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The Scottish Government

Dear Colleague

GUIDANCE TO FURTHER STRENGTHEN THE SAFE AND EFFECTIVE USE OF NEW MEDICINES ACROSS THE NHS IN SCOTLAND

Introduction

The Scottish Government is committed to patients in Scotland receiving medicines of established cost-effectiveness and therapeutic value. This guidance sets out further measures to strengthen previous guidance issued under CEL 17 (2010)[1] and SGHD/CMO(2011)3[2].

Purpose

The key purpose of this guidance is to address 3 main issues to further strengthen the extant guidance published in 2010 and 2011 (as set out above):

(i) the need to standardise a timeframe for NHS Boards to consider Scottish Medicines Consortium (SMC) accepted medicines and to publish advice accordingly;

(ii) the need for NHS Boards to have sufficient information on which to consider those medicines accepted by the SMC that represent therapeutic advancement; and

(iii) measures to assist NHS Boards in their consideration of Individual Patient Treatment Request (IPTR) arrangements.

Scope

The guidance provides further advice for NHS Boards in relation to the introduction of newly licensed medicines (as an update to CEL 17 (2010). The guidance:

- removes the extant facility for the SMC to designate medicines as "unique";

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Addresses

For action
NHS Board Chief Executives
Special NHS Board Chief Executives
NHS Board Directors of Public Health
NHS Boards Directors of Pharmacy
NHS Board Medical Directors
NHS Board Chairs or Area Drugs & Therapeutics Committees
NHS Board IPTR Leads
Regional Cancer Network Managers
Regional Cancer Network Lead Clinicians
Regional Cancer Pharmacy Leads

For information

Chair, Scottish Medicines Consortium
Chief Executive, Healthcare Improvement Scotland
Area Clinical Forum Chairs

[1] http://www.sehd.scot.nhs.uk/mels/CEL2010_17.pdf

[2] http://www.sehd.scot.nhs.uk/cmo/CMO(2011)03.pdf

- reminds NHS Boards about their responsibilities with regard to ensuring transparency in local consideration of SMC accepted medicines;
- introduces a standard timescale for making and publishing formulary decisions;
- clarifies that NHS Board decisions about SMC accepted medicines should be published in a standardised way;
- reminds NHS Boards about their responsibilities to maintain an overview of the effectiveness of the arrangements for the introduction of new medicines;
- reminds NHS Boards about their responsibilities to review these as part of their formulary and IPTR management processes and to take action where appropriate.
- sets out additional measures to improve NHS Board consideration of IPTRs including consideration of seeking peer support for IPTR requests; establishment of IPTR registers by NHS Boards which articulates the rationale for IPTR decisions and the need for NHS Boards to get together at least annually to identify and share good practice in relation to IPTRs; and attaches anonymised worked examples of IPTRs as an illustration of how the process can be applied in practice.

How to use the Guidance

As set out in CEL 17 (2010), decisions regarding the provision of NHS services remain matters for NHS Boards; and clinicians remain responsible for clinical decisions regarding the care of individual patients. However, the need to adopt consistent and standardised approaches to the introduction of newly licensed medicines whilst reflecting their local circumstances is key to ensure that patients continue to receive medicines of established cost-effectiveness and of therapeutic value.

The guidance comprises an overview and two annexes:

- **Annex A** which sets out a specific guidance framework for NHS Boards to apply when updating their written policy in relation to NHS Board formulary decision-making for SMC accepted medicines; and

- **Annex B** which sets out additional guidance which NHS Boards should, as a matter of good practice, seek to apply when dealing with requests for medicines which have not been recommended by the SMC.

Actions for NHS Boards

NHS Boards are asked to confirm by **no later than 1 April 2012** that their policies on formularies and management of IPTRs have been updated to reflect this additional guidance.

Yours sincerely

Harry Burns *Bill Scott*

SIR HARRY BURNS **PROFESSOR BILL SCOTT**

GUIDANCE TO FURTHER STRENGTHEN THE SAFE AND EFFECTIVE USE OF NEW MEDICINES ACROSS THE NHS IN SCOTLAND – OVERVIEW

Introduction

Medicines are an essential part of clinical care and it is the responsibility of NHS Boards to ensure that patient care is optimised through the most effective and efficient use of the most appropriate medicines.

Context

NHSScotland has robust systems in place at national and NHS Board level to ensure that clinically and cost-effective treatments are made available to patients in Scotland and to assist prescribing rationalisation of the large numbers of medicines available in the market place. The Scottish Medicines Consortium (SMC) appraises all newly licensed medicines for clinical and cost-effectiveness and publishes advice for NHS Boards. Where the SMC accepts a medicine, then there is a clear expectation that NHS Boards will consider it and will make it (or its equivalent) available.

New Medicines Appraisal Arrangements at National Level

The role and remit for the Scottish Medicines Consortium was fully articulated in CEL 17 (2010). The benefits of having a national body to appraise all newly licensed medicines, new formulations of existing medicines and new indications for established products near to the launch of the products are well understood and the certainty of having this advice published quickly means that the Scottish arrangements are the envy of many other countries in Europe and beyond.

In addition to the extant advice arrangements, the SMC will explore opportunities for co-ordinating a programme of activity through seminars and utilisation of their website, in order that NHS Board Non-Executive Directors, clinicians, patients and the general public have a better understanding of the SMC arrangements.

New Medicines Appraisal Implementation Arrangements at Local Level (Formulary Decision-making)

CEL 17 (2010) clarified that where the SMC has accepted a medicine, NHS Boards are expected to make it, or its equivalent, available. There is a need to provide clarity around what this means in practice – i.e. how NHS Boards reach decisions about the implementation of SMC accepted advice; where information about which medicines are available on the NHS Board formulary can be obtained; and the timescales involved. Specific guidance on NHS Board management of formulary decision-making is set out in **Annex A**.

Key Messages for NHS Boards in relation to Management of Individual Patient Treatment Requests (IPTRs)

In response to concerns raised by Patient Interest Groups and the Pharmaceutical Industry regarding consistency of approach to NHS Board management of IPTRs, **Annex B** contains further key messages to support local NHS Board decision-making.

NHS Board Consideration of SMC Accepted Medicines (Formulary Decisions)

SMC Accepted Advice

As set out in CEL 17 (2010), the SMC undertakes a robust and rapid appraisal of newly licensed medicines and publishes advice for NHS Boards on their clinical and cost-effectiveness.

Since its inception in January 2002, the SMC has had the facility to designate an innovative medicine for a condition where no other treatment options exist as "unique". There has only been one such designation, which was later annulled when another medicine to treat the condition in question became available. With this one exception, the SMC has found no cause to so designate a medicine. Therefore, the facility to categorise medicines as "unique" by the SMC is removed with immediate effect.

Medicines which represent a Therapeutic Advancement

The SMC will review the content of its advice to NHS Boards to highlight situations where the evidence presented to the SMC, indicates that a medicine represents a therapeutic advancement over and above comparator medicines to treat the condition in question. This will include an articulation of the SMC's assessment of the estimated Quality Adjusted Life Year (QALY) gain[3] (where possible) and consensus of opinion of the place that the medicine would have in therapy as provided by clinical experts (where this has been articulated). This will provide NHS Boards with the additional information they need on which to base local clinical decisions in relation to both SMC "accepted" medicines (via the formulary management arrangements) and SMC "not recommended" medicines (via the IPTR management arrangements).

NHS Board Consideration of SMC Accepted Advice

The means by which SMC accepted medicines are considered locally are through the NHS Board Area Drug and Therapeutics Committees (ADTCs) who do so through one of two routes:

1. through ADTC consideration of the SMC accepted advice as a matter of course by,

    - taking full account of the SMC assessment of the medicine's therapeutic advancement over and above comparator medicines to treat the condition in question;
    - considering its place in therapy within current treatment pathways;
    - agreeing the treatment protocol; and
    - assessing its resource and service implications.

[3] The Scottish Medicines Consortium published A Guide to Quality Adjusted Life Years on their website to explain how they use this tool to decide whether or not a medicine is value for money in the NHS in Scotland. This Guide can be viewed via the following link: http://www.scottishmedicines.org.uk/About_SMC/Policy_Statements/A_Guide_to_Quality_Adjusted_Life_Years

An illustration of this process is attached at **Flowchart 1**.

2. through a process whereby application for formulary inclusion for the newly licensed medicine is proactively sought by:

    - contacting relevant NHS clinicians in the Board area and inviting an application for the newly SMC accepted medicine to be included on the NHS Board formulary;
    - where clinicians support inclusion in the formulary, a formal application will be submitted to the ADTC for consideration (as set out above);
    - where clinicians do not support inclusion in the formulary, a submission to the ADTC will not be progressed;
    - where clinicians do not respond to the invitation to apply for formulary inclusion, a submission to the ADTC will not be progressed.

An illustration of this process is attached at **Flowchart 2**.

Timescale for Formulary Decisions

NHS Boards are expected to reach a decision on an SMC Accepted medicine **within 90 days** of the issue of SMC advice to NHS Boards (i.e. this advice is confidential for the first 30 days). However, there may be certain circumstances which will necessitate a degree of flexibility in relation to the time frame e.g. to allow for training; premises requirements; testing etc. NHS Boards are expected to publish on the website, the formulary decision **within 14 days** of the decision being reached.

Standard Advice on NHS Board Formulary Decisions

NHS Boards are expected to issue standard advice to reflect formulary decisions as follows:

- **Included** on the NHS Board formulary for the indication in question;
- **Included** pending protocol;
- **Not Included** on the NHS Board formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question;
- **Not Included** on the NHS Board formulary because clinicians do not support the formulary inclusion;
- **Not Included** on the NHS Board formulary because clinicians have not responded to an invitation to apply for formulary inclusion for this medicine;
- **Not included** pending protocol.

Where a medicine has not been included in the formulary, there will be a link to the formulary in order that the comparator medicines can be viewed.

Access to SMC Accepted Medicines Before and After SMC Advice is Published

NHS Boards are expected to ensure clinicians are fully conversant with the routes of access to SMC accepted medicines during the period of pre-published SMC advice – (through the IPTR route); and post-publication of SMC advice – (either through the NHS Board formulary where the medicine has been accepted onto the formulary; or through a non-formulary request where the medicine has not been accepted onto the formulary). NHS Boards are expected to provide training as required to ensure clinicians are familiar with the IPTR and non-formulary processes.

Formulary Decisions Pending Protocol

Where it has been agreed to include an SMC accepted medicine in the formulary but the medicine requires a protocol to be in place then this should normally be within the 90 day period. If the required protocol cannot be in place within this timeframe then the formulary advice needs to be updated once the protocol has been agreed.

Transparency of NHS Board Decisions

NHS Boards are expected to present formulary decisions in a consistent and transparent way. As a minimum, NHS Boards are expected to maintain on their website, an up to date list of SMC accepted medicines with standard advice to confirm whether these medicines are included or not included within the NHS Board formulary. An illustration of the type of list we would expect NHS Boards to provide is outlined in **Appendix 1**.

Consistency of Decision-making Processes

NHS Boards are expected to apply common principles and processes in the introduction of newly licensed medicines in order to facilitate consistency of approach to local decision-making. However, such decisions will be based on clinical opinion within the local context and, as such, cannot be generalised.

Non Formulary Request Process

CEL 17 (2010) clarified that where the SMC has accepted a medicine, NHS Boards are expected to make it (or its equivalent) available. In these situations, the NHS Boards are expected to use their current formulary guidance to identify the appropriate comparator medicine to be used.

NHS Boards are expected to have a written policy on the facility for clinicians to access medicines which are not on the Board's formulary through the non-formulary request process. As set out in CEL 17 (2010), the NHS Board is expected to provide an opportunity for public involvement in the development of the policy through their patient focus and public involvement arrangements; the policy should be impact assessed and should be written in such a way that is sensitive to the communication and language needs of their audience. The NHS Board is expected to signpost patients and their carers to the NHS Board policy for non-formulary requests.

Overview of Effectiveness of Formulary Arrangements - Monitoring

<u>Maintaining Local Records of Non-Formulary Decisions and Rationale</u>

As set out in both CEL 17 (2010), NHS Boards are expected to maintain accurate and up to date information on Non-formulary requests and the outcomes. In addition, it would be beneficial for NHS Boards to maintain a record of the rationale for such decisions.

<u>It is important that NHS Boards ensure that there are separate data collections and records in relation to non-formulary requests; prescribing of unlicensed/"off-label" medicines and IPTRs.</u>

Review of Formulary Decisions and Rationale

NHS Boards should, as a matter of good practice, undertake periodic reviews of their formulary decisions to take account of changes of clinical evidence. This would provide an opportunity for reassessment of medicines for formulary inclusion where appropriate. It would also be beneficial for NHS Boards to identify and share good practice in formulary management.

Illustration A: NHS Board Consideration of SMC Accepted Medicines Where ADTCs Review SMC Accepted Medicines Routinely

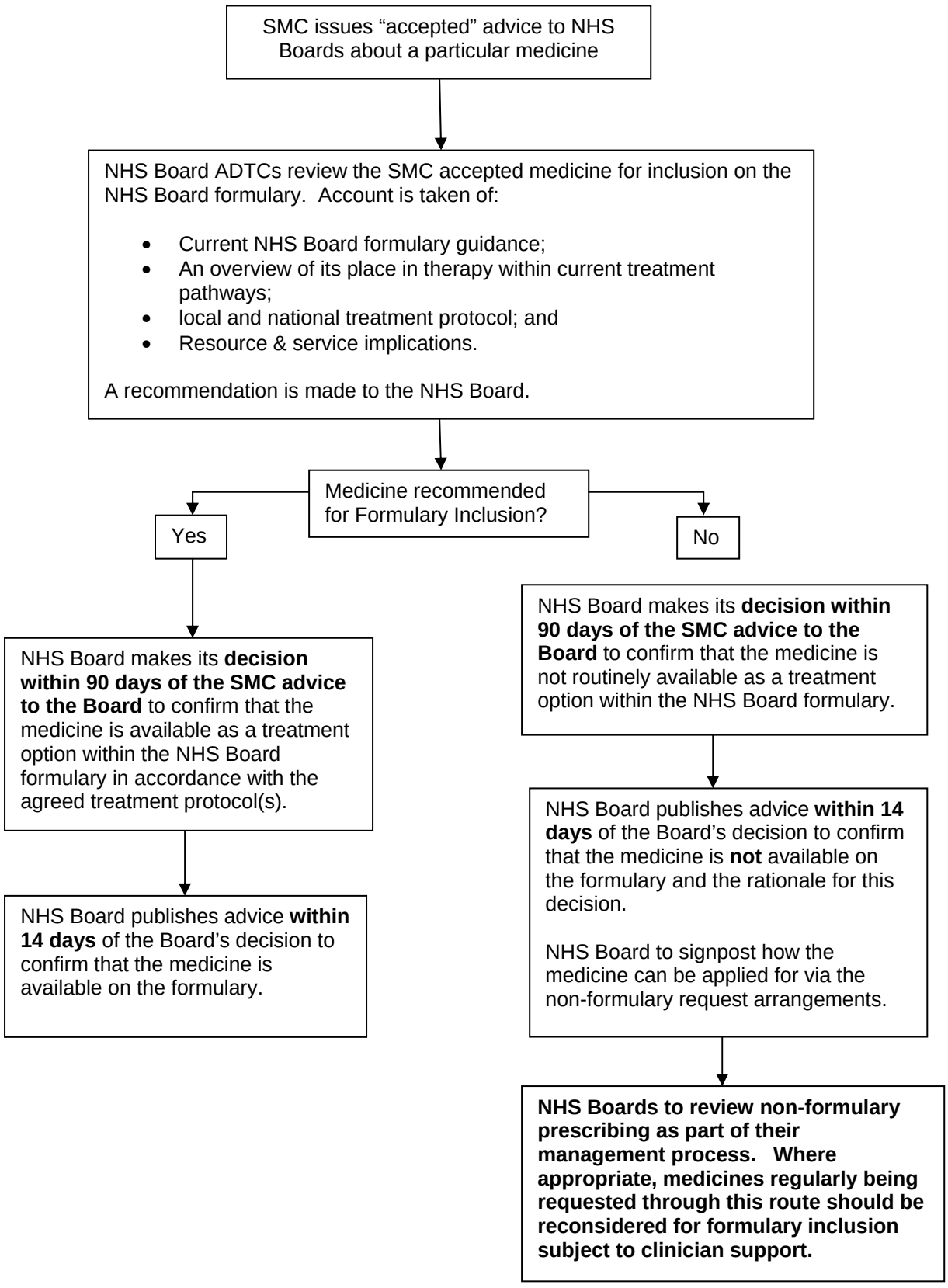
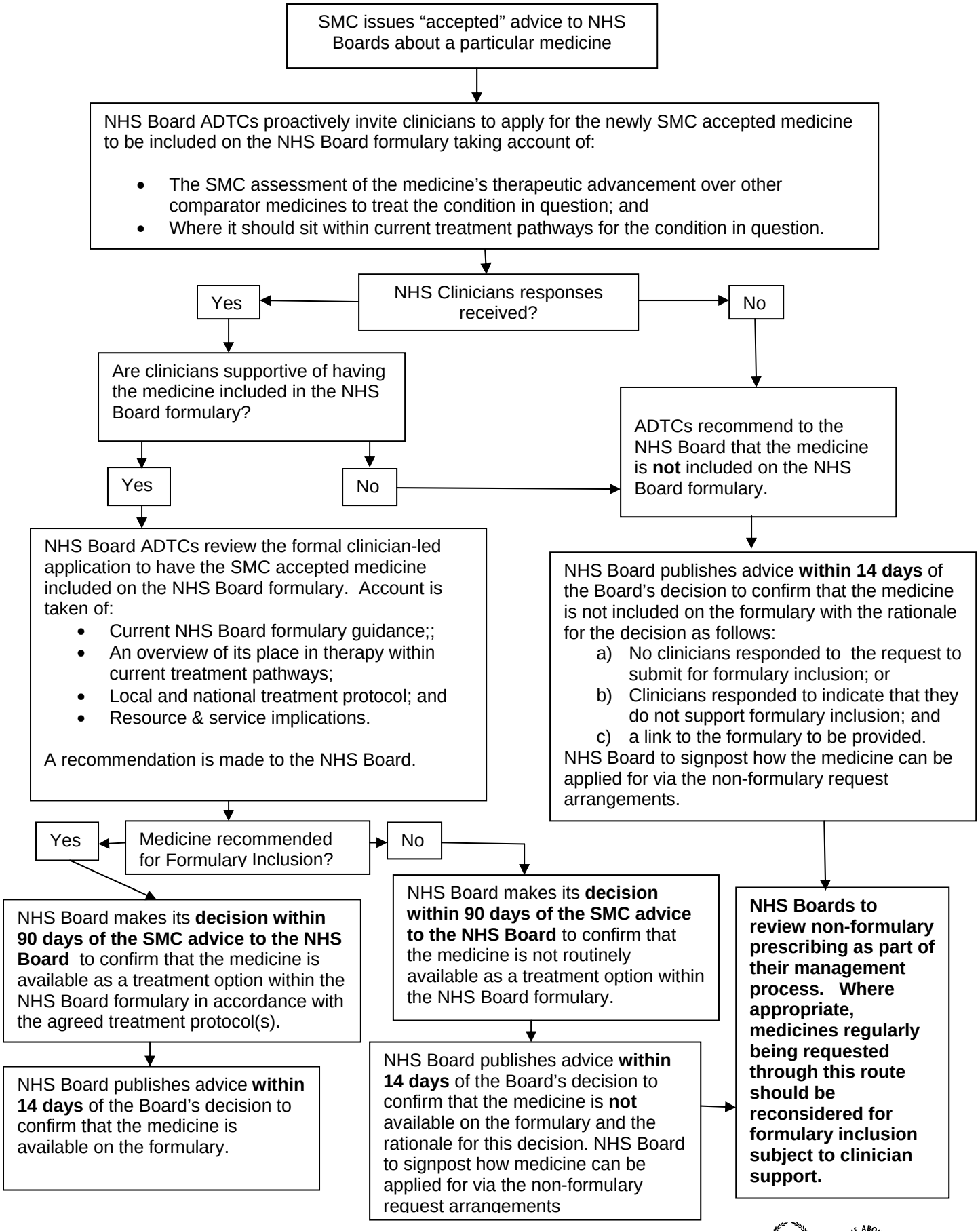


Illustration B: NHS Board Consideration of SMC Accepted Medicines Where Clinicians are Invited to Apply for Formulary Inclusion



Appendix 1

NHS Board Formulary Information on SMC Accepted Medicines

NHS Boards are expected to publish updated lists of SMC accepted medicines **included** and **excluded** from their formularies together with the rationale for such decisions:

SMC Accepted Medicine	Indication	Formulary Decision & Rationale for non-inclusion (See Note 1 Below)	Date

Note 1: Categories for Formulary Decision are:

- **Included** on the NHS Board formulary for the indication in question;
- **Included** pending protocol;
- **Not Included*** from the NHS Board formulary because the NHS Board decision is that the medicine does not represent sufficient added benefit to other comparator medicines to treat the condition in question which are already available in the formulary;
- **Not Included*** from the NHS Board formulary because clinicians do not support the formulary inclusion;
- **Not Included*** from the NHS Board formulary because clinicians have not responded
  to an invitation to apply for formulary inclusion for this medicine;
- **Not included*** pending protocol.

* Where a medicine has not been included in the formulary, there will be a link to the formulary in order that the comparator medicines can be viewed.

ANNEX B

Key Messages in relation to NHS Board Consideration of SMC Not Recommended Medicines (Individual Patient Treatment Requests)

Overview

NHS Boards are asked to take account of the following key messages, as a matter of good practice, when dealing with requests for medicines, which have been appraised within their licensed indication by the Scottish Medicines Consortium or Healthcare Improvement Scotland, but have not been recommended for use within NHSScotland (as an update to SGHD/CMO (2011)3).

IPTRs play an important role in the provision of individual clinical care and provide an opportunity to prescribe SMC "not recommended" medicines in a range of situations.

Scope of IPTR Requests

IPTRs can only be sought for a medicine within its licensed indication – i.e. it does not cover requests for medicines which have not yet been licensed or for medicines outside their licensed indication.

The IPTR process can be particularly valuable when a patient, for clinical reasons, is unable to be treated for their condition with other medicines which are accepted for use by the SMC. IPTRs can only be pursued where the patient's clinician fully supports the request.

Eligibility Criteria for IPTRs

The criteria as set out in SGHD/CMO(2011)3 offers equitable and fair criteria on which to make such decisions whilst offering NHS Boards a degree of flexibility to meet individual patient needs.

Making an IPTR Referral to the NHS Board – Support from Peers/Multidisciplinary Teams

Where a clinician has decided to submit an IPTR for a medicine which has not been recommended by the SMC, he/she may wish to seek peer support for the application from colleagues either from within the NHS Board or from another NHS Board. The purpose of such peer support is to provide the requesting clinician with an opportunity to "sense check" his/her assessment of the potential added benefit that the patient would gain from the medicine in question. Similarly, where the care of the patient in question is under the care of a multi-disciplinary team, clinicians can consider seeking their support for the IPTR application.

However, obtaining such support should not adversely impact on the timescale for the application.

Shared Care Arrangements

Where the care of a patient is shared between Primary and Secondary care, the clinician who supports the use of an SMC "not recommended" medicine should take responsibility for the IPTR request.

IPTR Panels

Members of IPTR panels are expected to be fully conversant with the national guidance set out in CEL 17 (2010); SGHD/CMO(2011)3 as well as this guidance and the local NHS Board policy on IPTRs. IPTR panels are expected to include a practising medical consultant with (or with access to) specialist knowledge of the relevant clinical area. NHS Boards are expected to ensure panel members have an opportunity to undertake adequate training as required.

Timescales for IPTR Decisions

The timescales for consideration of IPTRs should be prioritised in accordance with the patient's clinical needs. NHS Boards are expected to undertake preliminary examination of IPTR requests to ensure that due consideration is given to the urgency of the request given the patient's clinical condition.

Overview of Effectiveness of IPTR Arrangements - Monitoring

Maintaining Local Records of IPTR Decisions and Rationale

As set out in both CEL 17 (2010) and SGHD/CMO(2011)3, NHS Boards are expected to maintain accurate and up to date information on IPTR requests and the outcomes, including the outcome of any appeals. In addition, it would be beneficial for NHS Boards to maintain a record of the rationale for such decisions, which will provide an opportunity for these to be reviewed with a view to identifying and sharing good practice. It would be beneficial for NHS Boards to meet at least annually to share good practice in relation to IPTR management.

It is important that NHS Boards ensure that there are separate data collections and records in relation to non-formulary requests; prescribing of unlicensed/"off-label" medicines and IPTRs.

NHS Boards should consider reviewing GP prescribing of SMC "not recommended" medicines as part of their ongoing review of primary care prescribing

Consistency of Decision-Making Processes

NHS Boards are expected to apply common principles and processes in the introduction of newly licensed medicines in order to facilitate consistency of approach to local decision-making. However, IPTR decisions will be based on local clinical opinion on a "case by case" basis for individual patients and, as such, cannot be generalised.

NHS Boards are encouraged to identify and share good practice in relation to the rationale for IPTR decisions in order to achieve greater consistency of approach. In order to illustrate how the IPTR process can been applied in practice, anonymised worked examples of IPTRs will follow.