**Dumfries and Galloway NHS Board**

*Chief Executive's Office*
*Communications- FOI*

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Ref.: 10-088
Date: 30 April 2010

Keith Small
Morhamburn

Dear Mr Small

**Freedom of Information**

The following is NHS Dumfries and Galloway's response to your FOI request

1. A medicine that has not yet been reviewed by SMC, is treated in the same way as a medicine that is not recommended by SMC. A clinician must therefore apply to use it on an individual patient basis. The application is considered by the multidisciplinary Exceptional patient panel.

2. A clinician would need to make a request for use to the Area Drug Therapeutic Committee and identify if it is for routine use or for occasional use. If routine use further detail is required to determine whether formulary inclusion is appropriate.

3. Please find attached copy of the current guidance around prescribing items relating to the above 2 points

Under the Freedom of Information (Scotland) Act 2002 if you are dissatisfied with our response you are entitled to request a review. A request for a review must be made in writing to John Burns, Chief Executive, NHS Dumfries and Galloway. Mid North, Crichton Hall, The Crichton, Dumfries, DG1 4TG, no later than 40 working days from 30 April 2010. You must provide your name, an address for correspondence, details of your original request and say why you want a review. If our decision is unchanged following a review and you remain dissatisfied with this, you then have the right to make a formal appeal to the Scottish Information Commissioner.

Yours sincerely

John A Glover
Head of Communications/Freedom of Information Officer

# DUMFRIES AND GALLOWAY NHS BOARD

**2 March 2009**

## NHS Board Handling of Scottish Medicines Consortium (SMC) Advice

**Author** Dr Angus Cameron

**Sponsoring Director**
Dr Angus Cameron, Medical Director

**Date**: 11 February 2009

**RECOMMENDATION**

This paper sets out proposals for making medications available for patients in Dumfries and Galloway. It is based on the response of the Scottish Government Health Department to the Scottish Parliamentary Public Petitions Committee Enquiry into the Availability of Cancer Drugs in Scotland. The proposals however cover all drugs rather than exclusively cancer drugs.

The Scottish Government Health Department advises that Board proposals should be subject to a consultation process with patients and other local stakeholders; this paper therefore seeks approval from the Board to consult on the proposals outlined.

**SUMMARY**

This paper describes how expert advice from the Scottish Medicines Consortium (SMC) is received and acted upon within NHS Dumfries and Galloway. In principle we believe that the assessment of drugs by the SMC is carried out to an extremely high standard which could not possibly be replicated within a small Board such as NHS Dumfries and Galloway. It seems appropriate therefore to accept the advice provided by SMC on all but exceptional cases.

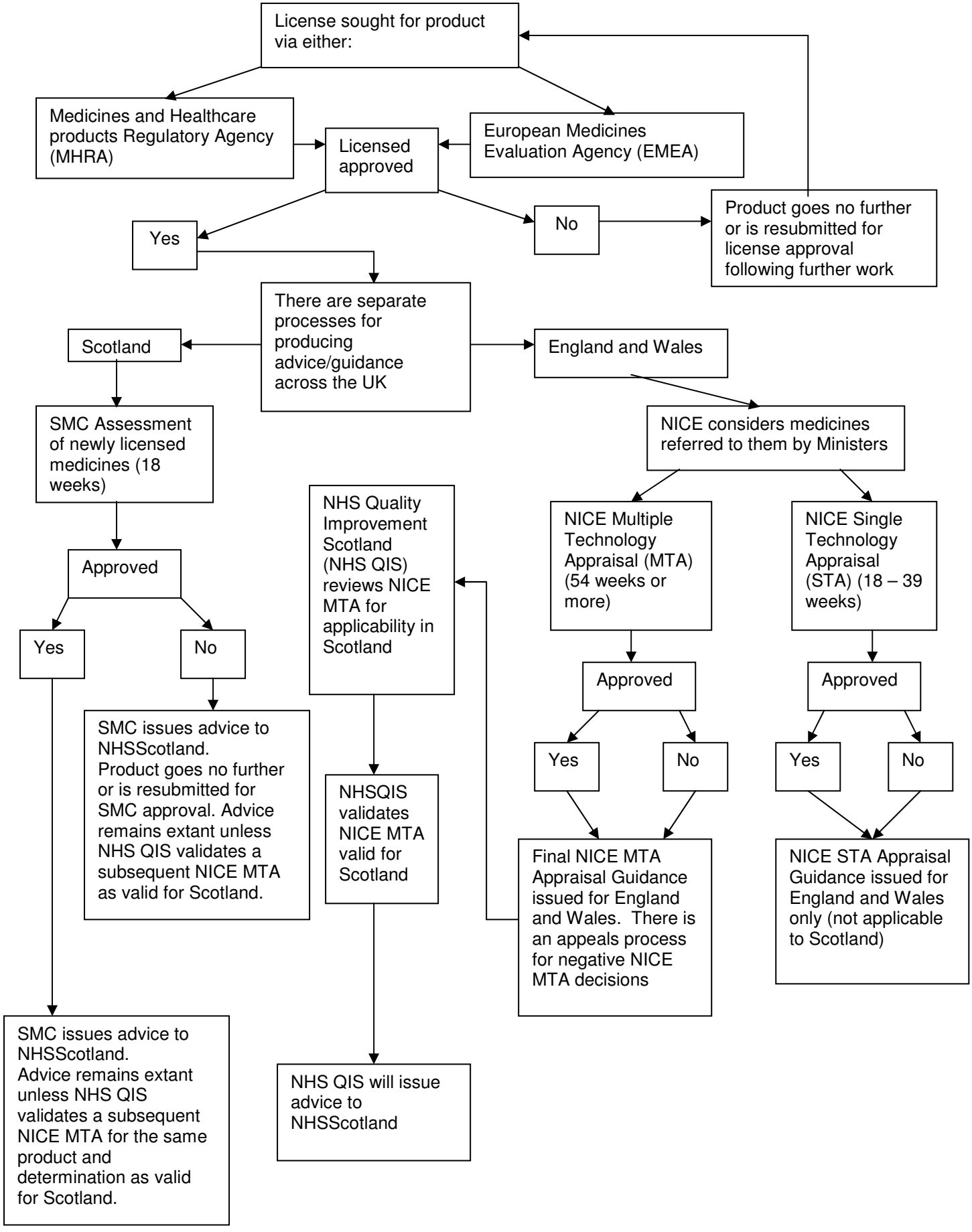
The Scottish Medicines Consortium was set up approximately 5 years ago to provide a rapid and authoritative review of new medications. The SMC has a permanent staff but is also able to call upon a wide range of highly qualified professionals from across NHS Scotland to enable it to carry out expert assessments on medications.

In addition to pharmacists and clinicians SMC also seeks advice from health economists, and specifically invites comments from stakeholders particularly organisations which represent groups of patients that may have an interest in the medications under consideration.

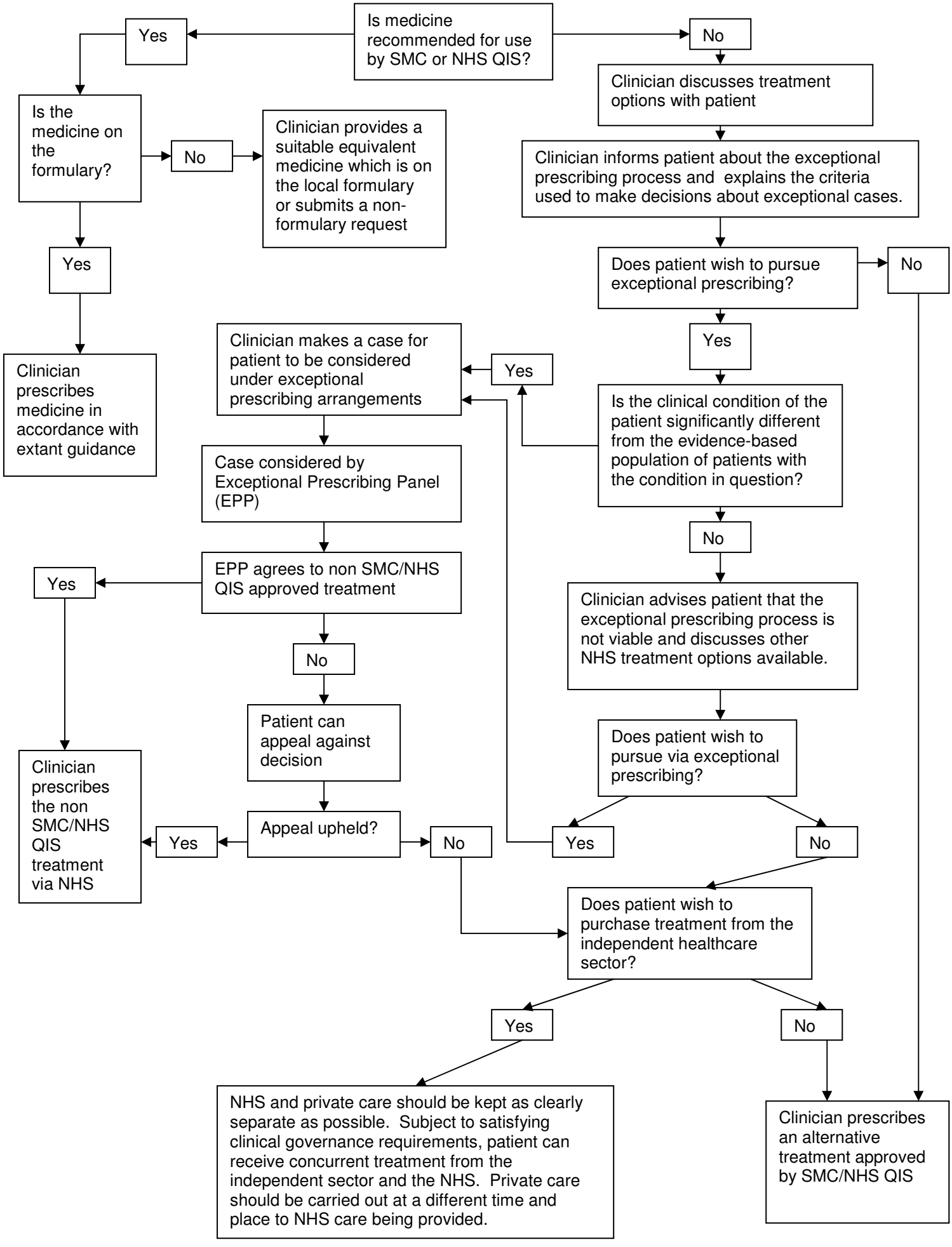
The review by SMC takes place generally within 18 weeks of the medication being licensed and therefore it seems appropriate not to prescribe any new medication that has not been reviewed by SMC.

A diagram of the proposed process to be followed in Dumfries and Galloway is provided below :

**UK process for Licensing of Medicines and guidance for their use in the NHS**



## NHS Board arrangements for prescribing medicines



The principles developed by the Area Drug & Therapeutics Committee in relation to new medications will be as follows :

**New Medications**

1. Medicines that have not been licensed will not be provided for patients in Dumfries and Galloway unless a clinician makes a special case for its use and is prepared to accept full liability in the event of approval to proceed from the Exceptional Prescribing Panel. The process of dealing with requests to fund unlicensed medication is described at the Appendix to this paper.

2. A medication that has been licensed but not reviewed by SMC will not be approved for use within Dumfries and Galloway unless an individual clinician has contact the Exceptional Prescribing Panel pleading an exceptional case for their patient. Thus, all medications that have not been reviewed by SMC are considered in the same way that medications that have been reviewed by SMC and not approved.

3. SMC has 3 potential verdicts in relation to any medication, namely :

   a) Approved for general use in Scotland
   b) Approved fro restricted use in Scotland (ie. Specialist use only)
   c) Not approved

   A monthly report from SMC is discussed at the Area Drug & Therapeutics Committee. Medications that have been approved for use in Scotland will be made available across Dumfries and Galloway. Consideration will be given to including a new approved medication in the Dumfries and Galloway Formulary of advised first and second choice medications. The Drug and Therapeutics Committee sends out a monthly newsletter after each meeting advising clinicians of recent SMC decisions and whether a medication is to be included in the Dumfries and Galloway Formulary. Dumfries and Galloway operates a policy of strongly encouraging clinicians to use formulary drugs, but does require formal approval to use a non-formulary drug.

   We note that compliance by General Practitioners with the policy of not using medications that have not been approved by SMC is generally high.

4. Exceptional Cases – where an individual clinician believes that there is an exceptional case for a patient to be provided with a medication that has not been approved by SMC he or she may contact the Medical Director, giving details of the patient's circumstances and why they should be considered "exceptional".

   The clinician's request, along with supporting information from the SMC's assessment, is circulated by email from the Medical Director's office to the Exceptional Prescribing Panel (EPP) consisting of 2 Senior Pharmacists, 2 senior Consultants and 2 experienced GPs. They will then meet (on a

monthly basis) to determine whether the patient should be considered as an “exceptional case”.

Arrangements can be made for the patient, the patient’s representative or the requesting clinician to attend the EPP.

It should be noted that in terms of “exceptional”, the EPP are looking for evidence that the patient is “exceptional” in relation to the cohort of patients who have been included in the research work that has been considered by SMC.

No consideration is taken of the patient’s social circumstances, age or sex; the EPP is quite clear that it is assessing whether the patient is “exceptional” as described above, rather than making a valued judgement on whether the patient is deserving.

In considering whether a patient is “exceptional” no note is taken of the cost of the medication and so the EPP will decline to approve the prescription of even a cheap medication if they feel there is no evidence to consider the patient to be clinically exceptional.

The Medical Director will inform the clinician of the decision of the EPP.

A record of all EPP decisions is maintained and recent decisions are reviewed at the Area Drug & Therapeutics Committee every month to ensure consistency.

5. Patients suffering from cancer who attend Edinburgh Cancer Centre are treated by clinicians who have a different system in place within Lothian. We have indicated to them that ultimately NHS Dumfries and Galloway will decide on what medication is available for its patients. For this reason if Lothian or SCAN consider that a patient should have a medication that has not been approved by SMC, this opinion is considered to be “advice only” and would be further considered within Dumfries and Galloway, applying the “exceptionality” criteria as described above. The same rules apply to the smaller number of patients treated at the Glasgow Cancer Centre.

6. Following discussion at a regional level, a regional approach has been agreed with respect to other patients who are treated by tertiary centres.

a) If the patient is referred to a tertiary centre as an outpatient for advice on the diagnosis and management of a condition then any opinion expressed by the tertiary centre will be considered as “advice only” and any advice to prescribe a non SMC-approved drug would be considered through the “exceptional” process described above.

b) Where a patient is undergoing treatment provided by a tertiary centre it is agreed that the decision on the use of a medication will be taken by the tertiary centre and NHS Dumfries and Galloway will, if required, in these circumstances, fund non SMC-approved medications. This would mean

that a patient who was considered “exceptional” in a tertiary Health Board can promptly be provided with a medication, particularly when they are undergoing inpatient treatment in the tertiary centre.

**New Indications**

When SMC considers a new medication it considers it in the light of specific indications. Not infrequently once a drug has been licensed for some time new indications will be found for its use and clinicians may wish to use medications that have been approved by SMC for one indication, for a clinical indication that has not been reviewed by SMC. In this case the clinician will apply to the EPP of the Area Drug & Therapeutics Committee as above to seek approval for the use of the medication under the new indication.

**Patient Participation**

The Scottish Government Health Department advises that patients should have a clear understanding of the process used to consider “exceptional cases” and should be able to contribute their views to the process. It is felt that this process of patient participation will be aided by the development of a Liaison Adviser who will support the patient during the process and make sure that the patient understands the decision-making process. It is necessary for the members of the EPP to engage in free and frank discussion regarding applications; for this reason patient participation will be in the form of a written submission which will be developed with assistance of the Liaison Adviser and the patient will have the opportunity to speak to the EPP (or be represented) prior to the decision-making process. Currently it is proposed that the Liaison Adviser will be the Head of Patient Services or alternatively arranged through PAS.

**Appeals**

When the clinician involved in the request has communicated the decision of the EPP to the patient, the patient may wish to appeal the decision. Within Dumfries and Galloway it is proposed that appeals should be dealt with by an Appeals Panel which will consist of the Director of Public Health, a local Consultant and a local General Practitioner. Neither the Consultant nor the General Practitioner will have been involved in the original EPP decision. The 3-man Tribunal will meet under the Chairmanship of the Director of Public Health and the Medical Director will present the reasoning behind the original decision. The patient’s doctor will present the patient’s case, and the patient will be able to address the Tribunal prior to the decision-making. The full details of the meeting will be minuted and shared with the patient. The decision of the Appeal Panel will be final.

**“Grandfather Clause”**

Some medications have been in clinical use for many years and are an accepted part of medical practice but have never been licensed. This applies particularly to medications used in Paediatrics where the small volume of medication use and the difficulties of conducting trials in children has resulted in companies not applying for

licensing of medications. Applications to use unlicensed medications are considered as per the “Unlicensed Medications Policy” which is attached as an Appendix to this paper.

**SUMMARY**

The Board believes that SMC provides high quality assessment of the role of new medicines in modern healthcare and believes it should follow SMC advice consistently.

The only exception to following SMC advice will occur when a clinician demonstrates that the patient is “exceptional” in comparison to the cohort of patients on whom the medication has been tested.

The proposal for considering “exceptional cases” in Dumfries and Galloway will be presented for consideration if it is approved by the Board as appropriate to consult on.

The Scottish Medicines Consortium attended a recent meeting of Dumfries and Galloway Area Drug & Therapeutics Committee and expressed satisfaction with the way we propose to deal with SMC advice and “exceptionality”.

**MONITORING FORM**

| | |
|---|---|
| Policy/Strategy Implications | *Meets aim to provide evidence-based cost effective care – and includes detail on individually tailored flexibility.* |
| Staffing Implications | *Nil* |
| Financial Implications | *Financial implications of following SMC advice variable* |
| Consultation | *Discussed at ADTC and with SMC* |
| Consultation with Professional Committees | *ACF* |
| Risk Assessment | *This process should reduce risk of litigation in regard to Board prescribing policy* |
| Best Value | *SMC advice is based partially on cost-effectiveness* |
| Compliance with Corporate Objectives | *Yes – evidence based care – best value.* |
| **DIVERSITY ASSESSMENT** | |

# Policy for the Use of Unlicensed (and off label use) Medicines in NHS Dumfries & Galloway

## Background

The manufacture and sale or supply of medicinal products was first brought under legal control by the Medicines Act 1968. This was subsequently incorporated into European Law by EEC Directive 65/65.

This directive states that no medicinal product may be placed on the market unless a marketing authorisation (formerly called a product license) has been issued. The directive also ensures that full control of manufacturing and marketing applies to relevant medicinal products on the market but allows for exemptions in relation to medicinal products to fulfil special needs. Such products are known as 'specials' and are supplied in response to a bona fide, unsolicited order, formulated in accordance with specifications of an authorised healthcare professional and for use by his/her individual patients on his/her direct personal responsibility.

This legislation only applies to relevant medicinal products which includes all licensed medicines and specials. Products extemporaneously prepared in the Pharmacy in response to a prescription are not defined as relevant medicinal products. (1,2)

UK manufacturers of relevant medicinal products (licensed and unlicensed) are required to hold a manufacturers license.

A marketing authorisation defines the clinical indications for which a licensed medicinal product can be marketed, it also defines the form, dose, route of administration and the patient age group which the medicine can be used in and the container in which the product is supplied. A pharmaceutical company cannot promote an unlicensed medicine or a licensed medicine for an unlicensed indication.

Additional guidance which should be used in conjunction which this policy is contained within MCA guidance note 14 (2).

## Definitions

***Licensed Medicines*:** These are medicines with a UK marketing authorisation. When prescribed within the terms of the marketing authorisation the manufacturer is likely to be found liable for any harm caused by that medicine.

***Off Label Medicines*:** These are medicines with a UK marketing authorisation which are prescribed for an unlicensed indication or via a different route etc. (i.e. out with the terms of the marketing authorisation). If a patient is harmed by such use of medicine then the manufacturer is unlikely to be found liable unless the harm is directly attributable to a defect in the medicine rather than the way in which it was prescribed.

***Unlicensed Medicines*:** These are medicines without a UK marketing authorisation and include:-

- Medicines prepared by a UK manufacturer but not for sale in the UK and may include medicines that are ongoing clinical trial, medicines awaiting a UK marketing authorisation, medicines withdrawn from UK market or medicines manufactured for export. Such medicines are usually available on an individual named patient basis.
- Medicines prepared out with the UK with a marketing authorisation from the country of origin. Such medicines are imported into the UK.

- Extemporaneously dispensed medicines prepared for a specific patient under the supervision of a pharmacist in according with a practitioner's prescription including TPN compounding, IV additives and cytotoxic reconstitution.
- Repackaged medicines – these are medicines which are removed from their original containers and repacked during dispensing of ward stock pack down procedures.
- Chemicals used to treat rare metabolic disorders.

***Specials:*** Specials are a specific category of unlicensed medicine. They are products which can be prepared to meet an individual patients needs and are generally bespoke. They are prepared by a NHS or commercial supplier with a manufacturers specials license. Such medicines can be supplied against an unsolicited order or prescription. There may be additional risks associated with the use of a 'special' which need to be considered.

Some of the above examples are common practice e.g. repackaged medicines and raised little concern for prescribers of patients whereas others though sometimes accompanied by published evidence of efficacy raise concerns of unfamiliarity with prescribing, quality assurance and liability.

## Aims

The aims of this document are to:-

- Outline best practice in the use of unlicensed and off label medicines in NHS Dumfries & Galloway
- Provide support for primary and secondary care prescribers and pharmacists in the use of unlicensed and off label medicines
- Describe a system of categorisation of unlicensed and off label medicines
- Describe the process by which medicines will be assigned to an individual category

## The Use of Unlicensed Medicines in the UK

Unlicensed / off label medicines can be prescribed by doctors, dentists and in some cases supplementary prescribers. Furthermore pharmacists can dispense such medicines and nurses and midwives can administer them to patients.

If an untoward incident occurs with a licensed medicine that is a result of a product defect or a problem with its use in an approved clinical situation (as defined in the marketing authorisation) any liability arising may in part or whole be transferred to the market authorisation holders. Should a patient suffer harm as a result of the effects of an unlicensed / off label medicine then the manufacturer is not liable (unless the medicine is shown to be defective) and a claim against the prescriber or the pharmacist is less easy to defend. Any legal action may also involve the NHS Board as a result of employers vicarious liability.

## Categories of Unlicensed / Off Label Medicines in NHS Dumfries & Galloway

Unlicensed / off label medicines will be assigned to one of five categories: green, amber or red, double red or black.

| Category | Proposed Prescribing Status | Examples |
|---|---|---|
| Green | Unrestricted general use: Products in this category can be used widely and in accordance with a respectable, responsible body of professional opinion e.g. medicines for children SIGN / NICE recommendation, Dumfries & Galloway Joint Formulary | |

| | | |
|---|---|---|
| Amber | General use with restrictions: Products in this category have been evaluated by the Drug & Therapeutics Committee and the Prescribing Support Team and use have been authorised as being acceptable. This may require development of a shared care protocol. Local use has peer group support. Specific consent is not normally required. | |
| Red | Specialist use only or specific named patients: Products may be placed in this classification if they have only a limited amount of evidence of efficacy available, they are rarely used or may have serious potential side effects and/or require close supervision. Specific consent from the patient is required. | |
| Double Red | Specialist use only as above but imported from abroad and have no English language labelling and/or information leaflets or are not labelled with the rINN drug name. This group of medicines must be specifically identified and stored and handled via a specially established procedure in Pharmacy. | |
| Black | Not approved for use. | |

## Implications for General Practice Pay and Report Products

Products in Green category will be paid under Pay and Report arrangements.

Products in Amber category will be paid if they are used in the specified circumstances

Products in Red and Double Red products will be paid only if prescribed for individual patients specifically approved by the Medical Director

Products in Black category will not be paid under Pay and Report arrangements.

Products highlighted under Pay and Report arrangements which have not been presented for classification will not be paid under Pay and Report arrangements.

## Procedure for Categorising Unlicensed / Off Label Medicines

1. Requests to initiate new treatments for groups of patients using unlicensed / off label medicines should be submitted by the responsible clinician, supported by the relevant clinical pharmacist to the Drug & Therapeutics Committee.
2. The submission should include:-
    a) the clinical indication and who the prescriber will be
    b) the medicine proposed to be used
    c) the UK licensed status of the medicine in terms of its proposed clinical usage
    d) details of the medicines availability
    e) the reason why unlicensed medicine is required
    f) the supporting evidence of efficacy and safety
    g) information on similar use elsewhere (peer support)
    h) associated treatment costs

3. If the Drug & Therapeutics Committee deem the submission to be appropriate they will also categorise it green, amber, red or black at this stage.
4. Green and amber submissions will be communicated onwards to the General Practitioners via Nostrum. For some medicines categorised as amber, the Drug & Therapeutics Committee may make a request for a shared care protocol to be developed. General Practitioners will be advised of such arrangements.
5. All medicines categorised green, amber or red will be placed on an approved list of unlicensed medicines for use in Dumfries & Galloway. It is envisaged that in time this approved list will be included as an appendix to the Dumfries and Galloway Joint Formulary and therefore be available to all prescribers.

## Policy Statement

1. Wherever possible licensed medicines will be used to treat patients.
2. It is recognised that the use of an unlicensed / off label medicine is sometimes necessary in order to provide the optimum treatment for a patient. Any liability associated with the use of approved unlicensed medicines (or medicines used off label) will be accepted by the employing authority provided that best practice as outlined in this policy has been followed.
3. Adverse drug reactions and medication incidents involving unlicensed medicines should be reported in the same manner as for licensed medicines.

## Responsibilities

***Prescribers***

1. Unlicensed / off label medicines should only be used where their use is clearly justified and their clinical / pharmaceutical benefits are considered to out weigh the risks involved. The prescriber is professionally accountable for this judgement and in so doing may be called upon to justify their actions. Junior medical staff should not initiate unlicensed / off label prescribing of medicines in the red and amber categories without direct Consultant instruction. This could take the form of an instruction in the Dumfries and Galloway Joint Formulary or through the inclusion of the medicine in an approved treatment plan.
2. Prescribers have a responsibility to advise the patient that they are being treated with an unlicensed / off label medicine. In addition they should provide the patient with accurate and clear information which meets their needs including information on side effects.
3. Other clinical staff involved in the treatment of a patient with an unlicensed / off label medicine should where appropriate (and particularly for unlicensed medicines in the red category) be:-
    a) made aware of its unlicensed / off label status
    b) informed of any problems and risks involved in how they deal with them
    c) be given significant information to administer and use the product safely and correctly

    In clinical areas where there is a requirement for high levels of usage of such medicines i.e. neonatal and critical care areas, staff should be made aware of the issues surrounding unlicensed drug usage and approach the use of such medicines and their areas accordingly.
4. General Practice recommendations - Consultants recommending the use of unlicensed medicines are responsible for ensuring that GPs are given sufficient information about the product and its availability as to allow safe and appropriate prescribing.
5. Whilst the decision to prescribe an unlicensed / off label medicine ultimately rests with the prescriber, it is anticipated that in general, GPs would be expected to prescribe medicines assigned to the green category. Medicines assigned to the amber category may require a shared care approach to prescribing. GPs will not be expected to prescribe medicines assigned to the red category or above except when they are approved for individual named patients e.g. essential continued prescribing of co-proxamol where no other option is available.

## Pharmacy Staff

1. Pharmacy staff will promote implementation of this policy.
2. Pharmacy staff will ensure as far as practicable that the prescriber is aware that the medicine they have requested is only available on an unlicensed basis and that advice is given on alternative licensed products.
3. Pharmacy staff must keep purchasing and general issue records of all unlicensed medicines for a period of at least 5 years. Patient specific records will only be maintained for unlicensed medicines which are assigned to the red category.
4. Pharmacy staff should:-
    a) notify prescribers of licensed alternative products becoming available where appropriate
    b) notify clinicians when they are alerted to problems with individual unlicensed medicines
    c) report any defect in an unlicensed medicine
    d) ensure that individual patients are given information regarding the availability of unlicensed medicines to pass on to the community pharmacist to ensure continuity of supply
5. If in the professional opinion of a pharmacist the use of an unlicensed medicine would be unsafe for a given patient and would not command the support of a peer group it is their professional responsibility not to supply it. Such cases may be referred to the Drug & Therapeutics Committee for review.

## Information for Patients (including Parents / Carers where appropriate)

1. Individual patients should be given information that meets their needs about relevant unlicensed medicines.
2. There is no explicit requirement to obtain consent on the basis of a medicine being unlicensed. However individual prescribers may wish to obtain consent from patients being treated with unlicensed medicines or with medicines being used off label.

## Clinical Trials

1. If the unlicensed / off label medicine is being used as part of a form of clinical trial the Health Board procedure for such trials must be followed.

## References


1. NHS Pharmaceutical Quality Assurance Committee. Guidance for the Purchase and Supply of Unlicensed Medicinal Products, notes for prescribers and pharmacists. June 2004; 3rd Edition
2. MCA / MHRA Guidance Notes No. 14. The Supply of Unlicensed Relevant Medicinal Products for Individual Patients – revised February 2000.