5.2.1: BRIEFING NOTES FOR CONSULTANTS SUBMITTING AN IPTR

INTRODUCTION

This briefing provides background information on the management of non-formulary requests within NHS GG&C, set against the Scotland and UK backdrop. It is intended as information for Consultants who are considering submission of an IPTR to their Associate Medical Director (AMD), or an appeal against an initial decision being submitted to the Board's Medical Director. In addition, it is prepared as a tool to assist Consultants providing information to their patients in such situations, as additional material to the NHS GG&C Patient Information Leaflet (appendix 1) and the Health Rights Information Scotland advice (appendix 2).

1. NHS UK

- Legislation and regulations relating to medicines are a UK Government responsibility e.g. The Medicines Act 1968. However, management of prescribing and of the associated budgets, is devolved separately to each country. This results in differing systems across each of the 4 UK countries for the introduction of new medicines, for budget allocations, and for the management of rarely used medicines such as orphan or ultra-orphan medicines
- NHS England usually provides advice to the service through National Institute for Health and Clinical Excellence (NICE). This advice is provided in the form of health technology assessments for each medicine or group of medicines.
- NHS Wales provides advice to the service through the 'All Wales Medicines Strategy Group'
- In addition to appraisal of medicines by NICE two further mechanisms for funding medicines exist outwith NHS Scotland.
    - In England, a Cancer Drugs Fund has been made available to fund cancer medicines that would not otherwise be available on the NHS. This may include drugs appraised by NICE and not recommended on the basis of cost effectiveness. This fund is administered regionally by the strategic health authorities.
    - NHS England and Wales have also set up separate processes for funding orphan and ultra-orphan medicines used in rare diseases. In England, if the service or treatment is approved by the Advisory Group for National Specialised Services, patients are referred to accredited specialists for assessment of eligibility for treatment, and if so, funding is provided by the National Commissioning Group.

2. NHS SCOTLAND

- Scotland manages the introduction of all new medicines through the Scottish Medicines Consortium (SMC), a consortium of Health Boards' Drug and Therapeutics Committees. New medicines granted a licence for use in the UK (i.e. the efficacy, safety and quality of the product have been established) are reviewed by the SMC for their clinical and cost effectiveness and advice provided to NHS Scotland. SMC aims to provide advice to the service as soon as possible after the medicine has gained marketing authorisation.
- The SMC applies a robust process to the assessment of all new medicines and new indications for existing medicines, including orphan medicines used to treat rare diseases. This process includes input from patient interest groups, clinical experts and representatives of ABPI Scotland. When assessing orphan / ultra orphan medicines, it takes into account the fact that clinical data availability will be more limited and also accepts a greater level of uncertainty in the economic case provided by the manufacturer.
- The upper threshold for cost effectiveness (expressed by cost per QALY), which is accepted by Health Technology Assessment agencies such as SMC is normally considered in the range £25,000 - £30,000. Where the cost per QALY is relatively high, other factors also play a role in SMC's assessment and may modify the final decision. These modifiers include (but are not limited to):
    - Evidence of a substantial improvement in life expectancy, with sufficient quality of life to make the extra survival desirable. (Substantial improvement in life expectancy would normally be a median gain of 3 months)

- Evidence of a substantial improvement in quality of life (with or without survival benefit);
- Evidence that a sub-group of patients may derive specific or extra benefit and that the medicine in question can, in practice, be targeted at this sub-group;
- Absence of other therapeutic options of proven benefit for the disease in question and provided by the NHS;
- Possible bridging to another definitive therapy (e.g. bone marrow transplantation or curative surgery) in a defined proportion of patients;
- Emergence of a licensed alternative to an unlicensed therapy which is established in clinical practice in NHS Scotland as the only therapeutic option for a specific indication.

Scottish Government has provided NHS Scotland with advice - CMO (2011)3 - for the management of medicines which have not been recommended for use by SMC for use in Scotland. This is referred to as the Individual Patient Treatment Request (IPTR) system. All territorial Health Boards are required to provide assurance to Scottish Government that their systems comply with this advice and to provide regular updates on its implementation in practice.

- The criteria for consideration of the prescription of a medicine for an individual patient where the medicine is not recommended for use by the SMC have been defined in CMO (2011)3 as:
  a) the patient's clinical circumstances (condition and characteristics) are significantly different from either:
     - The general population of patients covered by the medicine's licence (for medicines awaiting evaluation or non-submissions to SMC); or
     - The population of patients included in the clinical trials for the medicine's licensed indication as appraised by the SMC or NHS HIS

  AND

  b) That these circumstances imply that the patient is likely to gain significantly more benefit from the medicine than would normally be expected.

- Any patient for whom both these criteria can be evidenced will have the medicine in question funded by the NHS Board. In Scotland, the funding for some orphan and ultra-orphan medicines is through a Risk Sharing Scheme, managed for all Boards by National Services Scotland (NSS). However, the RSS may provide only partial compensation in the short term for the NHS Board. It is not cost avoidance.
- It should be noted that there is no separate Cancer Fund in Scotland.

3. NHS GG&C

- All policies relating to medicines in NHS GG&C are available at : www.ggcprescribing.org.uk and http://www.staffnet.ggc.scot.nhs.uk/Info%20Centre/GGC%20Formulary/Pages/MedicinesPolicies.aspx
- GG&C Area Drug and Therapeutics Committee (ADTC) reviews all products which have been assessed by SMC for suitability for the NHS GG&C Medicines Formulary. Products not recommended by SMC are not added to the local Formulary.
- Prescribers wishing to use a non-formulary medicine are required to refer to the non-formulary prescribing policy and are guided in this to the use of appropriate forms and authorisations. Depending on the circumstances, completion of an Individual Patient Treatment Request (IPTR) may be required to approve the prescription.
- The level of detail relating to the patient's clinical circumstances must be sufficient to allow an IPTR panel to be able to appropriately assess the IPTR on the basis of the information provided. Failure to provide sufficient detail may result in the IPTR being rejected. Submitting consultants may wish to liaise with the relevant AMD during the submission process to reach agreement on the level of information required
- In the Acute Division, the authorisation for use of a non-formulary medicine at level 3 (i.e. medicines costing >£3,000 per patient treatment or per annum) is provided by an IPTR panel chaired by the Directorate's Associate Medical Director. A process is in place whereby an appeal may be raised against a decision made at

Directorate level. The appeal is heard by a separate panel which includes a lay person and is chaired by the Board's Medical Director.

- NHS GG&C uses the criteria for the consideration of the prescription of a medicine not recommended by the SMC as laid down in CMO(2011)3 (above)
- IPTRs, which are approved, are funded from the individual Directorate's medicines budget. There is no additional allocation from either the NHS Board or from Scottish Government to cover these needs.
- It is the responsibility of the patient's consultant to discuss the system for consideration of a medicine through the IPTR process. A patient information leaflet is available to help with this. Copies can be found on the ADTC Website (www.ggcprescribing.org.uk).
- Special consideration is required on the management of IPTRs for patients referred to NHS GG&C from other NHS Boards. For patients resident in the West of Scotland Health Boards (Ayrshire & Arran, Forth Valley, Dumfries & Galloway, Lanarkshire), there is agreement, via the WoS Regional Planning Group that NHS GG&C processes will be duly followed. However, patients referred to NHS GG&C from NHS Highland require the submission of the IPTR directly to NHS Highland. Details for the IPTR process in NHS Highland, including the documentation to be used can be accessed via the NHS Highland website (www.nhshighland.scot.nhs.uk).

Appeal Rejection

If an appeal is rejected, the patient's Consultant should discuss the following options with the patient:

- Acceptance of the decision and consideration of other therapeutic options
- Potential private procurement of the requested medicine via a co-payment agreement (see 5.5 Policy for Patients to Receive Aspects of Their Treatment Through Private Healthcare Providers (Co-payments))
- Await any material change to the condition which would alter the patient's position in relation to the exceptionality of their case (Should new clinical evidence emerge for an individual case or there is a material change in the patient's condition that may impact on the outcome of the IPTR, application of a new IPTR at directorate level may be considered where the clinician is in support).
- Await any changes to national guidance on clinical and cost effectiveness of the medicine (If the medicine/indication/formulation subsequently becomes accepted for use within NHS Scotland through SMC or HIS, the individual case and appropriateness of the treatment will be re-evaluated by the patient's clinician).