there isn't an alternative medicine to the one accepted by SMC the Formulary Subgroup follows the SMC's approval and adds the medicine to the Highland Formulary making it a recommended medicine for Highland.

However, there are many new medicines which are very similar to the medicine NHSH already has on the Formulary. These medicines are known as 'me-too' medicines and for these the Formulary Subgroup, with the input of local doctors who would use the medicine, has to decide whether the new medicine is better than the one we currently use.

Following discussion with local doctors the Formulary Subgroup decides if the 'me-too' medicine gives better clinical effects and/or is more cost effective than the medicines recommended for local use in the Highland Formulary. If it does then the Formulary Subgroup may add the new medicine to the Formulary, recommending it for use in Highland.

What happens when SMC says no to a medicine?

When SMC decides that a medicine should not be used in Scotland NHSH follows that decision.

However, we recognise that there may be rare occasions when a doctor considers that the clinical circumstances of his/her patient would mean that they might be expected to respond better to the drug than those patients that were in the clinical trials on which the SMC made its decision. In other words the patient's clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal. This could mean that the SMC decision not to use the medicine doesn't apply to his/her particular patient.

In these situations the normal policy of not using that medicine might not apply to that individual patient and a decision whether to use the medicine for that individual patient needs to be made. In these situations we have a process to allow the doctor to request use of this medicine.

How does a doctor make a request to use a medicine which has not been accepted for use in NHSS or NHSH?

There is a request form known as Form A which the doctor fills out to request the use of a medicine that the SMC has not accepted (turned down) for use in Scotland. The doctor will make the case as to why the patient is significantly

different and how this makes using the medicine more clinically and cost effective than normal.

Using this evidence a decision making panel, comprised of local experts and patient participants, will decide whether the patient's clinical circumstances mean that they might be expected to respond better to the drug than those patients that were in the clinical trials on which the SMC made its decision. In other words the patient's clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal. If they are, then the NHSH general policy not to use the medicine does not apply to the individual patient and a decision to use the medicine in that individual patient needs to be made. The panel will then decide whether the clinical and cost effectiveness is acceptable and whether use of the medicine should be authorised.

Who do patients communicate with during this process?

If your doctor has made a request on your behalf you will obviously be in touch with your doctor. In addition you will be provided with the contact details of the person who is co-ordinating the request, as we understand that patients going through this process may need help and support. The co-ordinator will be happy to answer any questions and if a face to face meeting is required, will be happy to arrange that, to explain any areas of concern individual patients may have.

We can also provide details of an independent advocacy service for you.

Who will be on the decision making panel?

The panel is made up of local experts, a mixture of doctors, pharmacists, NHSH management, patient participants and representatives of our governance committees.

Can patients make representation to the panel?

The patient doesn't have to come to the decision making panel meeting. However, some patients may want to come to the meeting just to listen to the information presented or may want to say something to the panel themselves. The patient can speak to the panel at the meeting; use a recorded message; give a written message to the panel which can be read out on their behalf; or in any other suitable manner agreed with the co-ordinator of the process. The patient will then leave the meeting and the panel will move on to make a decision.

If the patient decides not to attend the decision making panel meeting, this will have no negative/detrimental effect on the consideration of their case.

How does the panel make its decision?

The first decision to be made by the panel is whether the individual patient might be expected to respond better to the drug than those patients that were in the clinical trials on which the SMC made its decision. In other words the patient's clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal. The panel is looking to show that there is acceptable evidence that the clinical circumstances of the patient under consideration, would in some way improve either the clinical or cost effectiveness of the treatment, to such an extent that Highland's policy not to fund a particular medicine, should not apply to the patient as an individual case.

There is a delicate balance to be achieved between the safety of the patient in using this new drug; equity for the patient and the general population in NHSH; quality of life for the patient and value for money for NHSH.

If the panel decides that there is not acceptable evidence to improve clinical or cost effectiveness, then the NHSH policy on that medicine applies eg if SMC has decided that the medicine should not be used, the patient and the doctor would be advised that treatment will not be made available in NHSH.

If the panel concludes that the patient might be expected to respond more favourably, then the panel must go on to consider the second stage of decision making, ie whether the medicine should be authorised for this individual patient.

The second stage of decision making, 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 the implications of the request on the equity of service provision in Highland.

How long does decision making take?

We aim to bring a decision making panel together within 14 working days of a completed request, using Form A, being received by the co-ordinator of the process. The actual date that a panel will meet will depend on the availability of the patient and/or their representative, should either wish to attend and the panel members. Normally a decision will be made on the day but it is possible that additional information will be needed to make the decision, which isn't available on

the day. Sometimes, a second meeting might be required, although it is anticipated that this would be a rare event.

How long after the panel have met will the patient know the decision?

The decision, including the reasons for the decision, will be communicated to the patient within 24 hours of the panel meeting. Who communicates the decision will be confirmed at the panel meeting with the patient's choice being the priority.

A report summarising the decision, including the reasons for the decision, will be communicated to the doctor and the patient, as soon as possible thereafter.

Are there circumstances where this process does not apply?

The main circumstance where this process would not be used is where more than this one individual patient might be expected to respond better. In other words, the patient is one of a group of patients that have significantly different clinical circumstances to the patients to which the policy of not using the medicine applies. In these circumstances, NHSH will work with local doctors, pharmacists and the SMC (where possible) to assess the evidence for use in the entire subgroup of patients, either through an update of the advice from SMC or, where this does not happen, a local review managed by the Formulary Subgroup.

Is there an appeal process?

Appeals can be held on two grounds. Firstly, if the patient believes that the decision making panel has not followed the proper process and procedures laid down, then they may make an appeal. Secondly if they believe the decision to be irrational ie that no rational authority could make the decision made by the panel, on the evidence considered. The appeals process is not designed to make a new decision but only to confirm that the process laid down was followed or that the decision made was rational based on the evidence considered.

Is there other information I might find useful?

The full set of documents describing this process are available by contacting Sharon Pfleger, Consultant in Pharmaceutical Public Health, Public Health Directorate, NHS Highland, Assynt House, Beechwood Business Park, Inverness. Telephone number: 01463 704950.

Guidance for chairpersons of the NHS Highland decision making panel on requests to use medicines that are not recommended for use in individual patients in NHS Highland

Key roles of the Chairperson

- To ensure the decision making panel meeting is undertaken as described in the guidance provided in "Policy for requests to prescribe medicines, which are not normally accepted for use, for individual patients in NHS Highland".

- To Chair the panel's discussion and decision regarding the request for treatment.

- To prepare a report of the decision making panel, with the support of the process co-ordinator, for the Exceptional Medicines Use Subgroup (EMUS) of the NHS Highland (NHSH) Area Drugs and Therapeutics Committee (ADTC).

Prior to the meeting

- You should meet with the co-ordinator a few days before the meeting to discuss the meeting papers.

- You should meet the co-ordinator on the day of the meeting at a time arranged by you (normally at least 30 minutes beforehand) to make final preparations for the panel meeting.

NB All of the organisation for the meeting i.e. production of papers, liaison with panel members and the patient will be undertaken by the process co-ordinator. The process co-ordinator will be your primary contact for all matters relating to the panel meeting.

During the meeting

- Before the meeting starts you and the co-ordinator should confirm that the panel is quorate (guidance in process document).
- You, along with the co-ordinator, should meet and greet the patient, the representative from Medicines Management and Information (presenting evidence on the medicine) and the clinician (who has requested the medicine).
- You should remind the patient of the running order of the meeting and that they will leave prior to the decision being made. You should also ask the patient who they would like to have to inform them of the panel's decision, e.g. the co-ordinator, their clinician etc.
- At the start of the meeting you or the co-ordinator should outline the purpose of the meeting emphasising the two stages in the process i.e. the decision regarding whether the patient's clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal and if this is the case, the decision whether the medicine should be funded. A reminder of the process after the meeting and when the patient will be informed of the decision should be stated.
- You should introduce everyone in the room or ask those present to introduce themselves.
- As chair it will be for you to run the meeting with the support of the co-ordinator (in relation to any procedural issues).
    - It will be important to ensure that each speaker is allowed to present without interruptions, other than clarification. There is an opportunity for presenters and the panel to question each presenter after each presentation.
- You should allow time at the end of all the presentations for questions to be asked/open discussion to take place.
- At the end of the presentations and discussion you should thank the speakers, remind the patient of when the decision will be communicated to them and remind the Medicines Management and Information representative that you may need to contact them by telephone if the panel has a further question.

- You or the co-ordinator should then usher the patient and speakers from the room.

Decision making

- The first decision to be made by the panel is whether the clinical case is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal; i.e. that there is acceptable evidence that the clinical circumstances of the patient under consideration is significantly different in some way that would improve either the clinical or cost effectiveness of the treatment to such an extent that Highland's policy not to support/fund a particular treatment should not apply to him/her as an individual case.

- If the panel concludes that this hasn't been shown then the NHSH policy on that medicine applies e.g. if SMC has not recommended that the medicine should be used, the patient and his/her prescriber would be advised that treatment will not be made available.

- If the panel concludes that the case has been proven then the panel must go on to consider the second stage of decision making i.e. whether the medicine should be authorised for this individual patient.

- The second stage of decision making, for those patients deemed to have a clinical case which is significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal exceptional clinical circumstances i.e. whether the medicine should be authorised for this individual patient, should be undertaken by the panel using a decision making framework to include consideration of:

    1. health benefit (including response rate, timing of benefits and likely benefit to the individual patient)
    2. value for money (including cost effectiveness and the relative opportunity cost of supporting treatment)
    3. implications of the request on the equity of service provision in Highland.

- Please note that demonstrating that the patient's case is significantly different does not automatically mean that the medicine should be funded. It is acceptable to conclude that a patient is significantly different but that the cost effectiveness of the medicine etc still does not provide a reason for funding.

- As Chair you will need to take the panel through a decision/judgement on each of these individual aspects, as the panel report will be expected to have addressed each.

- It is advisable to agree a form of words for each of the three elements with the panel so that final agreement on the report is made easier.

After the meeting

- It is advisable to outline the report immediately after the meeting. The co-ordinator can provide support in this.

- The report should be sent by e-mail to the panel membership as soon as possible after the meeting, for comments and agreement.

- Where necessary you may need to liaise with panel members by telephone.

- Once the report is finalised it should be sent to the Chair of the Exceptional Medicines Use Subgroup of the NHS Highland Area Drugs and Therapeutics Committee. The co-ordinator will advise of the deadline for the report being finalised.

Guidance for individuals coordinating the NHS Highland decision making panel on requests to use medicines that are not recommended for use in individual patients in NHS Highland

General

- It is important that the patient, clinician and NHS management have a single point of contact in charge of managing a request to use a medicine under that are not accepted for use for individual patients.

- The individual appointed as co-ordinator should remain as co-ordinator throughout the request, including any appeal process.

- Individuals co-ordinating the process should not be part of the decision making.

- Co-ordinators should have access to administrative support to arrange meetings, finalise letters and reports etc.

- To get everything done within the 14 working days is onerous and relies on the co-ordinator making very early contact with all involved and booking any meetings and rooms required in the first few days after receiving a request.

What to do once a request is received

1. Check whether the request been made using the appropriate form (Form A).

2. Check that the request meets the requirements described in Section 3 and Appendix 2 of the policy document "Policy for requests to prescribe medicines, which are not normally accepted for use, for individual patients in NHS Highland".

3. In particular check that the request:

    - is for an NHS Highland (NHSH) resident
    - has a full patient report included
    - clearly states the evidence which makes the patient's clinical case significantly different to normal in some way that means that using the medicine in that one patient is more clinically and cost effective than normal
    - is not for a medicine awaiting SMC guidance (see SMC work plan on website www.scottishmedicines.org.uk)
    - is for a single patient and not a group of patients or the first in a likely group.

4. Arrange for a response to the request using the letter templates provided to the clinician and to the patient.

5. Contact the Head of Medicines Management and Information to request and agree a systematic review of the published literature, to be undertaken as part of the evidence based report for the Decision Making Panel.

6. Contact the Chair of the Exceptional Medicines Use Subgroup of the Area Drugs and Therapeutics Committee, to produce a list of potential panel members and a potential Chair amongst those members.

7. Agree timescales of report production, in order to meet the 14 working day limit for decision making. Remember to include time for the clinician to review the report generated by Medicines Information.

8. Agree a suitable meeting date with the patient (and or representatives); Medicines Management and Information Pharmacist; Clinician making the request and the Decision Making Panel members. It is useful to approach more panel members than you actually need to ensure that you are quorate.

9. Book a suitable room with appropriate access (with PowerPoint available) and administrative support (minute taker) for the Panel meeting. **NB** refreshments will also be needed.

10. Arrange a pre-meeting with the patient if they have requested one. This meeting should be minuted (by someone other than you), with a draft note of the meeting being shared and agreed with the patient, before a definitive note of the meeting is released. It is particularly important to note any queries/issues and your responses to these. It is acceptable to say 'I don't know, but I'll find out' to a query and any response should be included in the note of the meeting as an addendum.

11. Confirm that the reports from Medicines Management and Information and the Clinician are on schedule.

12. Confirm that the clinician has had the opportunity to comment on the Medicines Management and Information report.

13. Produce an agenda for the meeting and collate all the papers.

14. All papers should be made available to everyone attending the panel meeting a week before the meeting.

15. You should confirm with the patient that they have received the papers (if they are sent by royal mail they should be sent recorded delivery).

16. Around a week before the meeting you should meet the Chair of the panel to ensure they are clear in relation to the purpose and running of the meeting and to go through the papers.

17. Arrange for hard copies of papers to be available at the meeting for anyone who has forgotten their copies.

At the meeting

1. Arrange to meet the chair of the panel 30 minutes before the start of the meeting to have a final briefing and to arrange the room if needed.

2. Meet the patient and remind them of how the meeting will work, that they will leave the meeting when the panel makes the decision and how and when the decision will be communicated to them. Ask the patient who they would like to have to inform them of the Panel's decision within 24 hours of the Panel meeting eg, you, their Clinician etc.

3. Make sure you have contact numbers for the Medicines Management and Information representative if you need to contact them with a query during the panel's deliberations.

4. Load any presentations on to the computer and make sure everything is ready for the meeting.

During the meeting

1. The Chair will introduce the meeting.

2. You will be asked to confirm that the process laid down in the policy document "Policy for requests to prescribe medicines, which are not normally accepted for use, for individual patients in NHS Highland" has been adhered to.

3. You or the Chair should escort the patient, and their representatives, out and remind them of how and when they will be informed of the panel's decision.

After the meeting

1. You should liaise with the Chair and the Administrative Support Officer to produce the report of the panel.

2. You should ensure that this report is submitted to the Chair the Exceptional Medicines Use Subgroup for ratification before the patient and clinician are informed of the decision.

3. You should ensure the patient and/or their representative and the clinician have been informed of the outcome within 24 hours of the panel meeting.

4. Form A should be completed with details of the decision and copies sent to the clinician and the Head of Service/Directorate General Manager.

5. Liaise with the Professional Secretary of the EMUS to ensure all details and learning points are communicated.

Glossary

ADTC	Area Drug and Therapeutics Committee
EMA	European Medicines Agency
EMUS	Exceptional Medicines Use Subgroup
FS	Formulary Subgroup
MHRA	Medicines and Healthcare Regulatory Agency
NHSH	NHS Highland
NHSS	NHS Scotland
NHSQIS	NHS Quality Improvement Scotland
NICE	National Institute for Health and Clinical Excellence
SMC	Scottish Medicines Consortium