SECTION 4.1: PROCESS FOR MANAGED ENTRY OF NEW MEDICINES

1. BACKGROUND

NHS Greater Glasgow and Clyde supports the introduction of new medicines that allow its population to benefit from advances in medical treatment. At the same time there is a need to achieve the maximum benefit for patients from the significant spend on existing medicines.

In addition to these advances in treatment, changing demographics and increasing public expectations place growing demands on the NHS. Despite ongoing review of services and prescribing to maximise efficiency, gaps may emerge between patient / clinician demand and the ability of the NHS to provide within available funding allocations.

There is a strong desire and necessity to reduce inequality of provision of drug treatments across the NHS in Scotland and eliminate 'post code prescribing'. The process by which new medicines are managed must be transparent, consistent and explicit to ensure clinicians, managers and the public have confidence in the process and the decisions made.

Clinicians are advised not to prescribe a new medicine until the national and local processes for clinical and cost effectiveness review have been completed. Any exceptions to this should be addressed through the Individual Patient Treatment Request (IPTR) process.

Established as a subcommittee of the Area Drug and Therapeutics Committee (ADTC), the Formulary & New Drugs Subcommittee (F&ND) considers medicines that have been the subject of national assessment. This is primarily advice from the Scottish Medicines Consortium (SMC) but also includes the National Institute for Health and Clinical Effectiveness (NICE) Technology Appraisals.

Further details on the subcommittee are contained in the appropriate Terms of Reference Document. Members and local expert advisors are required to declare any interest in relation to the medicines, competitor medicines, and the associated pharmaceutical companies, under consideration.

2. THE PROCESS

Designated Health Board representatives receive SMC advice approximately four weeks in advance of the date for release into the public domain. SMC considers all new drug entities, new formulations and new major indications of existing medicines.

NICE technology appraisals are identified from the monthly e-newsletter and are downloaded from the website. NHS Quality Improvement Scotland issues a statement shortly after publication of NICE guidance advising on the applicability of the advice in NHS Scotland. NICE technology appraisals are screened as follows:

- Multiple Technology Appraisals (MTAs) that refer to drug therapy or therapies typically focus on >1 medicine and report several months / years after marketing authorisation. Subject to NHS HIS endorsement this advice will supersede any previous SMC advice.
- Single Technology Appraisals (STAs) are noted and compared to relevant SMC advice, but these have no standing in NHS Scotland as described in HDL (2007) 26.
- "Non-drug" appraisals are forwarded to Clinical Effectiveness Leads.

A database is maintained and medicines are added from the SMC work programme and other sources advising of drug launch. Medicines not yet considered are noted as "pending" decision, and as such prescribers are advised that these should not be prescribed or recommended for prescribing.

A brief summary is prepared for each piece of guidance noting the key points and relevant background information, e.g. local prescribing data. For medicines accepted for use by SMC / HIS, local experts are asked to

review the advice document and consider the local implications for NHS Greater Glasgow and Clyde as a whole. This may require discussion with other clinicians, managed clinical networks or specialist interest groups. In the case of SMC advice, the document is shared in strict confidence, and clinicians advised of the date of embargo. Patient number estimates and potential budget impact are reviewed from a local perspective. Potential risk management issues are also highlighted. Advisors are generally lead clinicians based in acute care but where relevant may be General Practitioners or specialist pharmacists.

At each monthly F&ND meeting, a draft Formulary status is conferred including any restrictions. This will include at least those indicated by SMC/HIS but there may be occasions where additional local restrictions are proposed. Restrictions may be in terms of the prescriber (e.g. specialist initiation only) or for selected patient groups. Decisions on some medicines may be deferred to allow consultation with the relevant specialist group or until development of a treatment protocol. All oncology medicines are reviewed through the regional cancer prescribing advisory subgroup which co-ordinates the development of a protocol for all medicines that are to be added to the Formulary. The outcome will be one of the following:

SMC/HIS advice	Local Formulary decision
Accepted for use or Accepted for restricted use (i.e. use restricted beyond the licensed indication)	• Recommended for use - included in the preferred list (may include restrictions) • Included in the total Formulary (may include restrictions) • Not included in the Formulary: e.g. suitable Formulary alternatives may exist. Clinicians could appeal this decision through the Formulary appeal process (but not until one year has elapsed from the original ADTC decision).
Not recommended for use	• Not recommended for use – noting that exceptional use on an individual case basis may be pursued via the IPTR process. Formulary appeal could not be considered.

The ADTC meets bimonthly and a summary report of recommendations from the F&ND subcommittee is reviewed. The report is prioritised using the following five categories:

A. Medicines accepted by SMC – major changes to the Formulary
B. Medicines accepted by SMC – minor or no changes to the Formulary
C. Medicines not recommended by SMC
D. Medicines accepted by SMC but deferred for consultation
E. Outcomes from submitted Formulary appeals (separate to this process)

Formulary status is confirmed by ADTC. It is anticipated that new medicines with high cost implications will have been highlighted through the horizon scanning exercise. However, where the guidance has significant service implications or substantial cost implications in excess of the original prediction or not included in horizon scanning, it is referred to the Prescribing Management group (PMG) for further consideration.

The new medicines process aims to confer a Formulary status within three months of the publication of advice from SMC/NICE (excluding cancer medicines).

3. COMMUNICATION

It is important to have a system that can efficiently and effectively communicate decisions. In particular early communication to clinicians of medicines not recommended for use can prevent a pattern of use that may later result in difficulties in discontinuation.

After confirmation by ADTC, information on new medicines is made available via the bimonthly Postscript Bulletin and on the Formulary website (**www.ggcformulary.scot.nhs.uk**). The planned dedicated web based database (in development) will facilitate easy access to the local Formulary decision on any new medicine. The database will be searchable by drug name (approved or brand), by BNF therapeutic category or by date. Hyperlinks will link with SMC/NICE information, SPC, protocol (if available) and the NHS Greater Glasgow and Clyde drug Formulary.

4. APPEALS

There is no local appeal process for medicines not recommended by SMC. This would require the relevant pharmaceutical company to make a resubmission to SMC.

Local consultants, senior clinical pharmacists or senior nurses may complete a Formulary appeal for medicines which predate SMC or which are accepted by SMC but not added to the Glasgow and Clyde Formulary at the time of launch (see section 2: Formulary Appeals).

Requests to prescribe any non-Formulary drug, which will include all medicines "not recommended" by SMC is addressed through the Individual Patient Treatment Request (IPTR) process. The same process applies for medicines not yet considered by SMC.

5. MONITORING

Routine monitoring of SMC "not recommended" medicines is presented to practices in primary care. A target list of medicines which require an IPTR, which is based on medicines "not recommended" by SMC, is monitored within the acute sector. Further detail can be found in the Individual Patient Treatment Request Policy.

6. PROCESS FOR IMPLEMENTATION OF SMC/NICE ADVICE