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## 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 considered within remit, with the aim of ensuring timely access to medicines that provide most benefit based on the best available evidence. This advice is then considered for local implementation by the NHS Greater Glasgow and Clyde Area Drug and Therapeutics Committee (NHSGGC 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](#)).

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## 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](#).

This policy is applicable solely to procedures within NHSGGC. For therapeutic areas or medications included in the Regional West of Scotland Formulary, the regional processes should be adhered to.

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## 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 that are considered within remit.

A database is maintained by the Medicines Policy & Guidance Team (MPG) 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 NHSGGC 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.

A West of Scotland Medicines Formulary is in development. For medicines included in the WoS Formulary a similar process of consultation with clinical experts in all WoS Boards is adopted prior to the decision on inclusion in the WoS Formulary.

All oncology medicines are reviewed through the regional cancer prescribing advisory subgroup which coordinates 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/ guideline. The ADTC decision will be published in the Formulary Update bulletin of the relevant meeting as '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]'.

It is anticipated that new medicines with high-cost implications will have been highlighted through the annual horizon scanning and planning exercise. Where the medicine has significant service implications or substantial cost implications in excess of the original prediction or was not included in the horizon scanning process, it will be referred to the Acute Strategic Management Group (SMG) for consideration of service impact (see Appendix 1). New medicines delayed due to service issues will be tracked via ADTC and PMG sector groups and reported into the Acute Strategic Management Group ensuring appropriate clinical, management and finance colleague input.

Medicines not recommended by SMC cannot be added to the 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 bi-monthly and considers the SMC advice issued to Boards in the two previous months; including any advice deferred from a previous meeting. The outcome will be one of the following:

<b>SMC Advice</b>	<b>Local Formulary Decision</b>
Accepted for use or	<ul style="list-style-type: none"><li>- Routinely available in line with national guidance</li><li>- Routinely available in line with local/regional guidance</li></ul>

Accepted for restricted use (i.e. use restricted beyond the licensed indication)	<ul style="list-style-type: none"> <li>- 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)</li> <li>- 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]</li> </ul>
Not recommended for use	<ul style="list-style-type: none"> <li>- Not routinely available as not recommended for use in NHSScotland</li> </ul>

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

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#### 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 publicly 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 guidelines/ protocols to increase the usefulness of this tool.

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#### 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 GGC 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](#)).

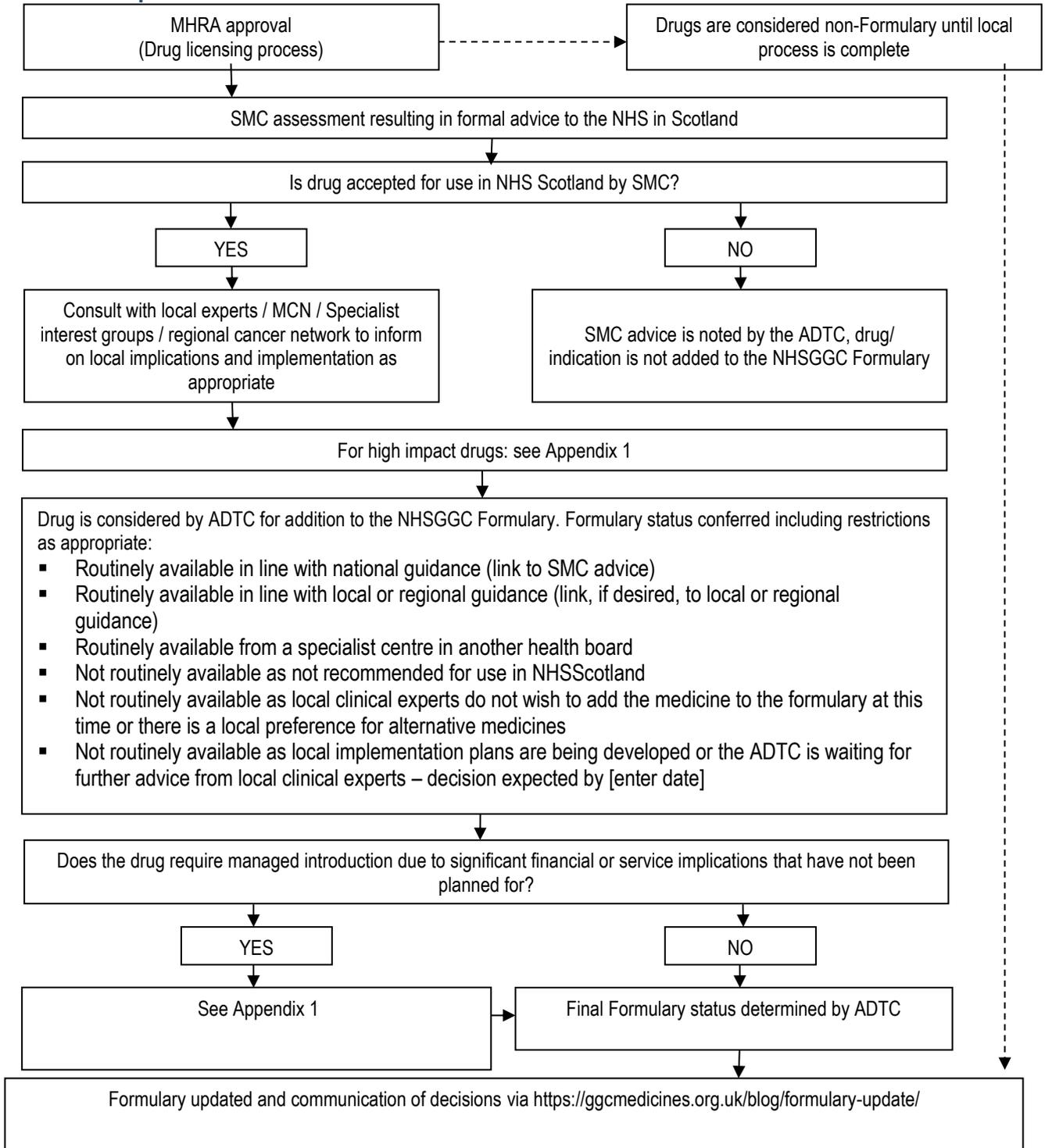
Requests to prescribe any medicine 'not recommended' by SMC or in advance of SMC advice on a case-by case basis are addressed through separate processes.

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#### 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



### Appendix 1 - Introduction process for medicines with additional service impact

