1. Introduction

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. The Scottish Medicines Consortium (SMC) provide advice to Health Boards on the clinical and cost-effectiveness of all new medicines, with an aim of ensuring timely access to medicines that provide most benefit based on best available evidence. This is advice is considered for local implementation by the NHS Greater Glasgow and Clyde Area Drug and Therapeutics Committee (ADTC).

Clinicians are advised not to prescribe a new medicine until the national and local processes have been completed. Applications for access can be considered on a case-by-case basis in situations of clinical urgency (see PACS2 and IPTR policies).

2. Scope

This policy only covers the implementation of advice from the SMC. For details pertaining to the processes for consideration of medicines that are considered outwith the remit of the SMC, see the Formulary Management Policy.

3. Overview of 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.

A database is maintained and medicines are added as the advice from SMC is received.

For medicines accepted for use by SMC, local experts are asked to review the advice document and consider the local implications for NHS Greater Glasgow and Clyde as a whole. This includes how the new treatment fits with current treatment options, plans for implementation, predicted uptake and any potential risk management issues. This may require discussion with other clinicians, managed clinical networks or specialist interest groups. The SMC advice document is shared in strict confidence at this stage and clinicians advised of the date of embargo. The potential budget impact is reviewed and compared, where relevant, to the estimates from the annual horizon-scanning and planning exercise. Advisors are generally lead clinicians and specialist pharmacists based in acute care but when relevant may be General Practitioners and Prescribing Advisors.

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 and defines their place in therapy within a series of tumour specific Clinical Management Guidelines.

As a result of the local review the clinical teams may determine a more defined place in therapy than the SMC advice would support. This may be in terms of the prescriber (e.g. specialist initiation only) or for selected patient groups or in relation to where the medicine fits into the treatment pathway.

Where there is the view that the new medicine does not fulfil a need locally or where there are suitable alternatives on Formulary, the new medicine may not be added to Formulary. It would still be available for use, but this would be expected to be non-routine.

Decisions on some medicines may be deferred to allow further consultation with the relevant specialist group or until development of a treatment protocol.

It is anticipated that new medicines with high cost implications will have been highlighted through the annual horizon scanning and planning 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 highlighted to the relevant finance lead for advice on in-year financial management with escalation to the Prescribing Management Group as required.

Medicines not recommended by SMC cannot be added to Formulary. The manufacturer of a medicine which has been not recommended by SMC can present a resubmission to SMC at any time.

The ADTC meets bimonthly and considers the SMC advice issued to Boards in the two previous months; plus any advice deferred from a previous meeting. The outcome will be one of the following:

SMC Advice	Local Formulary Decision
Accepted for use or Accepted for restricted use (i.e. use restricted beyond the licensed indication)	- Routinely available in line with national guidance - Routinely available in line with local/regional guidance - Not routinely available as local clinical experts do not wish to add the medicine to the Formulary at this time or there is a local preference for alternative medicines (link to local guidance) - Not routinely available as local implementation plans are being developed or the ADTC is waiting for further advice from local clinical experts – Decision expected by [enter date]
Not recommended for use	- Not routinely available as not recommended for use in NHSScotland

The new medicines process aims to confer a Formulary status within 60 days of the publication of advice from SMC.

4. Communication

It is important to have a system that can efficiently and effectively communicate decisions. Within 14 days of each ADTC meeting, the local decisions relating to the SMC advice on new medicines is made publically available via the GGC Medicines website (https://ggcmedicines.org.uk/blog/formulary-update/) in a nationally-agreed format.

Formulary entries are subsequently updated to ensure that there is clarity for prescribers. The formulary is searchable by drug name (approved or brand) and by navigations via BNF therapeutic category. Relevant hyperlinks can be included in Formulary e.g. BNF entry, SMC advice or local protocols to increase the usefulness of this tool.

5. Appeals

Appropriate NHSGGC staff and groups can submit 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 or where the place in therapy has changed and the additional initial restrictions are no longer appropriate (see Formulary Management Policy).

Requests to prescribe any medicine 'not recommended' by SMC or in advance of SMC advice on a case-by case basis are addressed through separate processes.

6. Monitoring

Routine recording of IPTR and PACS2 activity is undertaken and activity relating to the latter is reported to Scottish Government on request.

7. Overview of process