NHS Grampian

Westholme
Woodend Hospital
Queens Road
ABERDEEN
AB15 6LS

NHS Grampian

Date 8th December 2022
Our Ref off-label/DP/Dec22
Enquiries to David Pfleger
Extension 56348
Direct Line 01224 56348
Email david.pfleger@nhs.scot

Dear Colleague

This letter authorises the extended use of the following guidance until 1st June 2023 (please note the link to updated guidance for elements of this guidance)

NHS Grampian Staff Guidance For Processing Requests To Prescribe Unlicensed, Off-Label Or Non-Formulary Medicines (Including Medicines Awaiting Consideration By, Or Not Recommended For Use By, The Scottish Medicines Consortium)

The sections of this guidance relating to requests via Individual Patient Treatment Request (IPTR) have been superseded by the new Peer Approved Clinical System (PACS) available at http://foi.nhsgrampian.org/globalassets/foidocument/foi-public-documents1---all-documents/Policy_NonFormularyLicensed.pdf

The remainder of the guidance in NHS Grampian Staff Guidance For Processing Requests To Prescribe Unlicensed, Off-Label Or Non-Formulary Medicines (Including Medicines Awaiting Consideration By, Or Not Recommended For Use By, The Scottish Medicines Consortium) remain extant.

If you have any queries regarding this please do not hesitate to contact the Pharmacy and Medicines Directorate.

Yours sincerely

David Pfleger
Director of Pharmacy and Medicines Management

NHS Grampian

NHS Grampian Staff Guidance For Processing Requests To Prescribe Unlicensed, Off-Label Or Non-Formulary Medicines (Including Medicines Awaiting Consideration By, Or Not Recommended For Use By, The Scottish Medicines Consortium)

Coordinators:	Consultation Group:	Approver:
Deputy Director of Pharmacy and Medicines Management	Grampian Medicines Management Group Grampian Formulary Group	Chairman - Grampian Medicines Management Group

Signature:		Signature:
		

Identifier:	Review Date:	Date Approved:
NHSG/Guid/CEL17/ GMMG509	March 2014	March 2012

Uncontrolled When Printed

Version 3

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

Identifier: NHSG/Guid/CEL17/GMMG509

Replaces: Version 2.1 April 2011, NHSG/GMMNF/Guid/448

Across NHS Boards	Organisation Wide	Directorate	Clinical Service	Sub Department Area
	YES			

Authors: Pharmacy and Medicines Directorate

Subject Prescribing and prescription

Key word(s): Formulary Group, SMC, licence, license, marketing authorisation, unlicensed, non-formulary, off-label, Scottish Medicines Consortium, SMC, medicines, Grampian Joint formulary, GJF, prescribing, prescribers, FG1, Form A, Form B, Form C, FG1, IPTR, individual patient treatment requests, CEL 17, CMO (2012)1

Policy application: NHS Grampian

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

Responsibilities for implementation:

Organisational: Chief Executive

Corporate: Grampian Medicines Management Group

Departmental: Heads of service

Hospital/Interface services: General managers

Operational Management Unit: Consultant physicians and surgeons, General Practitioners, Clinical pharmacists

Policy statement: The implementation of national advice from the SMC and, in some circumstances the National Institute for Clinical Excellence (NICE), where ratified by Quality Improvement Scotland, is dealt with through the Grampian Formulary Group. Local processes of decision-making are in place to provide NHS Grampian with the relevant guidance and policies to support clinicians' prescribing decisions and to manage the use of medicines in Grampian.

Review: This policy will be reviewed at least every two years or sooner if current treatment recommendations change.

This document is also available in large print and other formats and languages, upon request. Please call NHS Grampian Corporate Communications on (01224) 551116 or (01224) 552245.

Responsible for review of this document:	Pharmacy and Medicines Directorate
Responsible for ensuring registration of this document on the NHS Grampian Information/ Document Silo:	Pharmacy and Medicines Directorate
Physical location of the original of this document:	Pharmacy and Medicines Directorate
Job/group title of those who have control over this document:	Grampian Medicines Management Group
Responsible for disseminating document as per distribution list:	Grampian Medicines Management Group

Revision History: See Appendix 6: Version control statements.

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

Contents **Page number**

Outline glossary 3

1. Purpose and scope of this guidance 4

2. Background 4

2.1. The regulatory process for licensing medicines available in the UK 4

2.2. The advisory process relating to licensed medicines used in NHS Scotland 5

3. Prescribing of non-formulary licensed medicines 8

3.1. Initiation of non-formulary licensed medicines 8

3.2. Continuation of non-formulary licensed medicines previously initiated 8

4. Prescribing of unlicensed and off-label medicines 9

4.1. Liability for unlicensed medicines or licensed medicines prescribed outside of their marketing authorisation. 9

4.2. Criteria to support prescribers deciding to use an unlicensed medicine or licensed medicine prescribed outside of their marketing authorisation. 9

4.3. Non-medical prescribers 10

4.4. Specials 11

4.5. Authorisation to prescribe an unlicensed or off-label medicine for an individual patient within the managed service 11

4.6. Exemptions from completing Form B for off-label use 12

4.7. Continuation of previously authorised unlicensed or off-label treatment 13

4.8. Requests to prescribe an unlicensed medicine for a group of patients or off-label use across a number of wards 13

4.9. Requests to use medicines via manufacturer-supported open access schemes 15

5. Requests to prescribe licensed medicines for individual patients in clinical circumstances contrary to agreed local NHS Grampian policies 16

5.1. Requests to prescribe licensed medicines which the SMC or Healthcare Improvement Scotland have recommended should not be used in NHS Scotland based on a full and complete submission by the manufacturer 17

5.2. Requests to prescribe licensed medicines which are awaiting SMC guidance, where there is a delay in SMC guidance or SMC non-approval has been based on a non/incomplete submission from a manufacturing company 18

5.3. Decision- making panel 20

6. Monitoring of adherence to this guidance in NHSG 21

Appendix 1: Summary of request forms and their uses in relation to this guidance 22

Appendix 2: Individual Patient Treatment Request process - Form C 23

Appendix 3: Decision-making framework to be used when considering requests for individual patient use of unlicensed medicines, off-label medicines and medicines turned down for use in Scotland by SMC/Healthcare Improvement Scotland or licensed medicines awaiting assessment by SMC/Healthcare Improvement Scotland in defined circumstances (Forms B and C) 32

Appendix 4: Overview of UK Process for Introducing New Medicines 33

Appendix 5: Overview of Arrangements for Licensed Prescribing Medicines 34

Appendix 6: Version control statements.....35

Outline glossary

Individual patient treatment request (IPTR)
Annex D of CEL 17 (2010) outlines a specific framework for the development of NHS Board written policies for individual patient treatment requests (IPTRs). An IPTR can only be requested for a medicine which has been appraised within the licensed indication by the Scottish Medicines Consortium (SMC) or Healthcare Improvement Scotland (HIS), but has not been recommended for use within NHS Scotland, or those licensed medicines which are awaiting consideration by the SMC (SGHD/CMO(2012)1).

IPTR requesting clinician
Throughout this document the clinician who initiates the IPTR process is considered to be the hospital consultant or general practitioner with overall responsibility for the request.

Marketing authorisation
Previously medicines were described as having a "product licence". Under the new arrangements, medicines are now more correctly described as having a marketing authorisation. A marketing authorisation defines the clinical conditions, routes of administration, dosages and precautions for which the licensing authority has approved a medicine treatment.

Significantly different clinical circumstances
This refers to a situation where the clinical condition or the patient clinical characteristics are significantly different to the general population of patients who have the condition in question and where the individual for whom the treatment is being sought is likely to gain significantly more benefit from the intervention than might normally be expected from the general population of patients with the condition in question.

Specials
Special formulations of medicines are produced for clinical reasons where an existing formulation of an available licensed product is not suitable for the patient. They are specially prepared unlicensed medicines, made according to different formulations by different companies as batch products or as bespoke products (the exact contents can differ every time) and often have no safety, stability or efficacy testing. The MHRA refers to specials as 'unlicensed relevant medicinal products placed on the market in order to meet the special needs of an individual patient'.

Unlicensed medicines and 'off-label' medicines
Prescribing practice may include the use of unlicensed medicines, (products which have not been licensed for human medical use) and off-label medicines (licensed medicines prescribed outside the terms of their marketing authorisation).

Formulary Medicine
Medicine approved by the Grampian Formulary Group for inclusion in the Grampian Joint Formulary (GJF). The Formulary Group oversees the management of the GJF. New medicines for inclusion are considered based on SMC recommendations and requests from clinicians, or for older drugs on the basis of local clinician requests.

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

1. Purpose and scope of this guidance

NHS Grampian recognises that there will be times when prescribers may wish to prescribe a medicine that:

- has not received a marketing authorisation (not been licensed),
- is to be used in clinical circumstances outside of the marketing authorisation,
- is licensed but is awaiting SMC advice,
- is licensed but where SMC/NHS Healthcare Improvement Scotland has advised the medicine should not be used in NHS Scotland,
- is contrary to NHS Grampian's local policy.

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

- licensed non-formulary medicines,
- unlicensed medicines,
- off-label medicines,
- licensed medicines which the SMC or NHS Healthcare Improvement Scotland have recommended should not be used in NHS Scotland,
- licensed medicines which are awaiting SMC or NHS Healthcare Improvement Scotland guidance,
- licensed medicines for individual patients contrary to agreed local NHS Grampian policies.

NHS Grampian makes a distinction between requests to prescribe for groups of patients, which normally require a submission to the Grampian Formulary Group, and requests for single patients where a number of different routes are available dependant on the circumstances of the request.

For a summary of the request forms and their uses see Appendix 1.

2. Background

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

2.1. The regulatory process for licensing medicines available in the UK

In the UK, a pharmaceutical company that wishes to bring a medicine to the market has to apply for a marketing authorisation (licence). For information about the process see MHRA website: http://www.mhra.gov.uk/Howweregulate/index.htm . 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. Following the development and clinical trial stages, the pharmaceutical company will usually seek a licence for the medicine.

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. The purpose of the licence application is to consider whether the medicine has a measurable effect against a placebo or comparator in a clinical trial and whether, on balance, the medicine is likely to have an acceptable level of safety and quality.

European Community (EC) legislation now takes precedence over the Medicines Act. The Medicines Act's Instruments and Orders are amended from time to time to align with new EC requirements. The current relevant legislation 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.

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

- Applying for a UK licence through the MHRA

or

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

Most new medicines are licensed by the EMA, to ensure that they are available to, and used in the same way across, all the member states of the European Union.

2.2. The advisory process relating to licensed medicines used in NHS Scotland

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 occurs at two levels; national and local.

2.2.1. National advisory structures

In NHS Scotland this assessment is provided at, or close to, the point of licensing by the Scottish Medicines Consortium (SMC). The SMC aims to consider the clinical and cost-effectiveness of all newly licensed medicines. The SMC provides advice to NHS Scotland as to whether the medicine is accepted for use, and if so, its place in treatment. Where a medicine is accepted by the SMC, NHS Boards are expected to make it (or its equivalent) available. Full details of the role, remit, processes and decisions of the SMC can be found at www.scottishmedicines.org.uk/.

In England, the National Institute for Health and Clinical Excellence (NICE) currently considers clinical and cost-effectiveness of medicines. The Multiple Technology Appraisal or MTA, usually looks at a disease condition and will appraise the different options for treatment giving a guidance type approach to its recommendations. Newer therapies are frequently compared to older more established therapies. The more rapid

Single Technology Appraisal or STA, is similar in function to the SMC process looking only at one specific drug. STAs are only undertaken on medicines referred to NICE by the Department of Health.

NICE STA recommendations have no formal status in Scotland and the SMC remains the primary source of advice on the use of all newly licensed medicines in Scotland. For MTAs, Healthcare Improvement Scotland (previously NHS Quality Improvement Scotland) decides on the applicability of the MTA guidance to Scotland. Healthcare Improvement Scotland publishes advice on its website to advise NHS Boards on whether the MTA is valid for Scotland. NHS Boards in Scotland will then be advised to follow the advice of Healthcare Improvement Scotland which will then take precedence over any previous SMC decisions.

See Appendix 4 for an overview of the UK process for introducing new medicines.

2.2.2. Local advisory structures

The implementation of national advice from the SMC and, in some circumstances the MTAs developed by the National Institute for Health and Clinical Excellence (NICE), where ratified by Healthcare Improvement Scotland, is dealt with through the Grampian Formulary Group (http://tinyurl.com/NHSGFGp).

The overarching aim of the Formulary Group is to develop and manage a Grampian Joint Formulary which is evidence-based, takes account of both clinical and cost-effectiveness and reflects local priorities, population needs and local affordability (http://www.nhsgrampian.org/gjf). The Formulary Group takes a population perspective and only considers requests to use medicines in groups of patients. The Grampian Joint Formulary, therefore, does not contain one hundred percent of the medicines prescribed in Grampian. There will be occasional circumstances when a formulary medicine does not meet the individual patient's clinical requirements and where the use of a non-formulary medicine may be the best course of action.

The Grampian Formulary Group reviews SMC advice to assess the place of SMC recommended medicines in the Grampian Joint Formulary. On receipt of SMC advice the Grampian Formulary Group contacts the relevant Grampian clinicians inviting them to submit an application for the newly SMC accepted medicine to be included in the Grampian Joint Formulary. Where local clinical opinion is that the new medicine has a place in local care, and the clinicians support inclusion, a submission is made to the Grampian Formulary Group to have the medicine added to the Grampian Joint Formulary.

Formulary Group members and clinicians' requesting medicines for inclusion in Grampian Joint Formulary must declare any interests to ensure impartiality of decision-making. For those requests support by clinicians, the Grampian Formulary Group takes 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 (where available); and
- assessing its resource and service implications.

NHS Grampian aims to reach a decision on a SMC accepted medicine within 90 days of the issue of SMC advice to NHS Boards and to publish this, on the Grampian Medicines Management website, within 14 days of the decision being reached. 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; development of protocols. NHS Grampian aims to ensure that all Formulary decisions are transparent and made available to the public. In publishing the Formulary Group decisions NHS Grampian will issue standard advice as follows in accordance with the CMO letter (2012)1:

- 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.

There are occasions where national advice from SMC (or NICE) is not available, e.g. consideration of using medicines that were licensed prior to SMC being established. In these instances local clinicians may request addition of such medicines to the Grampian Joint Formulary and a local process to assess the clinical and cost-effectiveness will be undertaken.

In some circumstances, the Formulary Group will put in place specific plans for the managed introduction of medicines joining the Grampian Joint Formulary. These may include restrictions relating to financial, administrative or clinical criteria.
NHS Grampian undertakes ongoing reviews of the Grampian Joint Formulary to take account of changes in clinical evidence. This allows for reassessment, where appropriate, of medicines for formulary inclusion and their place in treatment.

2.2.3. Patient Access Schemes

The pharmaceutical industry has begun to explore the use of novel pricing strategies in order to facilitate market access to some high cost new licensed medicines. In general, these schemes have been proposed for medicines with a high acquisition cost in situations where the cost-effectiveness ratio submitted by the company has been greater than that normally considered acceptable by SMC. Companies have stated that they are unable to reduce the acquisition price to NHS Scotland due to global pricing issues. The schemes can be performance or finance based but offer healthcare providers access to treatment at a lower than ‘list’ price across all patients treated, or for sub-groups of patients, e.g. those responding to treatment.

A national Patient Access Scheme Advisory Group (PASAG) was set up in 2009 to assess such schemes and advise SMC as part of its assessment process. SMC advice

for medicines for which a patient access scheme is available in Scotland now includes the access scheme in its advice to NHS Boards.

Where SMC advises that a medicine should be made available via a patient access scheme, the process of local decision-making as to whether that medicine is made available on the local formulary is the same as for all other SMC advice. Local decision-making will be required to ensure that appropriate record keeping and subsequent claims for financial adjustment are undertaken.

3. Prescribing of non-formulary licensed medicines

It is recognised that no formulary can cover one hundred percent of prescribing but wherever possible and clinically appropriate all prescribers in NHS Grampian are expected to prescribe within the Grampian Joint Formulary. Where a prescriber believes that a non-formulary medicine should be considered for addition to the Grampian Joint Formulary he/she may request such addition, completing the appropriate form:

- FG1 http://intranet.grampian.scot.nhs.uk/foi/files/FG1.

3.1. Initiation of non-formulary licensed medicines

It is recognised that there will be occasional circumstances where a prescriber considers that they wish to prescribe a licensed medicine that is not in the formulary and where that medicine has not been turned down by SMC/Healthcare Improvement Scotland or is not awaiting assessment by SMC.

On these occasions it is essential that the prescriber considers the clinical and cost-effectiveness of such use and where appropriate seeks advice from appropriate medical and pharmacy colleagues. In the majority of cases the Formulary Group will have previously assessed such medicines and agreed that there are more clinically and cost-effective medicines available and recommended these for use as part of the Grampian Joint Formulary. Where the Formulary Group has not previously considered this licensed medicine, or where there is new evidence available to support a review of an original decision, the prescriber may wish to make a Formulary Group submission using the appropriate form as above.

3.2. Continuation of non-formulary licensed medicines previously initiated

If a patient is admitted to hospital on a non-formulary licensed medicine initiated elsewhere, and it is not appropriate to substitute a formulary medicine, Form A will be used to gain authorisation to allow ordering of the medicine from the Pharmacy Department. If the patient has a sufficient supply of their own medicine they can continue to use this while in hospital.

A pharmacist will authorise such requests confirming that a therapeutic switch for the non-formulary medicine is not appropriate. Once completed, Form A will be stored in Pharmacy at Aberdeen Royal Infirmary to maintain a record of non-formulary medicine continuation. Non-formulary medicines supplied using Form A will be recorded in an electronic database.

Regular analysis of the requests will be carried out to:

- Assess patterns of requests,
- Identify and feedback to primary care to reduce non-formulary usage,
- Identify when a formulary request should be initiated.

Such analysis will be carried out at least annually.

4. Prescribing of unlicensed and off-label medicines

The licensing of medicines is covered by the Medicines Act with additional requirements enshrined in European Law. A medicine holding a full marketing authorisation will do so after a full evaluation by the MHRA or EMA of all data required for the medicine. The marketing authorisation holder is required to ensure that full product information is supplied to both the prescriber and dispenser of the product. The marketing authorisation confers liability upon the Holder for the medicine in use when the terms of the licence are complied with.

The majority of medicines prescribed within NHS Grampian are covered by marketing authorisations and the manufacturer is held liable for any harm caused where the cause can be solely attributed to a defect in the medicine, and it can be proved that the product was prescribed and used in accordance with the terms of the marketing authorisation.

4.1. Liability for unlicensed medicines or licensed medicines prescribed outside of their marketing authorisation.

Prescribers of unlicensed medicines, or medicines prescribed outwith their marketing authorisation (off-label), have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine. NHS Grampian carries a liability for the actions of its employees and may accept liability for the prescription of unlicensed medicines, or medicines prescribed outwith their marketing authorisation (off-label), where such use has been authorised and agreed, provided that local policies and procedures are adhered to.

Where it is intended that such prescribing of an unlicensed medicine or off-label medicine will be continued after patient discharge, clear arrangements require to be agreed between primary and secondary care regarding clinical and prescribing responsibilities, using appropriate processes such as shared care arrangements. Prescribers are referred to the NHS Grampian Shared Care Policy which contains guidance for such arrangements. There may occasionally be circumstances where retention of prescribing responsibility within secondary care may be considered as an option.

4.2. Criteria to support prescribers deciding to use an unlicensed medicine or licensed medicine prescribed outside of their marketing authorisation.

Where a licensed medicine is available, it should normally be prescribed in preference to any unlicensed equivalent alternative. The MHRA has produced guidance on the hierarchy of risk on basis of product origin.

The MHRA's preferred choice of supply, where a licensed product is not available, is listed in descending order below:

1. Off-label use of a UK-licensed medicine.
2. An imported product licensed in the country of origin.
3. A UK manufactured "special" made in MHRA licensed facilities.
4. Crushing UK-licensed tablets or opening capsules.
5. An extemporaneously dispensed medicine.
6. An imported product not licensed in the country of origin.
7. A non-UK-made unlicensed medicine or food supplement.

The following criteria should be considered prior to the decision to prescribe, or request authorisation to prescribe, a medicine that is not licensed, or is for use off-label.

1. Availability of suitable licensed alternatives available to prescribe.
2. The risk-benefit assessment for the patient or group of patients is in favour of prescription of the unlicensed medicine.
3. There is an acceptable clinical and economic evidence-base to support use.
4. Prescribing is supported by multi-professional opinion.
5. The patient/carer has been fully informed and has consented or will consent to use of the medicine.

There may be occasions where following a review of the evidence relating to safety and clinical and cost-effectiveness, NHS Grampian considers that there are benefits associated with using an unlicensed or off-label medicine in preference to a licensed medicine. It is not expected that these situations will be particularly common. Where such decisions are taken they will be made through existing medicines management advisory structures with engagement of local clinicians and include consideration of the criteria above. The Grampian Formulary Group may consider the use of unlicensed medicines, or licensed medicines prescribed outside of their marketing authorisation, where this relates to a group of patients and the points above are applicable, see 4.8. Otherwise, the process in 4.5 below is followed.

4.3. Non-medical prescribers

Nurse and pharmacist independent prescribers are permitted to prescribe unlicensed medicines within their competence. Optometrist independent prescribers are not permitted to prescribe unlicensed medicines. Unlicensed medication can be prescribed by a supplementary prescriber but only as part of a clinical management plan (CMP).

It is possible under current legislation for nurse and pharmacist independent prescribers to prescribe outwith their marketing authorisation, i.e. off-label. They must, however, accept professional, clinical and legal responsibility for that prescribing, and should only prescribe 'off-label' where it is accepted clinical practice.

It is possible under current legislation for supplementary prescribers to prescribe outwith a marketing authorisation. Such use must have the joint agreement of both prescribers and the status of the drug should be recorded in the CMP.

Non-medical prescribers must also follow the guidance laid down in the NHSG Staff Policy and Framework for Non-Medical Prescribing including Independent Contractors see the webpage http://tinyurl.com/NHSGNMRx.

4.4. Specials

It should be noted that prescribers of medicines obtained as “specials”, have a personal liability for their prescription that cannot be transferred to the manufacturer or importer of the medicine. Due consideration should be given to use of alternative licensed products (licensed in either the UK or abroad) or products used “off-label” before a “special” medicine is prescribed (see 4.2 above).

4.5. Authorisation to prescribe an unlicensed or off-label medicine for an individual patient within the managed service

Where a request is made to use an unlicensed or off-label medicine for a single patient, as opposed to a group of patients or the first of a group of patients, Form B should be used to request authorisation to prescribe such medicines within the managed service. Prescribers should consider carefully whether the request is truly for a single patient or whether in fact the patient is the first of a group of patients with shared clinical characteristics likely to require treatment with the unlicensed or off-label medicine, in which case FG1 Form should be completed (Form B is not the appropriate route for ‘group’ requests - see 4.8).

Requests for use of an unlicensed or off-label medicine for a single patient, using Form B will be considered by an in-service decision-making group from within the service consisting of:

- The requesting Clinician,
- The Unit Operational Manager (UOM),
- A Lead Clinician for the speciality/unit,
- A Senior Pharmacist.

Decision-making by the in-service decision-making group uses the same framework as for IPTRs provided in Appendix 3. For unlicensed medicines, it is particularly important for the in-service decision-making panel to assess whether the medicine offers an acceptable balance of clinical benefit and risk of medicine-related harm. The requesting clinician must demonstrate the requirement for the medicine through supporting clinical evidence and verification that this would be acceptable practice within a cohort of his/her peers. The Pharmacy Quality and Assurance Department will provide a medicines risk assessment of the product for any unlicensed medicine.

The in-service decision-making group must also consider the budget impact on the service of using the medicine. The in-service decision-making group may authorise use of the medicine where they consider the benefit/risk of use to be acceptable and the total cost of use for the individual patient does not exceed £2000 per total treatment course/per annum for ongoing treatment. The funding of such use must be considered affordable within the service budget.

Where anticipated use of the medicine will incur an individual patient treatment cost of £2000 total treatment course/per annum for ongoing treatment or more, additional authorisation will be required from the sector-based decision-making group. The sector-based decision-making group will consist of:

- the Sector Manager,
- the Sector Lead Clinician,
- a Principal Pharmacist or designated deputy.

The sector-based decision-making group may authorise use where it considers the benefit/risk of use to be acceptable and where it represents a cost-effective use of resource.

Where a request is successful, agreement should be made between the treating clinician and patient as to how success of individual treatment will be defined in terms of clinical outcomes and timescales. These outcomes and timescales will reflect those agreed in the authorisation process. If the patient is non-English speaking, a “face to face” interpreter or the “Language Line” telephone interpretation service should be made available. If the patient has a communication disability, appropriate communication support should be provided. It is important that the patient is able to make an informed decision. These outcomes will be a written part of the authorisation, when use of a medicine has been agreed, and should explicitly define the circumstances when the treatment with the medicine will cease.

Once completed and signed, one copy of Form B will be added to the patient notes, one copy will be retained by the requesting clinician and the original will be stored in Pharmacy at Aberdeen Royal Infirmary. Form B requests will be recorded on a database to include a record of the outcome of the request and the rationale for the decision.

Form B is NOT required when a licensed medicine is administered in a different route/way to which it was intended, e.g. injection given orally or tablets/capsules crushed or dispersed in a liquid to administer via a naso-gastric tube for the licensed indication, and is in accordance with recognised good clinical practice/guided by a locally peer reviewed protocol. Advice should be sought from Medicines Information on suitability and stability of the specific medication to be used via alternative routes.

4.6. Exemptions from completing Form B for off-label use

The Royal Aberdeen Children's Hospital, Neo-natal Unit, Theatres, Intensive Care Unit and High Dependency Unit are currently exempted from making individual patient requests to use licensed medicines off-label, using Form B, due to the high levels of use of medication off-label. However, there must be local protocols in place to support any off-label use.

A number of other areas and specialities have been identified as having a high proportion of off-label usage. Mental Health Services (Royal Cornhill Hospital and Dr Gray’s), ophthalmology, dermatology, acute pain team and palliative care have been given time-limited exemptions due to the volume of off-label prescribing undertaken in these areas. Clinicians in these areas have been requested to develop protocols and guidelines to support off-label use. There is an expectation that these exemptions will continue but that these areas and specialities should have completed the development of the vast majority of local protocols by April 2012.

Where these areas are currently using unlicensed or non-formulary medicines they will still be required to make a Formulary submission using FG1.

4.7. Continuation of previously authorised unlicensed or off-label treatment

It is accepted that patients will be transferred between units within hospital and continuation of previously authorised unlicensed or off-label treatment will be required. In these circumstances the original Form B should be retrieved and the 'repeat supply' section completed. The form should be annotated to show the patient's new ward. It is good practice to ensure that a review date for reconsideration of the use of the unlicensed or off-label treatment is included in the notes. Reference to the authorisation using Form B should be included in the patient notes.

Where patients are to be discharged into primary care there is a need to ensure that timely communication is made with the responsible clinician in the primary care setting. This is to ensure that there is agreement between the primary care and secondary care clinician that responsibility for such prescribing should be handed over to primary care and where required is subject to appropriate shared care arrangements or patient specific protocols.

4.8. Requests to prescribe an unlicensed medicine for a group of patients or off-label use across a number of wards

Where off-label[*] use of a licensed medicine for a group of patients has developed historically (prior to 2008) and is limited to a single ward or speciality but does not exceed an individual patient treatment cost of £2000 per total treatment course/per annum for ongoing treatment, prescribers should develop a local ward-based protocol. The protocol should provide guidance on when and how such off-label use should take place.

Where off-label use is likely to be needed across wards and specialities then prescribers should request such use to be recognised through an application to the Formulary Group using the appropriate form (FG1) as for unlicensed medicine use. Such applications should be supported by references to peer reviewed published literature and include any protocol(s) or guidance to support such medicine usage. It is unlikely that such use cannot be anticipated and it is appropriate that such use is supported by advice from the Formulary Group.

Where off-label use has been recorded and agreed by the Formulary Group, or is within a single local ward/speciality protocol and within the £2000 financial limit, future use of medicines for the indications and patients defined within the local guidance or protocol is covered. Once a protocol or guideline is in place for these circumstances for a specified off-label use of the medicine, further authorisation for individual patient use is not required.

Where a request needs to be made to use an unlicensed medicine for a group of patients, or for the first patient amongst a group of patients (existing or anticipated), a request should be made to the Formulary Group using the existing Formulary Group application form (FG1). Such applications should be supported by references to peer reviewed published literature and include a Pharmacy Quality Assurance Unlicensed

[*] The Royal Aberdeen Children's Hospital, Neo-natal Unit, Theatres, Intensive Care Unit and High Dependency Unit are currently exempted from making individual patient requests to use licensed medicines off-label, using Form B, due to the high levels of use of medication off-label. However, there must be local protocols in place to support any off-label use.

Medicine Risk Assessment and any protocol(s) or guidance to support such medicine usage.

Requests for use of unlicensed medicines for a group of patients should **not** be seen as a mechanism to pre-empt SMC advice.

The Formulary Group will not normally consider unlicensed or off-label usage across a number of wards for addition to the Grampian Joint Formulary. Such use should be limited and, therefore by its nature, not for widespread or common use. The Formulary Group will however assess a request to have such usage recorded as an addendum to the Joint Formulary. The purpose of the Formulary Group in assessing requests to use unlicensed medicines in a group of patients or off-label medication across a number of wards is to satisfy itself that the correct process has been undertaken for prescribing to expand beyond individual patients/a single ward.

The Formulary Group will assess requests to use unlicensed medicines in a group of patients or off-label use across a number of wards on the basis of the following criteria:

1. Has the requesting clinician/group of clinicians provided peer reviewed evidence to support the requested use?
2. Has the requesting clinician/group of clinicians provided a clear explanation as to why alternative licensed medicines or use of medicines within their licence do not provide the treatment goals offered by the medicine requested?
3. Has the requesting clinician/group of clinicians provided adequate information as to the protocol or guidance that is available or will be developed and provided to support the use of the medicine requested?
4. In the case of unlicensed medication in particular, has the requesting clinician/group of clinicians provided evidence as to the safety of the medicine?
5. Is the requested use affordable within the existing service budget? N.B. this use is the total use rather than any restriction for use put in place to limit budgetary impact.
6. For unlicensed medicines has the requesting clinician/group included a Pharmacy Quality Assurance Unlicensed Medicine Risk Assessment?

The focus of the Formulary Group decision-making will be whether the request satisfies the following criteria of clinical effectiveness, cost-effectiveness, health gain to NHS Grampian, service impact, equity and safety.

Subject to the request meeting these criteria, the requested use will be recorded as an addendum to the Grampian Joint Formulary, i.e. the usage will not have full Grampian Joint Formulary status.

4.8.1. Requests for use of an unlicensed medicine as part of a clinical trial

Where the unlicensed use is part of a clinical trial the existing processes to authorise this use are applied. Prescribers, lead clinicians/investigators and service managers are reminded of their responsibilities to advise the patient prior to recruitment as to the exit strategy at the end of such trials and explain their impact on the individual patient. In particular, patients should be advised that unless specific arrangements have been made, at the end of the trial there is no ongoing commitment from NHS Grampian to provide the medicine made available through the trial, regardless of individual response

to treatment, i.e. their unlicensed medicine provided during the trial will stop at the end of the trial. Patients need to be advised as to how their treatment will be managed at the end of the trial as part of their recruitment to such studies. Appropriate language or communication support should be provided for patients, if required. Prescribers, lead clinicians/investigators and service managers are reminded that where medicine companies are offering open-label/open access extensions to funding these do not necessarily cover fully the costs of these medicines between licensing, the SMC guidance and the decision whether or not to use in NHS Grampian.

4.9. Requests to use medicines via manufacturer-supported open access schemes

NHS Grampian has in the past supported the use of open access schemes as part of prospective planning to provide exit strategies for clinical trials. Under these arrangements NHS Grampian has accepted manufacturer funded medicines for patients who have been part of a clinical trial which has ended and for which the medicine has either not yet been licensed or has been turned down by SMC. The important proviso in these arrangements is that funding continues for the length of time that the patient requires the medicine or until the time at which that medicine becomes recommended for use by the SMC or Healthcare Improvement Scotland, whichever is the sooner. As this use is for a group of patients, prescribers are required to make a Formulary Group submission. Prescribers are reminded that consideration should be given to all costs associated with treatment, e.g. acquisition costs, monitoring costs and any costs associated with managing adverse events.

More recently such schemes have been offered to non-clinical trial patients prior to licensing of the medicine or between licensing and assessment by the SMC. The NHS Grampian policy in these situations is usually not to support these open access arrangements, the exception being those specific situations where in the clinician's clinical judgement their patient's condition will significantly deteriorate without access to treatment.

Where no alternatives exist and the patient's condition will significantly deteriorate, and the medicine is unlicensed, prescribers may use the Form B authorisation route for individual patients or make a Formulary Group submission for treatment of a group of patients.

N.B. Where the open access scheme is for a licensed medicine awaiting SMC assessment NHS Grampian policy is not to use the medicine unless the manufacturer is supporting **all** treatment costs up until at least the time when an approval decision is made by SMC, i.e. acquisition costs, monitoring costs and any costs associated with managing adverse events. If a situation arose where SMC advised the medicine should not be used the manufacturer would be expected and have agreed to support the ongoing costs of treatment until no longer clinically appropriate.

5. Requests to prescribe licensed medicines for individual patients in clinical circumstances contrary to agreed local NHS Grampian policies

There may be occasions where a prescriber feels that his/her patient will benefit from a licensed medicine that has been recommended not to be used in NHSG. The most common example will be medicines either awaiting SMC guidance or which the SMC has recommended should not be used in NHS Scotland. An individual patient treatment request (IPTR) can only be sought for a medicine within its licensed indication for the condition in question, and can only be progressed where the clinician responsible for the patient fully supports the request and is in agreement with the patient as to the most appropriate course of clinical treatment.

Where an IPTR is under consideration, the patient or their representative will be provided with the leaflet "New medicines in Scotland - who decides what the NHS can provide?" http://www.hris.org.uk/patient-information/information-about-health-services/access-to-new-medicines/

N.B. If patients are referred to centres outside NHS Grampian for diagnosis/assessment and recommendation of treatment, other centres may recommend the use of medicines either awaiting SMC guidance or which the SMC has recommended should not be used in NHS Scotland. These requests for use will also be subject to decision-making in NHS Grampian.

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 NHS Grampian or from another NHS Board (SGHD/CMO (2012)1). 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.

Timescales for consideration of IPTRs may be accelerated in accordance with the patient's clinical needs. The Senior Pharmacist of Unit Operational Manager responsible for managing the IPTR process will undertake a preliminary examination of the IPTR request to ensure that due consideration is given to the urgency of the request given the patient's clinical condition.

5.1. Requests to prescribe licensed medicines which the SMC or Healthcare Improvement Scotland have recommended should not be used in NHS Scotland based on a full and complete submission by the manufacturer

Where SMC recommends that a licensed medicine is not used in NHS Scotland and that recommendation is based on a full and complete manufacturer's submission, NHSG follows this guidance, i.e. such medicines should not be prescribed. However, there may be occasional circumstances where a prescriber believes that:

- The patient's clinical circumstances (condition and characteristics) are significantly different from either the general population of patients covered by the medicine's licence, or the population of patients included in the clinical trials for the medicine's licensed indication as appraised

and

- The individual for whom the treatment is being sought is likely to gain significantly more benefit from the medicine than would normally be expected.

This includes situations where a prescriber wishes to use a medicine outwith a restriction placed on approved usage in Scotland but within the licensed indication.

In these circumstances an IPTR to use a licensed medicine in significantly different clinical circumstances should be made using Form C.
Decision-making takes place in two stages to answer the following:

1. Is the clinical condition or are the patient clinical characteristics significantly different from the general population of patients covered by the medicine's licence/or the population of patients included in the clinical trials for the medicine's licensed indication as appraised? **And** is the individual for whom the treatment is being sought likely to gain significantly more benefit from the medicine than might normally be expected?

2. Should NHS Grampian support and fund the request for treatment?

   The second part of decision-making is only considered if the criteria in 1. above are met. The IPTR decision-making panel will then go on to decide whether use of the medicine for the individual patient offers acceptable cost-effectiveness to NHS Grampian, usually £20K to 30K per QALY.

N.B. Meeting the criteria in 1. above does not automatically result in authorisation to use the medicine.

Once completed by the requesting clinician, a copy of Form C (including the required patient report) should be sent to the Senior Pharmacist or Unit Operational Manager who will ensure the required information has been provide and initiate the process of decision-making.

The process to be followed requesting use of a medicine for an IPTR is outlined in Appendix 2. Membership of the IPTR panel is provided in 5.3.

Where a request is successful, agreement will be made with the treating clinician and patient as to how success of individual treatment will be defined, i.e. what clinical outcomes would need to be achieved for continuation of treatment to be allowed and in what timescale those outcomes should be achieved. These outcomes and timescales will relate to those agreed in the authorisation process. If the patient is non-English speaking, a "face to face" interpreter or the "Language Line" telephone interpretation service should be made available. If the patient has a communication disability, appropriate communication support should be provided. It is important that the patient is able to make an informed decision. These outcomes will be a written part of the authorisation. Where these outcomes are not achieved, or the patient is not achieving clinical benefit from the medicine, the agreement should explicitly state that treatment with the medicine would cease.

Form C requests will be recorded on a database to include a record of the outcome of the request and the rationale for the decision.

5.2. Requests to prescribe licensed medicines which are awaiting SMC guidance, where there is a delay in SMC guidance or SMC non-approval has been based on a non/incomplete submission from a manufacturing company

This process applies to requests where a clinician wishes to use a:

- licensed medicine post-marketing, but prior to SMC advice,
- licensed medicine that SMC has recommended should not be used in NHS Scotland because of non-submission,
- licensed medicine that SMC has recommended should not be used in NHS Scotland because of an incomplete submission.

NHSG policy is that medicines awaiting SMC or Healthcare Improvement Scotland guidance should not be used until such guidance has been published, the guidance discussed with local clinicians and the place of the medicine in local treatment decided through the Formulary Group. The NHSG Formulary Group manages this process. Where SMC recommends that a medicine be made available for use in NHS Scotland the Formulary Group, with input from local clinicians, decides which of these drugs should join the Grampian Joint Formulary.

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 timely 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 approved for use in NHS Scotland and the company manufacturing the medicine makes a further submission. Where this occurs NHS Grampian policy will follow this advice not to use the medicine and the route for prescribers to request use of such medicines for individual patients, is via an IPTR, using Form C.

There are also instances when SMC delays its advice for a significant period so that a drug may be licensed for many months without accompanying SMC advice as to its use in NHS Scotland. Where such a delay occurs and there is no suitable licensed alternative available, approved by SMC or in the Grampian Joint Formulary, there may be circumstances where a clinician assesses that his or her patient would experience

significant, material, irreversible deterioration or harm without using a newly licensed medicine for which the SMC has not provided advice.

Where a clinician wishes to use a licensed medicine post-marketing but prior to SMC advice or to use a licensed medicine that SMC has recommended should not be used in NHS Scotland because of non-submission or an incomplete submission, the clinician may initiate an IPTR to use the medicine, using Form C. Once completed by the requesting clinician a copy of Form C (including the required patient report) should be sent to a Senior Pharmacist or Unit Operational Manager who will ensure the required information has been provided and will initiate the IPTR process.

The process of decision-making falls into two parts.

The first part assesses whether the patient circumstances allow the case to be made that Grampian should put aside its general policy not to use a licensed medicine where SMC has yet to provide advice. In considering this, the IPTR decision-making panel considers whether:

1. there is no other suitable licensed alternative, approved by SMC or in the Grampian Joint Formulary, for the indication the medicine is requested for,
2. there is published, peer reviewed evidence of clinical-effectiveness,
3. waiting for SMC to provide advice to NHS Scotland, based on a complete and full manufacturer's submission, would lead to the patient missing an opportunity for cure, long-term remission (five years), a significant extension of life or avoidance of permanent disability. This would include situations where the medicine requested is a bridging treatment to other treatments that would provide these benefits and situations where the only alternative medicine would be associated with significant, permanent harm to the patient and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

The second part of decision-making is only considered if the criteria above are met, the IPTR decision-making panel will go on to decide whether use of the medicine for the individual patient offers acceptable cost-effectiveness to NHS Grampian, usually £20K to 30K per Quality Adjusted Life Year (QALY). N.B. Meeting the criteria above does not automatically result in authorisation to use the medicine.

Clinicians will be required to make the clinical case for using the requested medicine, show that his or her patient's clinical circumstances meet criteria 1 and 3 above and to provide evidence of clinical-effectiveness, and where available cost-effectiveness.

Requests for use are less likely to be successful where other UK health technology assessment agencies, e.g. NICE, have provided a negative assessment of the medicine or where the acquisition cost/benefit ratio of the medicine is poor enough to make it unlikely that the medicine would achieve the levels of cost-effectiveness normally acceptable to the NHS, usually £20K to 30K per QALY.

The IPTR decision-making panel will either approve or not approve the request providing a statement of their decision on the request form. A copy of the request form stating the decision and signed by the Chair of the panel along with the agreed note of the meeting will be provided to the requesting clinician following the decision. A further

copy of the request form and the agreed note of the meeting will be held on file in Pharmacy at Aberdeen Royal Infirmary. Form C requests will be recorded on a database to include a record of the outcome of the request and the rationale for the decision.

Where a request is successful, agreement will be made with the treating clinician and patient as to how success of individual treatment will be defined, i.e. what clinical outcomes would need to be achieved for continuation of treatment to be allowed and in what timescale those outcomes should be achieved. These outcomes and timescales will relate to those agreed in the authorisation process. If the patient is non-English speaking, a "face to face" interpreter or the "Language Line" telephone interpretation service should be made available. If the patient has a communication disability, appropriate communication support should be provided. It is important that the patient is able to make an informed decision. These outcomes will be a written part of the authorisation. Where these outcomes are not achieved, or the patient is not achieving clinical benefit from the medicine, the agreement should explicitly state that treatment with the medicine would cease.

Where a patient is already receiving treatment via Form C and achieving the agreed outcomes and SMC advises that the medicine should not be used in NHS Scotland, NHSG will continue to authorise the treatment until these outcomes are no longer met.

Where SMC fails to provide advice, based on a full and complete manufacturer's submission, for a period of more than six months and local clinicians are requesting the medicine for individual patients, the Grampian Formulary Group will be asked to decide whether this route of access should continue for the medicine on an individual patient basis (IPTR) as described above or whether a Formulary Group submission and decision are required.

The process to be followed requesting use of a medicine for an IPTR is outlined in Appendix 2. Membership of the IPTR panel is provided in 5.3.

5.3. Decision- making panel

The decision-making panel will consist of a core of four members constituted from individuals working in the sector from where the request has been made, e.g. ARI, Mental Health, Dr Gray's.

The panel will include:

1. A senior doctor, e.g. associate medical director/clinical lead who will also be a practising medical consultant with (or with access to) specialist knowledge of the relevant clinical area,
2. Clinical group lead, or equivalent, from another area to the requesting clinician
3. Senior pharmacist,
4. Senior service manager, e.g. budget holder.

The panel is chaired by the senior doctor.

The choice of individuals invited to participate in IPTR decision-making is dependent on the medicine being requested. Some degree of flexibility may be required to decide

how best to manage this process within the timescales required, particularly when the timing of a decision is urgent, due to the patient's clinical circumstances, and may need to be accelerated to avoid missing a window of opportunity from providing the medicine and achieving benefit from its use. Additional members may be co-opted onto the group dependent on the nature of the IPTR and any additional expert advice required.

Whilst the requesting clinician is not a formal member of the decision-making panel it is expected that the panel will wish to engage the clinician as part of the discussion and deliberations. Therefore, the requesting clinician will be requested to remain during decision-making to provide additional information where required but will not take part in the decision-making itself.

The decision-making panel will either approve or not approve the request providing a statement of their decision on the request form. Once completed with the decision panel outcome, one copy of Form C will be added to the patient notes. A copy of the request Form C stating the decision and signed by the Chair of the panel along with the agreed note of the meeting will be provided to the requesting clinician following the decision. A further copy of the request form and the agreed note of the meeting will be held on file in Pharmacy at Aberdeen Royal Infirmary. Form C requests will be recorded on a database to include a record of the outcome of the request and the rationale for the decision.

6. Monitoring of adherence to this guidance in NHSG

In order to monitor adherence to this guidance in NHSG, an annual report summarising use of medicines authorised through Forms A, B and C will be provided to the Grampian Medicines Management Group.

To support adherence to this guidance, use of particular medicines may be subject to additional recording and reporting to ensure that use is in line with the authorisation criteria. This is of particular importance in situations where high cost licensed medicines are subject to requests for off-label use or where SMC guidance restricts licensed use to particular patient sub-groups.

Requirements for such additional recording and reporting may be made through the existing medicines management structures (Grampian Medicines Management Group, Grampian Formulary Group, Grampian Medicines Guidelines and Policies Group) or through individual Sector Management.

Appendix 1: Summary of request forms and their uses in relation to this guidance

Form A - http://intranet.grampian.scot.nhs.uk/foi/files/FormA.doc

- Requests for continuation of previously initiated non-formulary licensed medicines in NHS Grampian managed service.

Form B - http://intranet.grampian.scot.nhs.uk/foi/files/FormB.doc

- Requests for use of an unlicensed medicine for a single patient in the managed service.
- Requests for use of an off-label medicine for a single patient in the managed service where local (ward) or Grampian-wide protocols or guidelines are not currently in place.

Form C - http://intranet.grampian.scot.nhs.uk/foi/files/FormC.doc

- Requests for use of medicines which the SMC/Healthcare Improvement Scotland have recommended should not be used in NHS Scotland where a prescriber believes, following review of published evidence, that his/her patient has:

    1. a clinical condition or clinical characteristics that are significantly different to the general population of patients who have the condition in question **and**;
    2. where the individual for whom the treatment is being sought is likely to gain significantly more benefit from the intervention than might normally be expected from the general population of patients with the condition in question.

- Requests to prescribe a licensed medicine post-marketing but prior to SMC advice or to use a licensed medicine that SMC has recommended should not be used in NHS Scotland on the basis of non-submission or an incomplete submission where:

    1. there is no other suitable licensed alternative, approved by SMC or in the Grampian Joint Formulary, for the indication the medicine is requested,
    2. there is published, peer reviewed evidence of clinical-effectiveness,
    3. waiting for SMC to provide advice to NHS Scotland, based on a complete and full manufacturer's submission, would lead to the patient missing an opportunity for cure, long-term remission (five years), a significant extension of life or avoidance of permanent disability. This would include situations where the medicine requested is a bridging treatment to other treatments that would provide these benefits and situations where the only alternative medicine would be associated with significant, permanent harm to the patient and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

FG1 - http://intranet.grampian.scot.nhs.uk/foi/files/FG1

- Requests for use of an unlicensed medicine for a group of patients or an off-label medicine for use across a number of wards or group of patients to be recorded by the Formulary Group.
- Requests to have any licensed medicine added to the Grampian Joint Formulary.

Appendix 2: Individual Patient Treatment Request process - Form C

Where SMC recommends that a licensed medicine is not recommended for use in NHS Scotland, NHSG follows this guidance, i.e. such medicines should not be prescribed. However, there may be occasional circumstances where a prescriber believes that the medicine being sought for an individual patient is clinically appropriate and may wish to initiate an Individual Patient Treatment Request (IPTR).

The IPTR process, (Form C), should be followed for medicine requests for:

1. a licensed medicine that SMC has recommended should not be used in NHS Scotland based on a full and complete manufacturer's submission
2. a licensed medicine post-marketing but prior to SMC advice or a licensed medicine that SMC has recommended should not be used in NHS Scotland on the basis of non-submission or an incomplete submission where:

An IPTR can only be sought for a medicine within its licensed indication for the condition in question, and can only be progressed where the clinician responsible for the patient fully supports the request and is in agreement with the patient as to the most appropriate course of clinical treatment.

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 NHS Grampian or from another NHS Board (SGHD/CMO (2012)1).

A clinician may wish to submit an IPTR for use of a medicine

A. which the SMC/Healthcare Improvement Scotland have recommended should not be used in NHS Scotland but where a prescriber believes, following review of published evidence, that his/her patient has a clinical condition or clinical characteristics which are significantly different to the general population of patients who have the condition in question.
and
where the individual for whom the treatment is being sought is likely to gain significantly more benefit from the intervention than might normally be expected from the general population of patients with the condition in question.

OR

B. when waiting for SMC to provide advice to NHS Scotland, based on a complete and full manufacturer's submission, would lead to the patient missing an opportunity for cure, long-term remission (five years), a significant extension of life or avoidance of permanent disability. This would include situations where the medicine requested is a bridging treatment to other treatments that would provide these benefits and situations where the only alternative medicine would be associated with significant, permanent harm to the patient and the risk of that harm is high enough to preclude the alternative medicine as a treatment option
and
where there is no other suitable licensed alternative, approved by SMC or in the Grampian Joint Formulary, for the indication the medicine is requested
and
where there is published, peer reviewed evidence of clinical-effectiveness.

Appendix 2: Individual Patient Treatment Request process - Form C

1. Initiation of the request

1.1 It will be for the treating clinician to make a request to prescribe a medicine through this process and demonstrate that the patient concerned does meet the criteria as described in either A or B above.

1.2 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 NHS Grampian 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.

1.3 Clinicians are required to fully complete sections A to C of Form C. Particular attention is drawn to the questions relating to clinical circumstances and the patient report section. Providing insufficient information will lead to delays in decision-making. The requesting clinician should be clear in the expected outcomes of treatment and criteria for stopping therapy.

1.4 Form C should be completed with the patient report and review of published evidence (undertaken to the standards used by UK Medicines Information) to support the decision-making. It should then be submitted by secure NHS mail, via the pharmacist working with the clinician submitting the request, to the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR.

1.5 The Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR will assess Form C for completeness and liaise with the requesting clinician to address any gaps in information provided.

1.6 Decision-making should be supported by robust scientific evidence which must be provided by the requesting clinician. The Grampian Medicines Information Centre will assist the clinician in searching and retrieving papers and may be asked to provide additional support in specific circumstances as deemed necessary by the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR.

1.7 The requesting clinician's review of evidence, including search strategy, where appropriate, and results, will be provided to the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR **and** Grampian Medicines Information Centre for comment and consideration prior to completion of the review and circulation to the decision-making panel.

1.8 A decision-making panel will be convened within a time frame appropriate to the clinical needs of the patient and in accordance with advice from the requesting clinician. This is usually subject to a normal minimum of 5 working days from the time a completed Form C and comprehensive report presenting a review of

the evidence (conditional on 1.6 above) are submitted to the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR.

1.9 The timescales for consideration of IPTRs may be accelerated in accordance with the patient's clinical needs. The Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR will undertake a preliminary examination of IPTR requests to ensure that due consideration is given to the urgency of the request given the patient's clinical condition.

2. Decision- making panel

2.1 The decision-making panel will consist of a core of four members constituted from individuals working in the sector from where the request has been made, e.g. ARI, Mental Health, Dr Gray's.

2.2 The panel will include:

- A senior doctor, e.g. associate medical director/clinical lead who will also be a practising medical consultant with (or with access to) specialist knowledge of the relevant clinical area,
- Clinical group lead, or equivalent, from another area to the requesting clinician,
- Senior pharmacist,
- Senior service manager, e.g. budget holder.

The panel is chaired by the senior doctor.

The choice of individuals invited to participate in IPTR decision-making is dependent on the medicine being requested. Some degree of flexibility may be required to decide how best to manage this process within the timescales required, particularly when the timing of a decision is urgent, due to the patient's clinical circumstances, and may need to be accelerated to avoid missing a window of opportunity from providing the medicine and achieving benefit from its use. Additional members may be co-opted onto the group dependent on the nature of the IPTR and any additional expert advice required.

Whilst the requesting clinician is not a formal member of the decision-making panel it is expected that the panel will wish to engage the clinician as part of the discussion and deliberations. Therefore, the requesting clinician will be requested to remain during decision-making to provide additional information where required but will not take part in the decision-making itself.

For requests that are outside of the funding available within the sector (N.B. not the individual service) the request will need additional authorisation through the Chief Operating Officer. The Chair or Vice-Chair of the Grampian Medicines Management Group will facilitate such authorisation. It is therefore preferable to assess funding availability at an early stage in the process to reduce duplication of discussion and delays in decision-making.
A senior administrator/secretary will be in attendance to ensure a detailed record is made of the process and decision.

2.3 Quorum: No business will be transacted unless the Chairperson and the core membership, as detailed, above are present.

2.4 Members of the decision-making panel are required to make declarations of interest in the product being requested in advance of the meeting. Where there is a potential conflict of interest alternative representation must be sought.

3. Patient representation

There is no requirement on the patient to come to the decision-making panel meeting. Patients/patient representatives will be informed by the requesting clinician of the composition of the panel. They will be offered information about the process, access to meeting papers and a copy of the final decision panel report should they so wish. However, it is accepted that some patients may wish to make representation to the decision-making panel either through their clinician or via a pre-prepared statement. Therefore, the patient will be offered the opportunity to make representation to the decision-making panel regarding their case for receiving the requested treatment. Support will be provided by the requesting clinician, or another health professional identified by the requesting clinician who is acceptable to the patient/patient representative. Patient representation may be through a recorded message, in writing or in any other suitable manner agreed with the coordinator of the process.

N.B. The patient or their representative will not normally be permitted to be in attendance during the decision-making panel's deliberations/decision making. If the patient decides not to make representation to the panel this will have no negative/detrimental effect on the consideration of their case.

The patient or their representative will be provided with the leaflet "New medicines in Scotland – who decides what the NHS can provide?" http://www.hris.org.uk/patient-information/information-about-health-services/access-to-new-medicines/

4. Decision-making

4.1 Requests to prescribe licensed medicines which the SMC or Healthcare Improvement Scotland have recommended should not be used in NHS Scotland based on a full and complete submission by the manufacturer.

4.1.1 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:

- The individual for whom the treatment is being sought presents with clinical circumstances (condition and characteristics) which are significantly different from either the general population of patients covered by the medicine's licence, or the population of patients included in the clinical trials for the medicine's licensed indication as appraised

and

- The individual for whom the treatment is being sought is likely to gain significantly more benefit from the medicine than would normally be expected.

4.1.2 If the panel concludes that significantly different clinical circumstances are not demonstrated then the NHS Grampian policy for that medicine applies, e.g. if SMC or Healthcare Improvement Scotland has recommended that the medicine should not be used the patient and the requesting clinician would be advised that treatment will not be made available.

4.1.3 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 authorised for this individual patient.

4.1.4 The second stage of decision-making, for those patients deemed to have significantly different clinical circumstances, should be undertaken by the panel using a decision-making framework to include consideration of (see Appendix 3):

- clinical-effectiveness
- cost-effectiveness
- health gain
- disbenefits
- service impact
- implications of the request on the equity of service provision in Grampian.

Meeting the criteria in 4.1.1 above does not automatically result in authorisation to use the medicine.

4.2 Requests to prescribe licensed medicines which are awaiting SMC guidance, where there is a delay in SMC guidance or SMC non-approval has been based on a non/incomplete submission from a manufacturing company

4.2.1 The process of decision-making, for licensed medicines which are awaiting SMC guidance, where there is a delay in SMC guidance or SMC non-approval has been based on a non/incomplete submission from a manufacturing company, is in two parts.

4.2.2 The first assesses whether the patient circumstances allow the case to be made that Grampian should put aside its general policy not to use a licensed medicine where SMC has yet to provide advice. In considering this, the IPTR decision-making panel considers whether:

1. there is no other suitable licensed alternative, approved by SMC or in the Grampian Joint Formulary, for the indication the medicine is requested
2. there is published, peer reviewed evidence of clinical-effectiveness
3. waiting for SMC to provide advice to NHS Scotland, based on a complete and full manufacturer's submission, would lead to the patient

missing an opportunity for cure, long-term remission (five years), a significant extension of life or avoidance of permanent disability. This would include situations where the medicine requested is a bridging treatment to other treatments that would provide these benefits and situations where the only alternative medicine would be associated with significant, permanent harm to the patient and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

Clinicians will be required to make the clinical case for using the requested medicine, show that his or her patient's clinical circumstances meet criteria 1 and 3 above and to provide evidence of clinical-effectiveness, and where available cost-effectiveness.

4.2.3 If the panel concludes that the individual patient's circumstances do not demonstrate that NHS Grampian should put aside its policy not to use a licensed medicine, where SMC has yet to provide advice, then the requesting clinician will be advised that treatment will NOT be made available.

4.2.4 If the panel concludes that the individual patient's circumstances demonstrate that NHS Grampian should put aside its policy not to use a licensed medicine, where SMC has yet to provide advice, then the panel will move onto the second stage of decision-making.

4.2.5 The second stage of decision-making, for those patients deemed to have demonstrated that NHS Grampian should put aside it's policy, 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 (see Appendix 3):

- clinical-effectiveness
- cost-effectiveness
- health gain
- disbenefits
- service impact
- implications of the request on the equity of service provision in Grampian.

Meeting the criteria in 4.2.2 above does not automatically result in authorisation to use the medicine.

5. Reporting

5.1 Prior to the meeting the method of informing the patient of the panel decision will be agreed. This will normally be via the patient's clinician. In most instances the decision of the panel will be communicated to the patient within 24 hours of the decision being made. If the patient is non-English speaking, a "face to face" interpreter or the "Language Line" telephone interpretation service should be made available. If the patient has a communication disability, appropriate communication support should be provided. Where communication is made by telephone or face-to-face meeting this should be followed by a written communication from the patient's clinician. Where there is a delay,

contact will be made with the patient to explain the reasons for such delays and the revised timescale of reporting.

5.2 Following the meeting the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR will liaise with the Senior Pharmacist /Head of service/requesting clinician and finance as appropriate to communicate the decision and make the medicine available to the requesting clinician if its use has been authorised.

5.3 The report summarising the decision-making panel's decision will be presented to the Grampian Medicines Management Group for recording of the decision.

5.4 In the event of the decision-making panel turning down a request to use a medicine the IPTR the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR will ensure that the patient is informed about the appeals process. This will normally be via the requesting clinician initially with the offer of further contact with the Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR to explain any queries the patient may have.

5.5 The Senior Pharmacist or Unit Operational Manager responsible for managing the IPTR will coordinate any appeal lodged by the patient or the requesting clinician.

6. Record keeping

The decision-making panel will either approve or not approve the request providing a statement of their decision on the request form. A copy of the request form stating the decision and signed by the Chair of the panel along with the agreed note of the meeting will be provided to the requesting clinician following the decision. A further copy of the request form and the agreed note of the meeting will be held on file in the Pharmacy at Aberdeen Royal Infirmary.

The note of the meeting should clearly document the criteria considered and the basis for the decision. It should also clearly define the circumstances around the decision to make available or not to make available the medicines.

Where a request is successful, agreement will be made with the treating clinician and patient as to how success of individual treatment will be defined, i.e. what clinical outcomes would need to be achieved for continuation of treatment to be allowed and in what timescale those outcomes should be achieved. These outcomes will be a written part of the authorisation. Where these outcomes are not achieved, or the patient is not achieving clinical benefit from the medicine, the agreement should explicitly state that treatment with the medicine would cease.

Form C requests (IPTRs) will be recorded on a database to include a record of the outcome of the request and the rationale for the decision.

Appendix 2: Individual Patient Treatment Request process - Form C

7. Appeals of the panel decision

7.1 Appeals will only be accepted 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)

7.2 Patients or requesting clinicians wishing to appeal should write to the Chief Executive of NHS Grampian Board identifying the grounds of their appeal. Appeals should be made within three calendar months of the original panel decision being communicated to patients/requesting clinicians.

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

7.4 Appeal Panel 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 or their designated deputy
- Senior Clinical Manager – Medical Director or Nursing Director
- NHSG Legal Advisor
- Director of Pharmacy and Medicines Management
- Lay representative

7.5 Patient/requesting clinician representation

The patient (or guardian where applicable) and/or the requesting clinician will be offered the opportunity to make representation to the appeal group, either in person or through their chosen representative (this representative may be a solicitor but should not be acting in a legal capacity during the panel meeting, i.e. the meeting is not a court of law) regarding the grounds of their appeal.

7.6 Reporting

A report of the appeal panel will be made to the Chief Executive, NHS Grampian and will be made available to the patient within five working days of the appeal panel meeting.

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

7.8 Successful appeals will result in a new decision being made (N.B. Not necessarily a different outcome).

7.9 Decision-making following a successful appeal will be coordinated as laid out in this guidance.

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

7.11 The note of the meeting should clearly document the criteria for the appeal and the basis for the decision. It should also clearly define the circumstances around the decision to recommend reconsideration of the original advice.

8. Review of the decision in the light of new evidence

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

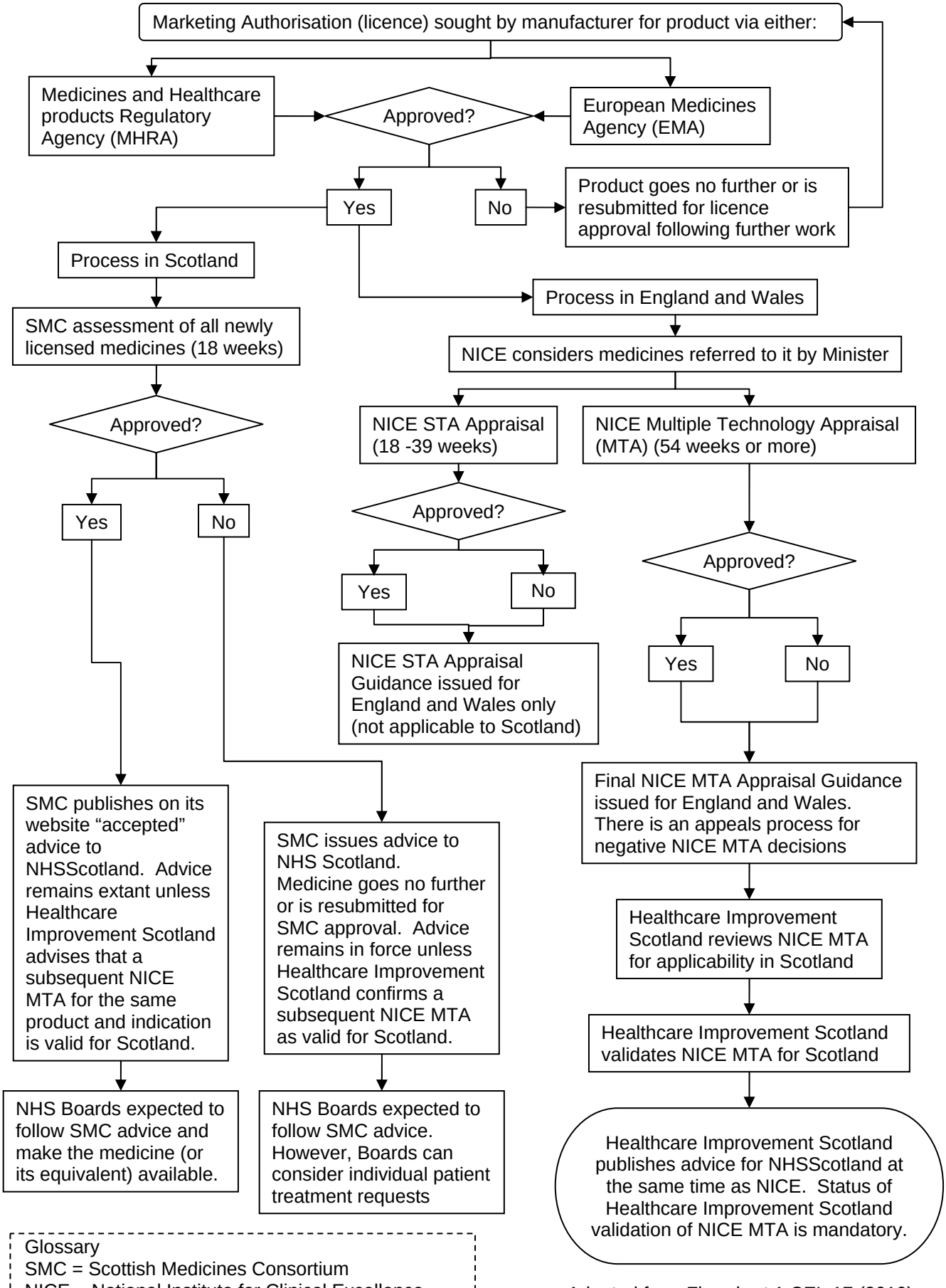
Where a clinician believes that the weight of the new evidence is such that it may affect a new decision they should reapply using Form C, initiating the decision-making process again including review of the new evidence. N.B. If the SMC is timetabled to consider the medicine, NHSG will wait for such advice to be made as this is NHSG policy, i.e. a decision-making panel will not be set up locally unless there are urgent clinical reasons for doing so and waiting for SMC to provide advice to NHS Scotland would lead to the patient missing an opportunity for cure, long term remission (five years), a significant extension of life or avoidance of permanent disability. This would include situations where the medicine requested is a bridging treatment to other treatments that would provide these benefits and situations where the only alternative medicine would be associated with significant, permanent harm to the patient and the risk of that harm is high enough to preclude the alternative medicine as a treatment option.

.

Appendix 3: Decision-making framework to be used when considering requests for individual patient use of unlicensed medicines, off-label medicines and medicines turned down for use in Scotland by SMC/Healthcare Improvement Scotland or licensed medicines awaiting assessment by SMC/Healthcare Improvement Scotland in defined circumstances (Forms B and C)

Dimension	In assessing a medicine for individual use the decision-making group should consider:
Clinical-effectiveness	1) The strength of the available clinical effectiveness evidence 2) The likely response rate and/or attributable risk reduction for the patient 3) The nature of the benefit, e.g. on a continuum from life saving to short-term prolongation of life with poor quality
Cost-effectiveness	1) The strength of the available cost-effectiveness evidence 2) The cost-effectiveness in comparison to either the most appropriate comparator (using appropriate economic outcome measures) or more generally the prevailing cost/QALY thresholds used by national health technology assessment groups such as the SMC
Health gain	1) The expected benefits of treatment in terms of mortality and morbidity 2) When such benefits occur 3) The likely duration of benefit
Disbenefits	1) Potential disbenefits are there for the patient using the medicine 2) Likelihood of these disbenefits occurring (e.g. attributable risk increase)
Service impact	1) Whether the service can use the medicine immediately or there is additional service development that needs to be put in place first, e.g. clinic spaces, diagnostic equipment 2) The budget impact 3) Whether the medicine quantifiably and significantly contributes to local NHS priorities, e.g. waiting time reduction, shifting the balance of care, HEAT targets, etc
Equity	1) The opportunity cost in investing funds into a particular medicine versus other medicines that might require funding by the service/sector during the remainder of the year 2) The impact on equity of access relative to other Health Boards, i.e. will funding bring NHSG in to line with other Health Boards/care routinely available on the NHS in Scotland

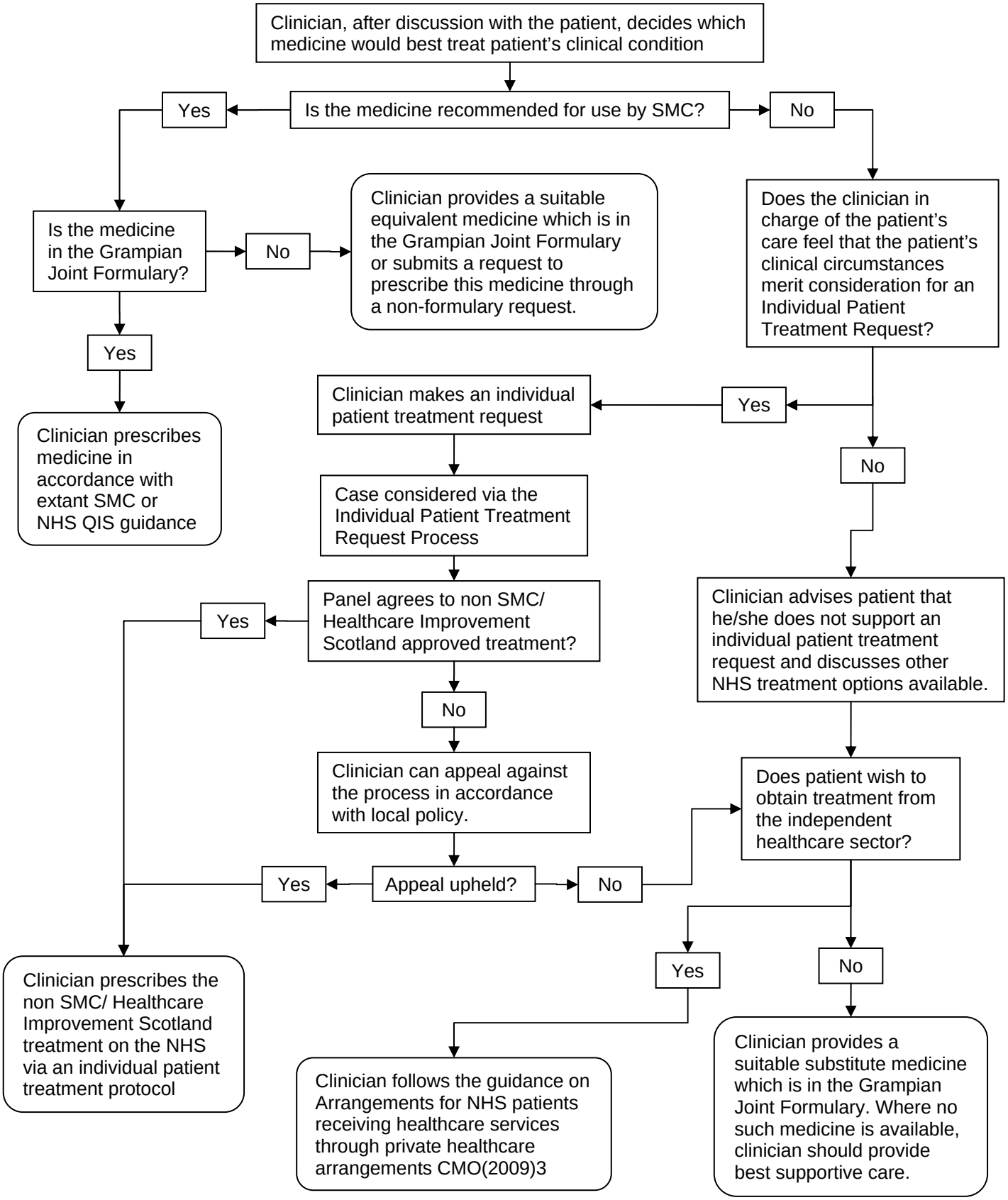
Appendix 4: Overview of UK Process for Introducing New Medicines



Glossary
SMC = Scottish Medicines Consortium
NICE = National Institute for Clinical Excellence

Adapted from Flowchart 1 CEL 17 (2010)

Appendix 5: Overview of Arrangements for Prescribing Licensed Medicines



Adapted from Flowchart 3 CEL 17 (2010)

Appendix 6: Version control statements.

Changes from Version 2.1 March 2012

- Glossary: definition of IPTR - changes; definition of “Specials” - changes. definition of “Formulary Medicine” - new.
- Section 1; Change of terminology marketing authorisation; “with significantly different clinical circumstances (to be known as “individual patient treatment request (IPTR)”)” deleted from the last bullet point.
- Throughout - change of wording to reflect CMO (2012)1 letter: Section 2.2.2 - including 90 day and 14 day time frames; addition of formulary consideration criteria to reflect CMO(2012)1; Section 5 and Appendix 2– addition of CMO(2012)1 letter advice re support from peers; Section 5 addition of “Form C requests will be recorded on database to include a record of the outcome of the request and the rationale for the decision”.
- Section 2.1: Addition of EU legislation, p.5.
- Section 2.2: Additional information – formulary submission process and Grampian joint Formulary.
- Patient Access Schemes moved, now 2.2.3.
- Section 3.2: “primary care” changed to “elsewhere”; change of “Senior Pharmacist” to “pharmacist”; change to “regular analysis of the requests”; addition of “Non-formulary medicines supplied using Form A will be recorded in an electronic database.”
- Section 4.2: addition of “The Grampian Formulary group may consider the use of unlicensed medicines, or licensed medicines prescribed outside of their marketing authorisation, where this relates to a group of patients and the points above are applicable….” .
- Section 4.5: addition of “The requesting clinician must demonstrate the requirement for the medicine through supporting clinical evidence and verification that this would be acceptable practice within a cohort of his/her peers. The Pharmacy Quality and Assurance Department will provide a medicines risk assessment of the product for any unlicensed medicine”, and “Form B requests will be recorded on a database…. …rationale for the decision.”
- Section 4.6: Removal of “for individual patients” from heading.
- Section 4.8: Clarification of Formulary Group decision-making criteria for off-label/unlicensed medicine requests for a group of patients.
- Section 5: heading changed; addition of IPTR application requirement; change of terminology from “prioritise” to “may be accelerated”.
- Sections 5.1 and 5.2 swapped (SMC full submission now first)
- (New) Section 5.1: Standardisation of text in stages of decision-making; removal of “Primary Care CHP” as an example; addition of “20k to £30k per QALY.
- Sections 5.1, 5.2 and Appendix 2: Addition of - “If the patient is non-English speaking, a “face to face” interpreter or the “Language Line” telephone interpretation service should be made available. If the patient has a communication disability, appropriate communication support should be

provided. ", "Meeting the criteria above does not automatically result in authorisation to use the medicine".

- New section 5.3 – Decision-making panel.
- Appendix 2: Changes throughout: as per CMO (2012)1, re-ordered text, bullets and numbering changed, and addition of term "Senior Pharmacist or Unit Operational Manager" in place of process coordinator; Decision-making panel changed "clinical" to "clinical lead"; Decision-making framework list amended - 4.1.4 and 4.2.5; updated to reflect current process - 4.2.2 to 4.2.5.
- Appendix 5: Addition of "Licensed" to title.

Changes from Version 2 March 2011
April 2011

- Section 4.5 page 10 –Appendix number corrected from 2 to 3.
- Corrections to Appendix A
  - 'Requests for the initiation of non-formulary medicines in NHS Grampian acute service' removed from appendix to be compliant with text.
  - 'Hyperlinks to forms updated

Changes from Version 1.1 March 2008
March 2011

- Exceptional clinical circumstances/prescribing changed to individual patient treatment requests - throughout.
- Sections expanded throughout
- Sections and appendices renumbered throughout document
  - 'Purpose and Scope' moved to section 1 from 2;
  - Glossary moved from Appendix 1 to beginning of document;
  - new sections 3.1 and 6;
  - sections 4 and 5 combined and information expanded within new section 4, interim Form D process now considered via Form C process;
  - section 6 now section 5 (IPTR) changed to reflect CEL 17 (2010) and SGHD/CMO(2011)3.
- Appendices - Forms removed, updated forms now hyperlinked in new 'Appendix 1: Summary of request forms'.

Changes from Version 1 March 2008

June 2008

- Front covers - updated to NHSG information governance covers.
- Text updated to Ariel 12pt – throughout.
- Sections 4.3 and 5 - additional text "Once a request…….authorisation is not required."