



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

A Guide to the Scottish Medicines Consortium

Providing advice about
newly licensed medicines
www.scottishmedicines.org

About the Scottish Medicines Consortium

The Scottish Medicines Consortium (SMC) provides advice to NHSScotland about the value for patients of every newly licensed medicine. It is part of Healthcare Improvement Scotland, the national healthcare improvement organisation for Scotland. SMC reviews new medicines that have received a licence from the Medicines and Healthcare products Regulatory Agency (MHRA – the licensing body for the UK) or the European Medicines Agency (EMA – the licensing body for the European Union). We also review new formulations of, and new ways to use, established medicines. Before a medicine can be prescribed routinely in Scotland, it has to be accepted for use by SMC. Our advice helps the health service plan for the quick, uniform introduction of beneficial treatments across NHSScotland.

SMC is a committee of clinicians, NHS board representatives, the pharmaceutical industry and the public, all of whom have a vote. Most of the clinicians have a direct role in patient care, while our three volunteer public partners ensure the views of patients and carers are taken into account during decision-making. This wide mixture of backgrounds helps ensure decisions are made from a broad perspective. The committee meets once a month and all members give up some of their own time to take part. SMC meetings are open to the public; you can register to attend on our website:

www.scottishmedicines.org.uk/About_SMC/Meetings_Minutes/meetingRegistration

The committee is supported by a core team, including pharmacists, economists, public involvement professionals and administration support.

We also carry out horizon scanning to ensure NHS boards are aware of new medicines expected to come to market over the next financial year. This helps NHS boards plan their budgets more effectively. You can find out more about horizon scanning on our website: **www.scottishmedicines.org.uk/About_SMC/What_we_do/Horizon_Scanning/Horizon_Scanning**.

Before SMC was established, 14 individual local Area Drug and Therapeutics Committees (ADTCs) advised their respective NHS boards which products should be accepted for use in their area. The introduction of SMC in 2002 provided a single point of advice, reducing duplication of work and differences in availability of medicines across NHSScotland.

How does SMC decide which medicines to accept?

When considering a new medicine we look at:

- how well the medicine works
- which patients would benefit from it
- whether it is as good or better than medicines the NHS already uses to treat the particular condition, and
- whether it is good value for money.

What do we mean by value for money?

NHSScotland has limited resources. SMC carefully considers every medicine submitted to make sure it benefits patients and is considered to be an acceptable use of NHS resources. When we assess a medicine we take account of all patients who need treatment, not just those who may be treated with the medicine under consideration.

You can find out more about how value for money is assessed on our website:

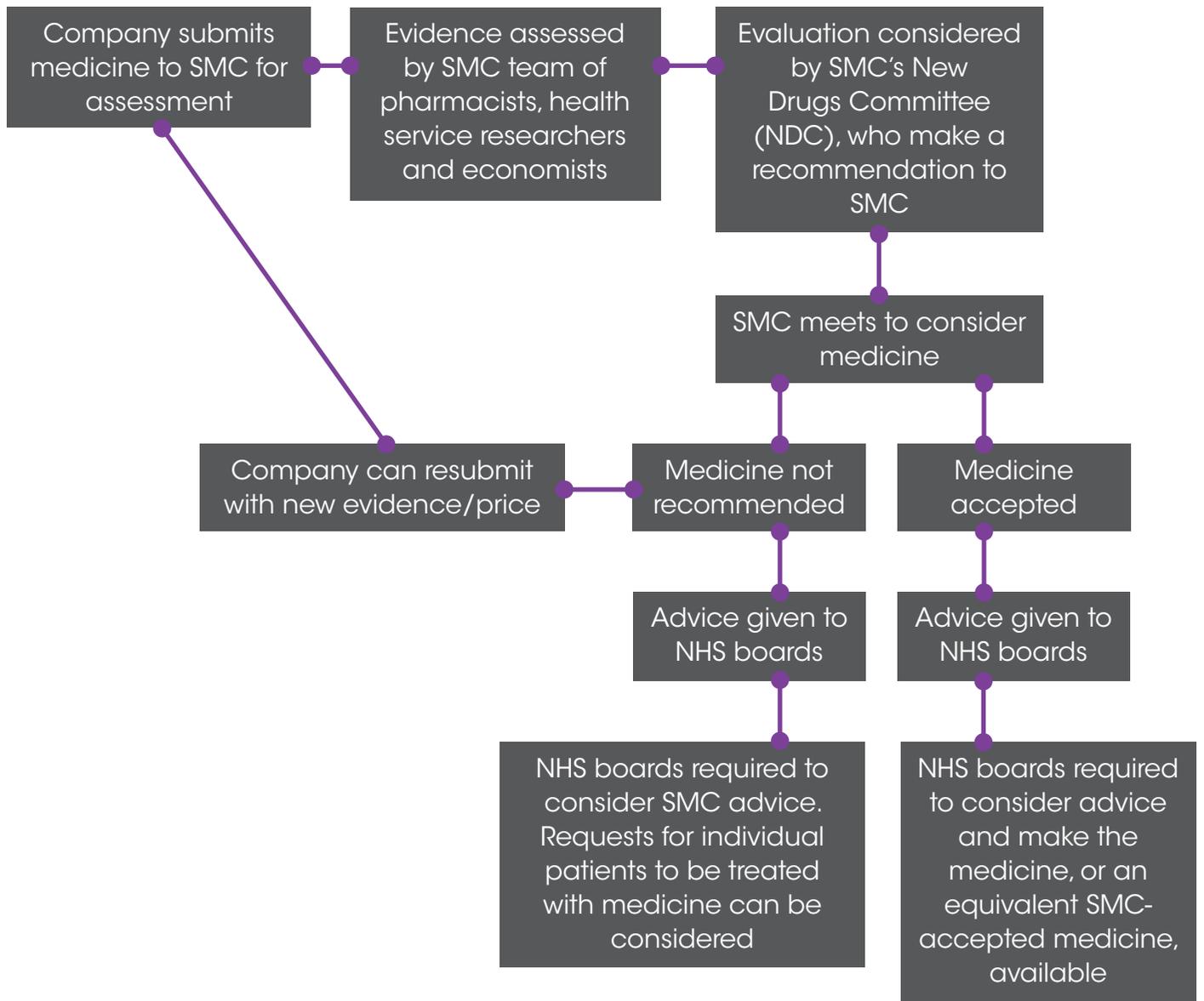
www.scottishmedicines.org.uk/About_SMC/Policy_statements/A_Guide_to_Quality_Adjusted_Life_Years



“The committee’s wide mixture of backgrounds helps ensure decisions are made from a broad perspective”



Process for medicines submitted to SMC (approximately 18 weeks)



Process for medicines used at the end of life or for very rare conditions

If the initial advice from our New Drugs Committee is to not recommend a medicine that would be used for an end of life or very rare condition, the pharmaceutical company may ask for the medicine to be considered at a Patient and Clinician Engagement (PACE) meeting. This additional step, introduced in April 2014, allows SMC to hear more evidence from patient groups and clinicians on the added value of a medicine which may not always be captured through the pharmaceutical company's submission. The output from this meeting is a major factor in SMC decision-making. You can find out more about PACE on our website: www.scottishmedicines.org.uk/Submission_Process/Submission_guidance_and_forms/PACE

SMC decisions

SMC can make one of three decisions on a medicine:

- **accepted**
- **accepted with some restriction(s) on which groups of patients should be treated, or**
- **not recommended.**

SMC now also has the opportunity to accept some medicines on an interim basis subject to ongoing evaluation and reassessment.

Some of the most common reasons for not recommending a medicine are:

- **the medicine that the company has chosen to compare the new product with is not the most relevant one for NHSScotland**
- **no better than a cheaper medicine**
- **not sufficiently strong economic case**
- **non-submission (see Medicines awaiting SMC appraisal).**

You can find out more about reasons we may not recommend medicines on our website: www.scottishmedicines.org.uk/Public_Involvement/New-Medicines-Approval

Once the decision is made, it is communicated to NHS boards and the pharmaceutical company to ensure the medicine can be considered by Area Drug and Therapeutics Committees and made available to patients as soon as possible.



“When we assess a medicine we take account of all patients who need treatment, not just those who may be treated with the medicine under consideration”



Patient Access Schemes

As part of their submission, pharmaceutical companies may propose a Patient Access Scheme (PAS) to improve the cost effectiveness of a medicine which may otherwise not be cost effective for NHSScotland. Patient Access Schemes are reviewed by the Patient Access Scheme Assessment Group (PASAG), which operates separately from SMC. When SMC accepts a medicine on the basis of a Patient Access Scheme that has been accepted by the Patient Access Scheme Assessment Group, an implementation pack which describes the operation of the scheme will be circulated to Area Drug and Therapeutics Committees and NHS boards together with the SMC advice.

You can find out more about the scheme on our website: www.scottishmedicines.org.uk/Submission_Process/Submission_guidance_and_forms/Patient-Access-Schemes

Availability of medicines in the NHS following SMC decisions

When SMC accepts a new medicine, NHS boards are expected to make it, or an equivalent SMC-accepted medicine, available. NHS boards are expected to publish updated lists of SMC-accepted medicines included and excluded from their formularies together with the reasons for such decisions.

Where a medicine is not recommended by SMC, all NHS boards have procedures in place to consider individual requests when a doctor feels the medicine would be right for a particular patient.

SMC advises the submitting company why the medicine has not been recommended and welcomes resubmissions.

Medicines awaiting SMC appraisal

We actively encourage submissions from pharmaceutical companies to ensure medicines can be made available as soon as possible. If a medicine is not submitted to SMC, “not recommended” advice is issued and NHS boards will treat requests for them in the same way as other not recommended medicines.

You can find out more about SMC’s work on our website,
www.scottishmedicines.org

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