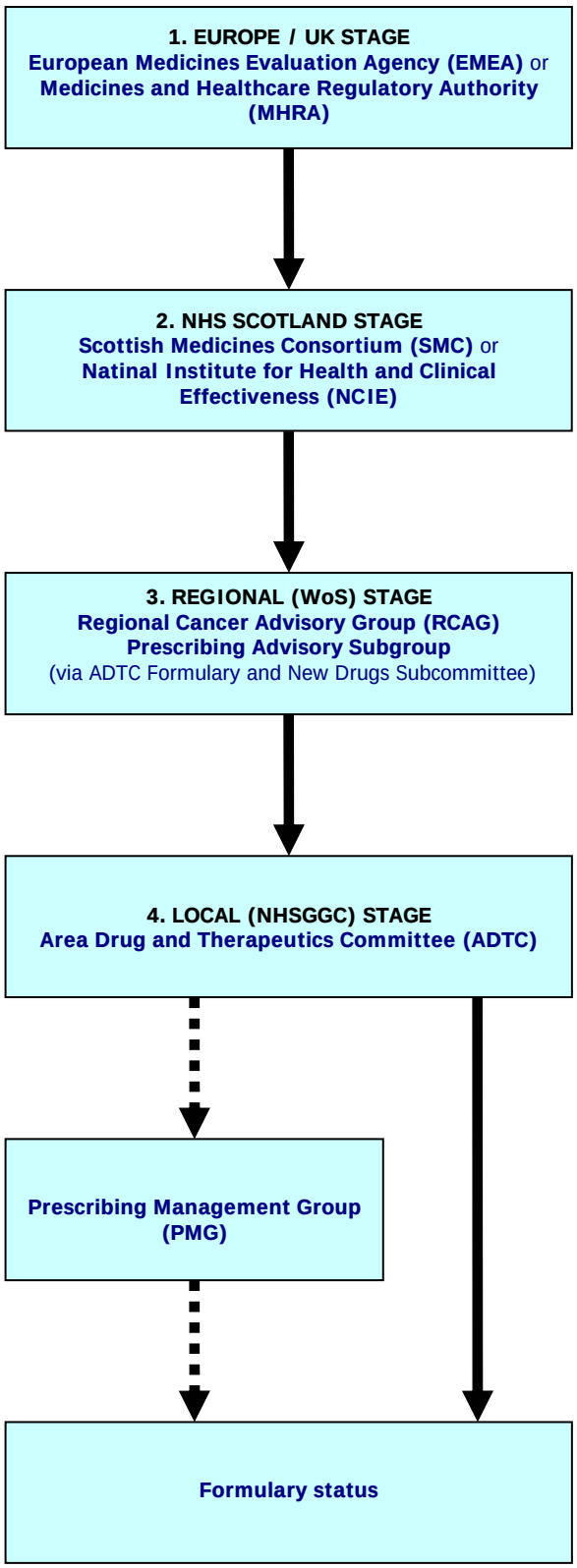
SECTION 4.2: ADDITION OF A NEW ONCOLOGY MEDICINE TO THE GGC FORMULARY

The process that a new oncology medicine has to follow prior to being added to the GGC Formulary is outlined below:



Licensing process:

- Medicine required to demonstrate:
  - Quality
  - Efficacy
  - Safety
- *Total time from the original patent approval of the new compound to completion of the requirements of the licensing authority may be 10 – 12 years.*

Clinical and cost-effectiveness review:

- SMC advice to all NHS Boards, as close as possible to launch
- NICE advice typically follows after several months/years
  - Only Multiple Technology Appraisals are applicable to NHS Scotland
- Medicine requires to demonstrate:
  - clinical effectiveness
  - Cost-effectiveness (value for money)
- *Time for completion: 3 – 4 months*

Regional practice implications:

- Consultation with local experts/MCN
- Medicine requires to demonstrate:
  - SMC acceptance
  - Advantage(s) over existing therapy
  - Support from local specialists
  - Role for medicine in context with existing clinical practice
  - Treatment protocol/guidelines with care management plan
  - Budget impact analysis
- *Time for completion: 2 – 3 months*

Formulary management:

- Implementation plan and communication to prescribers
- Medicine requires to demonstrate insignificant financial or service implications, otherwise referral to PMG is necessary
- *Time for completion: 1 – 2 months*

Planning and resource management:

- Horizon scanning
- Financial monitoring
- Focus on selected new developments which require managed introduction due to cost, service redesign or other resource implications.
- *Time for completion: 2 – 4 weeks*

Formulary status:

- Preferred List (all prescribers)
- Total Formulary (Specialist use)
- Non-Formulary (exceptional use)
- *Time for completion: immediate*

STAGES FOR ADDITION OF A NEW CANCER MEDICINE TO THE DRUG FORMULARY in NHS GREATER GLASGOW & CLYDE (*)

STEP 1
Medicines regulation aims to protect the patient interest. For a medicine to get a licence, it must show that it works, is safe, and is of good quality. The company which is granted the licence can then promote and sell their medicine in the UK and set a price for that medicine.

STEP 2
The company which makes the medicine presents its case to SMC. This step looks at the health gain from the medicine for the money it costs. This often means looking at the new medicine side by side with medicines already in use. It should indicate if the new medicine offers good value for money. The SMC may say it should only be prescribed by certain types of doctors or in particular groups of patients. SMC may also say a medicine should not be used in Scotland and we would generally follow this advice.

NICE/QIS may review the same medicine. This might be the medicine on its own or a group of medicines for the same disease. An example of this is medicines for the treatment of renal cancer. This advice may say which medicine should be used first, or second etc. Rarely, certain types of advice from NICE/QIS will overrule earlier SMC advice. This is thought to make good sense as more may be known about the medicine by the time of the NICE review.

STEP 3
Advice from SMC/QIS on cancer medicines goes to the Regional Prescribing Advisory Group. Local specialists for the relevant tumour type look over the advice and decide how and if they wish to use the medicine in patients in the West of Scotland. They write a set of guidelines for use which explains when, how, where and in whom a medicine should be used. If this means a change which will increase costs or time needed (e.g. nurse, pharmacy or patient time in a hospital bed) or need special equipment or tests, then this is examined in more detail. This group makes sure that the local guidelines fit with the national advice.

STEP 4
ADTC through the FND takes the advice from the regional group and the Formulary is updated as necessary. If there are high costs or need for a new service to be set up then this will be sent on to the PMG to decide how this should be handled.

STEP 5 (only required for high cost/ new service)
PMG will review cases where high costs are likely to result and decide if this was expected (part of the medicines plan) or if extra funding needs to be found. If changes in the service are needed then PMG will look at the how these changes might be managed. There may be a short delay to sort this, before the medicine is added to the Formulary, but this will be kept to a minimum.

STEP 6
Once a medicine is added to the Formulary, specialists can then use the medicine according to local arrangements. Medicines not on the Formulary can still be prescribed, but it is expected these will be reserved for exceptional circumstances where there are no alternatives for an individual patient.

IN SUMMARY
- Medicines regulation seeks to achieve the right balance between protecting the patient from harm and allowing access to new medicines.
- A safe and effective medicine gets a licence via a European or UK agency.
- National (NHS Scotland) review indicates if it is “good value for money”.
- The regional advisory group decides if this is a medicine it wants to use.
- The local Health Board decides if everything is in place for this to go ahead within local practice.
    - If yes, the medicine is added to the Formulary; clinicians decide if they want to prescribe the medicine for individual patients.

- If no, the medicine is excluded from Formulary; clinicians need to adopt additional procedures and seek management approval to prescribe for individual patients.

* *See following page for definitions and abbreviations*

DEFINITIONS

European Medicines Agency (EMEA) and the **Medicines and Healthcare products Regulatory Agency (MHRA)** are the European Union body (EMEA) and the UK Government agency (MHRA) who are responsible for medicines control. Medicines (and medical devices) must show they are good quality; they do what is meant and are suitably safe. The two organisations work in partnership. The EMEA has responsibility for certain types of medicines (e.g. for cancer, diabetes, biological treatments) across all the member countries. The MHRA retains responsibility for the majority of medicines within the UK.

Scottish Medicines Consortium (SMC) is made up of representatives from across all the Scottish Health Boards and from a range of professions: doctors, pharmacists, nurses, health economists, managers and lay people on behalf of patient interest groups. It provides advice to the NHS in Scotland about new medicines and about their "value for money". They may also identify the patients who could benefit most from the new treatment. This advice comes early after the medicine is marketed in the UK. It helps to make sure that medicines are equally available to patients across Scotland.

National Institute for Health and Clinical Effectiveness (NICE) provides guidance on the prevention and treatment of ill health for England and Wales.

Quality Improvement Scotland (QIS) is the Scottish body which comments on NICE advice on new medicines (called Multiple Technology Assessments) and says how these fit into practice in NHS Scotland. (NICE also produces other types of advice but these are not all adopted in Scotland).

Regional (West of Scotland) Cancer Advisory Group (RCAG), Prescribing Advisory Subgroup looks at the advice above (from SMC and NICE/QIS) for medicines used in the care of patients with cancer.

Area Drug and Therapeutics Committee (ADTC) advises the Health Board on everything to do with medicines. The overall aim is to promote effective use of medicines in NHS Greater Glasgow & Clyde (NHS GGC) as part of the total care.

The Formulary and New Drugs Subcommittee (FND) of ADTC is the group which has responsibility for dealing with new medicines and this group takes suggestions to ADTC for approval.

Managed Clinical Network (MCN) is a specialist planning group which involves different health professionals, managers and members of the public. There are MCNs for all the major tumour types.

Prescribing Management Group (PMG): manages the financial aspects of prescribing, planning for new medicines and watching over how they are used. It aims to get the maximum benefit from the high spend on medicines (over £300m in 2008/09) for the whole population which it serves.

Medicines Formulary is a limited list of medicines agreed for use in NHS GGC, chosen because they are shown to work effectively, specialists find them useful and patients find them acceptable. Formulary medicines therefore represent good value for money compared with other medicines that do the same job. All prescribers are expected to stick to this list for most patients. There can sometimes be special reasons why a medicine from outside this list is the best choice for a patient. Special procedures allow for such exceptions.

This local "Formulary" should not be confused with the British National Formulary which is a list of all medicines licensed for use in the UK.