Healthcare Policy and Strategy Directorate
Quality Division

The Scottish Government

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Addresses

For action
NHS Board Chief Executives
Special NHS Board Chief Executives
NHS Board Directors of Public Health
NHS Board Medical Directors
NHS Board Directors of Pharmacy
NHS Board Chairs of Area Drugs and Therapeutics Committees
NHS Board Exceptional Prescribing Leads
Regional Cancer Network Mangers
Regional Cancer Network Lead Clinicians
Regional Cancer Pharmacy Leads

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Dear Colleague

INTRODUCTION AND AVAILABILITY OF NEWLY LICENSED MEDICINES IN THE NHS IN SCOTLAND

Dear Colleague

This guidance sets out the policy framework with regard to the introduction and availability of newly licensed medicines in the NHS in Scotland which includes wider considerations such as the Pharmaceutical Price Regulation Scheme (PPRS) and Patient Access Schemes (PAS). It has been developed in consultation with key stakeholders and consolidates previous guidance issued under HDL(2003)60 and HDL(2006)29.

Purpose

The key purpose of this guidance is to provide a framework within which NHS Boards are expected to align their local policies regarding access to newly licensed medicines. The framework will provide a solid basis for the development of local policies and is designed to achieve a consistent approach to the introduction of newly licensed medicines across NHSScotland.

Scope

The guidance:

- Provides an overview of the "end to end" process from licensing of medicines through to individual patient treatment (exceptional prescribing) requests which NHS Boards can adapt for local use;
- Sets out the framework under which local NHS Board policies about access to newly licensed medicines are expected to be developed;
- Reminds NHS Boards about their responsibilities with regard to providing information for patients describing the arrangements and informing them of decisions;
- Identifies specific key features for NHS Boards to address when considering individual patient treatment requests (IPTRs); and
- consolidates previously issued guidance on the role of the Scottish Medicines Consortium (SMC) under HDL(2003)60 and the status of Single Technology Appraisals (STAs) from the National Institute for Health and Clinical Excellence (NICE) under HDL(2006)29.

How to use the Guidance

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, there is a need to ensure that NHS Boards adopt a consistent approach to management of the introduction of newly licensed medicines whilst reflecting their local circumstances. New medicines are medicines which have been granted a marketing authorisation (licence). For the purpose of this guidance, the term "licensing" will be used throughout this document to describe the granting of a marketing authorisation**.**

The drugs bill in Scotland for 2008/09 was in the region of £1bn, which represents approximately 10% of NHS Board expenditure. NHS Boards in Scotland are charged with making important decisions about which medicines to prescribe and to ensure that those selected are safe, effective and represent value for money. NHSScotland has systems in place at national and NHS Board level to ensure cost-effective treatments are made available to patients and to assist prescribing rationalisation of the large numbers of medicines available in the market place.

In developing local written policies based on the principles outlined in the guidance and making these available via their websites, NHS Boards will be able to demonstrate consistency of approach as well as openness and transparency of their policies and processes. An information leaflet for the public has been developed by Health Rights Information Scotland (HRIS) to describe how newly licensed medicines are introduced in NHS Scotland. The leaflet provides an overview of the arrangements and advises where additional information can be obtained, including from NHS Boards.

This guidance should be considered alongside guidance on Arrangements for NHS patients Receiving Healthcare Services Through Private Healthcare Arrangements issued under CMO(2009)3 on 25 March 2009.

The guidance comprises four Annexes:

- **Annex A** sets out the "end to end" process of introducing new medicines from licensing through to individual patient treatment (previously referred to as exceptional prescribing) requests; describes the role and status of NHS Quality Improvement Scotland advice; and provides an overview of the UK process for introducing newly licensed medicines (Flowchart 1);

- **Annex B** sets out the role of the Scottish Medicines Consortium; the status of its advice; and provides an illustration of NHS Board arrangements for consideration of SMC accepted medicines (Flowchart 2);

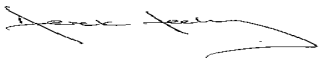
- **Annex C** sets out the general guidance framework for the introduction of newly licensed medicines within NHSScotland under which, NHS Boards should develop their written polices; and

- **Annex D** sets out a specific guidance framework for NHS Boards to apply when developing a written policy for individual patient treatment requests for medicines not accepted by the Scottish Medicines Consortium (SMC). It includes an overview of NHS Board arrangements for managing individual patient treatment requests (Flowchart 3).

Actions for NHS Boards

NHS Boards will be asked to provide written assurance that substantive progress has been reached in the development of such policies in accordance with the framework provided by 30 December 2010. NHS Boards will be asked to confirm that policies are in place by 1 April 2011. The guidance will be reviewed by the end of 2011, or earlier if required.

Yours sincerely



DEREK FEELEY

Annex A

Introduction and Availability of New Medicines in the NHS in Scotland – Process from Licensing through to Individual Patient Treatment Requests

Marketing Authorisation for New Medicines (Licensing)

In the UK, a pharmaceutical company who wishes to bring a medicine to the market has to apply for a marketing authorisation (license). The current relevant legislation for this approach is given in Directive 2001/83/EC relating to medicinal products for human use, amended by Directives 2002/98/EC, 2003/63/EC, 2004/24/EC and 2004/27/EC. This is an area reserved to the UK Parliament.

For the purpose of this guidance, the term "licensing" will be used throughout this document to describe the granting of a marketing authorisation.

Before a medicine gets to the stage of licensing it will, typically, have undergone 12 years of research and development. In this process the substances that were identified in basic research need to pass the pre-clinical and clinical tests.

Following the development process, the pharmaceutical company will seek a licence for the medicine. The purpose of this is to consider whether the medicine has a measurable effect against a placebo or comparator in a clinical trial (referred to as efficacy) and whether, on balance, the medicine is likely to have an acceptable level of safety and quality.

Safety, quality and efficacy are the only criteria on which legislation to control human medicines is founded. It is the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA) and the expert advisory bodies set up by the Medicines Act to ensure that the sometimes difficult balance between safety and efficacy is achieved.

There are two ways of obtaining a licence for the UK:

- Applying for a UK licence through the MHRA; For more information about the process, see their website: www.mhra.gov.uk and

- Applying for a European licence through the European Medicines Agency (EMEA), which relates to all EU member states. For more information about the process, see their website: http://www.emea.europa.eu/

Assessing the Clinical and Cost-effectiveness of Newly Licensed Medicines - Scotland

Once licensed, the pharmaceutical company is expected to provide evidence about the medicine to the appropriate body to assess its clinical and cost-effectiveness for use in the NHS. In Scotland, the clinical and cost-effectiveness of all new medicines is considered by the Scottish Medicines Consortium (SMC). The SMC is a consortium of NHS Board Area Drugs and Therapeutics Committees (ADTCs). It was introduced to avoid duplication of new medicines assessment by individual ADTCs, to avoid geographical inequity in decision making and to make the best use of expertise available across Scotland.

The SMC monitors when pharmaceutical companies are launching new products and proactively invites submissions for the medicine to be appraised so that advice may be issued as closely as possible to when the product is made available. On completion of the

SMC appraisal of the medicine, advice for NHSScotland is published on the SMC website. NHS Boards are expected to follow SMC advice. Where a medicine is accepted by the SMC, NHS Boards are expected to make it (or its equivalent) available. Further detail on the role and remit of the SMC is outlined in **Annex B**.

Assessing the Clinical and Cost-effectiveness of Newly Licensed Medicines - England

In England, clinical and cost-effectiveness of referred new medicines is considered by the National Institute for Health and Clinical Excellence (NICE) either through an evaluation process (Multiple Technology Appraisal) which takes some considerable time to complete or a more rapid process (Single Technology Appraisal) which is similar in nature to the SMC process.

Applicability of NICE advice in Scotland – NICE Multiple Technology Appraisals

NICE does not appraise all newly licensed medicines, only those referred to it by the UK Ministers. NHS Quality Improvement Scotland is involved in the NICE MTA process with one Scottish expert being assigned to an MTA throughout the whole process. In addition, a group of 4-5 experts in Scotland review the draft NICE MTA. When considering the suitability of the NICE MTA for Scotland, NHS QIS takes into account the principles and values of NHSScotland; epidemiology (frequency, distribution and stage at presentation); structure and provision of services; and other implications (such as rural issues, predicted uptake and existing advice from SMC). NHS QIS publishes advice on its website to advise NHS Boards on whether the MTA is valid for Scotland. Where NHS QIS validates a positive NICE MTA recommendation, NHS Boards in Scotland are required to make these medicines available.

Applicability of NICE advice in Scotland – NICE Single Technology Appraisals

The NICE STA process is a more rapid appraisal process which is similar to the SMC process. As NICE does not appraise all medicines, the NICE STA recommendations have no formal status in Scotland and the SMC remains the main source of advice on the use of all newly licensed medicines in Scotland. On the day that NICE STA final advice is published, NHS QIS publishes advice on its website to remind NHS Boards of the extant SMC advice in Scotland.

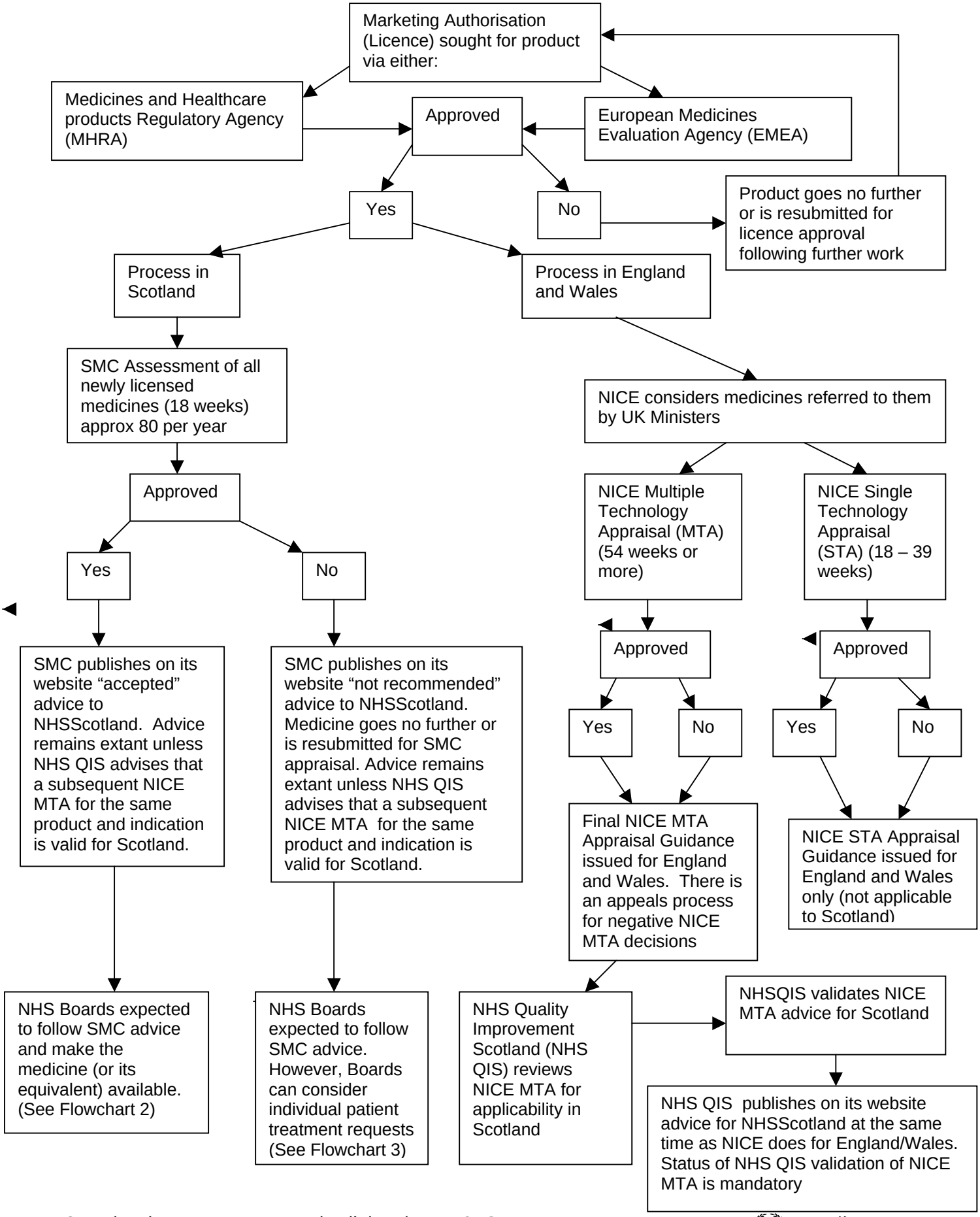
Requests for Medicines not recommended by SMC or NHS QIS

Medicines not recommended by SMC, including those not recommended due to a non-submission, should not routinely be made available by NHS Boards. However, Boards are expected to have published policies in place to articulate their arrangements for consideration of individual patient treatment (previously referred to as exceptional prescribing) requests. Specific guidance on developing a written policy for these arrangements is outlined in **Annex D**.

The UK “end to end” process for introducing newly licensed medicines is summarised in **Flowchart 1** attached for information.

Flowchart 1

Overview: UK Process for Introducing New Medicines



Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland - Appraisal of New Medicines by the Scottish Medicines Consortium

Role and Remit of the SMC

The Scottish Medicines Consortium (SMC) assesses new medicines or treatments for clinical and cost effectiveness so that we can be confident that they offer demonstrable benefits for patients in practice. It meets on the first Tuesday of every month and its remit is to provide advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002). This advice is made available as soon as practicable after the launch of the product involved.

The remit of SMC excludes the assessment of vaccines, branded generics, non-prescription-only medicines (POMs), blood products, plasma substitutes and diagnostic drugs. The review of device-containing medicines is confined to those licensed as medicines by the MHRA/EMEA.

SMC also has a horizon scanning function which aims to improve financial and service planning within NHS Boards through the provision of early intelligence on new medicines in development. An annual 'Forward Look' report is sent in strict confidence to key NHS Board personnel.

SMC Membership

SMC decisions are made by a panel of experts from different fields including clinicians (medical and pharmacy), public partners, health economists, NHS Board Chief Executives and the Association of the British Pharmaceutical Industry (ABPI). The full membership is listed on the SMC website (www.scottishmedicines.org.uk).

SMC Process

The New Drugs Committee (NDC), a subgroup of SMC, undertakes a rapid assessment of the evidence provided by the drug manufacturer and prepares draft advice for the SMC to consider about the costs and benefits of using the medicine. The SMC appraisal looks again at the evidence together with the NDC advice, the case put forward by the patient interest groups and the company's response to the NDC advice. These are difficult decisions which need to weigh up a range of factors including the clinical benefits and costs.

The SMC publishes its advice about medicines on the website. The SMC website can be viewed via the following link:
http://www.scottishmedicines.org.uk

SMC Advice

The majority of medicines reviewed by SMC are medicines for conditions where alternative treatments already exist. Whilst NHS Boards are expected to follow SMC advice, the implementation of SMC accepted medicines is subject to local NHS Board decision regarding whether or not to include these in their formularies.

There is the facility for the SMC to designate an innovative medicine for a condition where there are no other treatment options as "unique". In the event that such a medicine for a specific condition was accepted by SMC, NHS Boards would be required to introduce it to an agreed national programme.

Three NHS Board Chief Executives and three NHS Board Directors of Finance are members of SMC. Under the "unique" SMC categorisation arrangements, this executive cohort on SMC would agree a national implementation plan for unique products and NHS Boards would be required to follow this. Normally these medicines would be provided to meet clinical need within three months of publication of SMC advice, however, there may be some delay in certain circumstances, e.g. where there is a requirement to establish an audit. These executives also have a role of ensuring NHSScotland is alerted at an early stage to SMC advice that may have a high financial cost impact on the NHS.

Availability of Medicines in the NHS following SMC "Accepted" Advice

Where SMC has accepted a new medicine, NHS Boards are expected to make it (or its equivalent) available. NHS Boards therefore review the medicine in the context of other existing comparable medicines available within the Board formulary/approved list to treat the same condition. There is a need for a consistent approach to such considerations and NHS Boards should work together to agree good practice in this regard. An overview of the process is illustrated in **Flowchart 2** attached.

Availability of Medicines in the NHS following SMC "Not Recommended" Advice

Where SMC has issued "not recommended" advice in relation to a medicine, NHS Boards are not expected to make it routinely available. However, medicines "not recommended" by SMC, including those medicines "not recommended" due to a non-submission, can be made available under certain circumstances through individual patient treatment requests. Specific guidance on such requests is outlined in **Annex D**.

Medicines Awaiting SMC Appraisal

SMC proactively pursues submissions from pharmaceutical companies prior to the product being licensed so the timescale between licensing and SMC appraisal is generally short. NHS Boards should not routinely make available medicines which have not yet been appraised by SMC. If clinicians wish to pursue the use of such a medicine, they should do so via their local systems - individual patient treatment requests - using the best evidence base available to assess clinical and cost-effectiveness.

Medicines Not Submitted to SMC

Where a pharmaceutical company decides not to submit their new medicine to be appraised by SMC and it is not covered by any other NHS process/scheme, there is an expectation that such medicines would not be used in the NHS until the company complies with the SMC submission process.

Where a pharmaceutical company has chosen not to submit to SMC for approval, SMC will issue "not recommended" advice. NHS Boards are expected to take account of this advice and therefore such medicines are not expected to be available routinely. Requests for medicines "not recommended" by SMC due to a non-submission should be treated in the same way as requests for any other medicines "not recommended" by SMC (see above). Where medicines have been "not recommended" by SMC, it remains open to the pharmaceutical company to submit or re-submit evidence about the medicine to the SMC at any time.

NHS Board Funding for SMC accepted medicines

NHS Boards are expected to fund the cost of SMC accepted medicines from within their general revenue allocations in the context of their local formulary/approved lists.

The Pharmaceutical Price Regulation Scheme (PPRS) and Patient Access Schemes

The new PPRS includes as a component, a more systematic use of patient access schemes. Patient Access Schemes are schemes where an agreement is reached with a pharmaceutical company in order to reduce the costs of a medicine to the NHS and improve its cost-effectiveness, and enable patients to receive access to cost-effective, innovative medicines. Following consideration by a Short Life Working Group convened by the SMC, it was agreed that the introduction of Patient Access Schemes could bring benefits to patients in Scotland by facilitating access to medicines that are not, or might not be in the first instance, found to be cost-effective by the SMC or where a Patient Access Scheme has been accepted in the context of a NICE MTA.

A Patient Access Schemes Advisory Group (PASAG) has been established to assess proposed Patient Access Schemes against standard objective criteria. The PASAG brings together the key areas of expertise required to assess such schemes and operates under the auspices of NHS National Services Scotland.

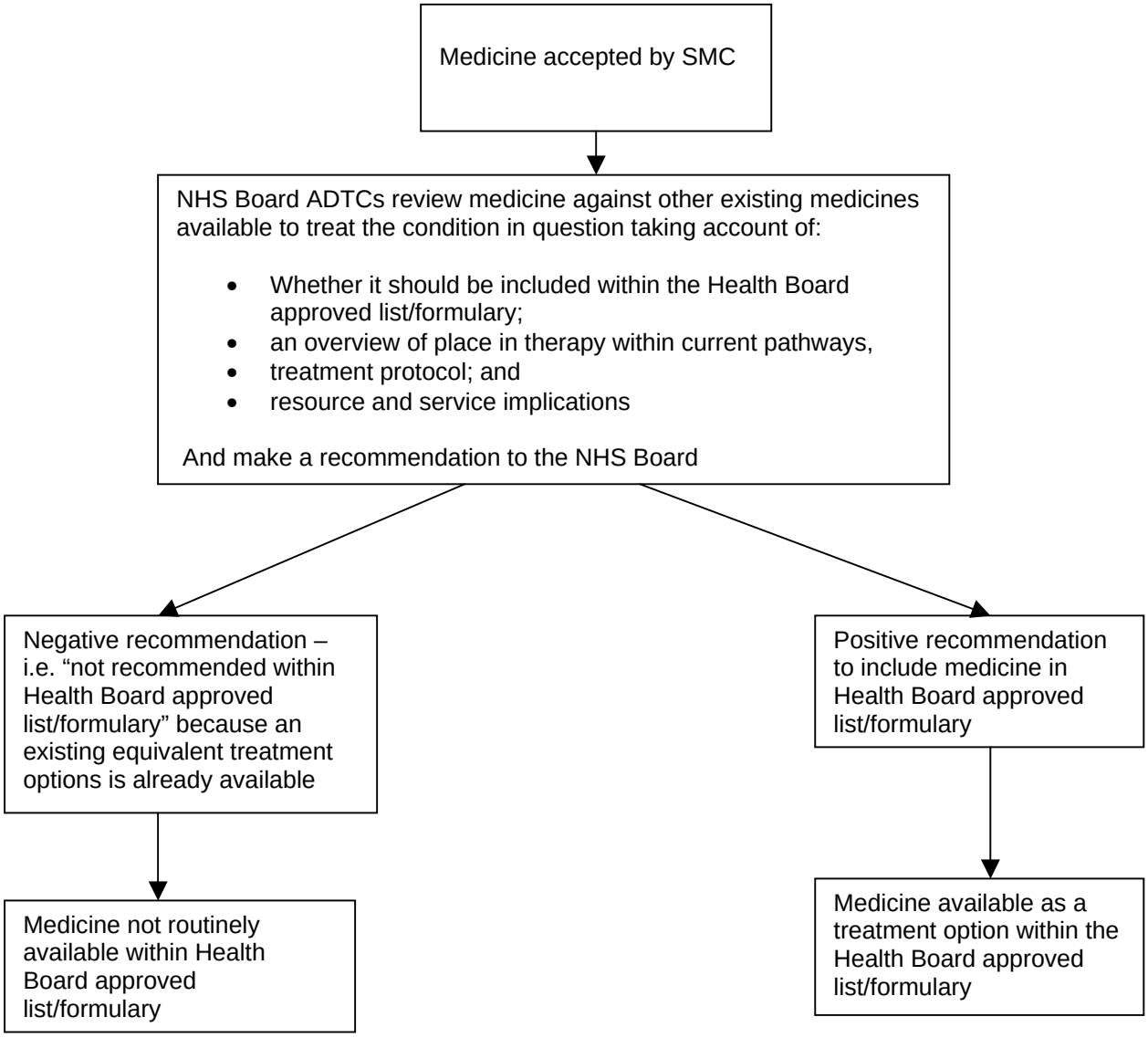
Decisions regarding patient access schemes will be communicated to pharmaceutical companies and to NHS Boards in accordance with the agreed arrangements**.**

SMC Forward Planning/Horizon Scanning

The SMC undertakes a horizon scanning function which aims to improve financial and service planning at NHS Board level through the provision of early intelligence on new medicines in development. Forward Look reports (due to their commercial in confidence nature) are sent in strict confidence to named NHS Board personnel including those involved in horizon scanning or financial planning. NHS Board Directors of Finance also receive a set of summary financial spreadsheets that can be adapted locally as required.

Flowchart 2

Illustration: NHS Board Arrangements for Consideration of SMC Accepted Medicines



NHS Boards are expected to have established local processes for non-formulary requests which are publicly available

General Guidance Framework for NHS Boards to Develop a Written Policy Concerning the Systems and Processes for the Managed Entry of Newly Licensed Medicines for Use in the NHS in Scotland

Introduction

NHS Boards, working within the principles of the NHS, are responsible for the planning and provision of health care and for ensuring NHS services are available on an equitable basis. NHS Boards are charged with ensuring that their processes for strategy development, performance management and resource allocation retain the full confidence of the populations that they serve.

NHS Boards in Scotland are expected to adopt a consistent approach to management of the introduction of newly licensed medicines, following advice from SMC and NHS QIS. NHS Boards are therefore expected to develop and make available on their website, a policy for the managed entry of newly licensed medicines which sets out the local process and decision making arrangements within the context of the framework provided in this guidance. These local policies are expected to include arrangements for managing individual patient treatment requests (previously known as exceptional prescribing requests) as described in **Annex D**.

The overall aim of the framework is to ensure there is consistency of approach across NHS Boards, while providing flexibility to ensure the arrangements reflect local circumstances.

In doing so, it is necessary to ensure that all healthcare professionals involved in local decision-making around newly licensed medicines understand and are conversant with local policies and procedures for the managed entry of newly licensed medicines. NHS Boards are expected to ensure a consistent process for consideration of newly licensed medicines on the basis of clinical need.

Local decisions must ensure that advice from the Scottish Medicines Consortium and NHS Quality Improvement Scotland regarding NICE Multiple Technology Appraisals are fully taken into account within local arrangements. In addition it is necessary to ensure that there is a consistent and systematic process for requests for medicines to be prescribed on a case by case basis for individual patients. Where processes link to regional arrangements such as regional cancer networks, clinical networks or other local processes to make medicines available for certain groups of patients, there is an expectation that these will be applied consistently across all NHS Boards through shared agreement and good practice.

Key Features of Local Decision Making Arrangements

In fulfilling the requirements of this guidance, NHS Boards will be expected to:

- have a written policy which describes the range of systems and processes for the managed entry of newly licensed medicines.

- describe the process to make formulary decisions within the wider board governance and accountability arrangements, including arrangements to make available to the public, the Board's formulary/approved list.

- equality impact assess their written policy.

- be sensitive to the communication and language needs of their audience.

- provide an opportunity for public involvement in the development of the policy through the NHS Boards' patient focus and public involvement arrangements.

- include within the policy, a description of the process for decision-making, including the constitution of any panels or committees; the timeframe for decisions; and a description of the authority on which decisions can be made.

- clarify within the policy, the need to ensure that members of panels or committees involved in local decision-making will be expected to declare any interests which could have an impact on impartiality in decision-making.

- describe the means by which decisions related to individual patients will be communicated to the patient concerned, their families and carers and the timescales which will apply, including how patients will be made aware of opportunities to seek a second opinion on proposed treatment(s) with links to further information as appropriate.

- make information available to the public to describe the arrangements for consideration of newly licensed medicines.

- provide an opportunity for public involvement in developing these arrangements within the NHS Boards' patient focus and public involvement arrangements.

- ensure all staff involved in local decision- making around new medicines are fully conversant with the policies and processes.

- identify suitably trained personnel to provide information to individual patients regarding these arrangements on request. The NHS Board will be expected to ensure clear signposting to this source of help[1].

- have arrangements in place and information available regarding situations where patients may require specialist treatment in tertiary or specialist centres (including services organised on a regional or national basis) or outside the Board's area.

- maintain an overview of the effectiveness of the arrangements for the introduction of new medicines.

- identify and share good practice regarding arrangements for new medicines. Such an approach will be expected to be adopted across clinical networks or for services provided at regional or national level. The Scottish Government will facilitate the sharing of models of good practice and ensure arrangements are in place to help NHS Boards to work collaboratively in the development of their policies in order to promote consistency of approach across Scotland.

[1] This is intended to address the Petitions Committee recommendation concerning local "liaison officers" to improve communication between the Board, clinician and patient whilst recognising that Boards may want to approach this in different ways.

Introduction and Availability of Newly Licensed Medicines in the NHS in Scotland – Specific Guidance Framework to Develop a Written Policy Concerning Arrangements for Individual Patient Treatment Requests

Introduction

As part of NHS Boards' written policy on systems and processes for the managed entry of newly licensed medicines, they will be expected to describe the arrangements in place to consider requests for medicines not recommended by the Scottish Medicines Consortium (SMC) or NHS Quality Improvement Scotland (NHS QIS).

The route for dealing with such requests is on a "case by case" basis via the Individual Patient Treatment Request (IPTR) route. This route should only be pursued where the clinician responsible for the patient for whom the medicine is being sought, is of the view that their clinical circumstances merit such consideration. In pursuing IPTRs, clinicians will be required to exercise their professional judgement on the basis of clinical need in individual cases and in accordance with the NHS Board's policy. An IPTR can only be sought where the clinician fully supports it.

Key Features

The Scottish Government will expect the following key features to apply to NHS Boards' written policies:

- individual Patient Treatment Requests will form part of the wider Board governance arrangements. The written policy on such treatment requests will include a description of the basis on which requests will be considered; the constitution of decision-making panels; what evidence will be considered; arrangements for securing expert advice and any new evidence; and arrangements for hearing and reaching decisions on appeals.

- clarity around the need to ensure that members of panels or committees involved in local decision-making will be expected to declare any interests which could have an impact on impartiality in decision-making.

- the written policy will describe opportunities for public involvement in the process within the NHS Board's patient focus public involvement arrangements

- the NHS Board written policy will be equality impact assessed.

- NHS Boards will provide information to individual patients, families, carers and their representatives on request, describing the arrangements for consideration of IPTRs.

- in making the written policy available, NHS Boards will be sensitive to the communications and language needs of their audience.

- all clinicians who will be involved in IPTR processes locally will be expected to be fully aware of and conversant with the policy.

- clinicians will be expected to be clear about the circumstances in which Individual Patient Treatment Requests will be supported and on their responsibilities with regard to communicating decisions.

- identification of personnel who are well placed, appropriately trained and available to support individual patients through IPTR process, providing information about what the process entails, how and when they will be informed of the decision and any future options, including appeals processes[2].

- timescales for the decision-making process will be established in accordance with the patient's clinical needs and be communicated to the patient by the clinician responsible for the patient's care, following discussion with those involved in dealing with the request. The NHS Board written policy will articulate the timescales that apply and clarify that there should be no undue delays, while ensuring sufficient time for proper consideration of the case.

- where it is clinically appropriate, patients or a patient advocate will be given the opportunity to participate in the process. However, the arrangements will be expected to ensure the application can be considered on the basis of free and open discussion by the clinicians involved and not breach any patient confidentiality requirements.

- support and information will be provided to the patient in relation to their options following a decision, including appeal processes.

- appropriate record keeping arrangements will be in place including records on decisions reached and the outcome of any appeal.

- further consideration will be given to development of national good practice models in relation to individual patient treatment requests (IPTRs). These good practice models will be expected to draw on work already completed by the Short Life Working Group (SLWG) established by the Scottish Cancer Taskforce and the Difficult Decisions Short Life Working Group.

Where the patient wishes to obtain treatment from the independent healthcare sector, the clinician will be expected to follow the guidance on Arrangements for NHS Patients Receiving Healthcare Services Through Private Healthcare Arrangements as set out in CMO(2009)3
www.scotland.gov.uk/Publications/2009/03/CMO20032009

A conceptual model of the process for Individual Patient Treatment Requests is attached at **Flowchart 3**. NHS Boards can adapt this for use locally as required.

[2] This is intended to address the Petitions Committee recommendation concerning local "liaison officers" to improve communication between the Board, clinician and patient whilst recognising that Boards may want to approach this in different ways.

Flowchart 3

Overview: NHS Board Arrangements for Prescribing Licensed Medicines