

ALL YOU WANT TO KNOW ABOUT HOW SIGN AND THE SMC WORK

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Helping clinicians to use medicines effectively is an important focus of the NHS in Scotland. This article looks at the role of two Scottish organisations, SIGN and the SMC, which assess medicines and make recommendations about their use

Medicines are central to the NHS, because of their importance in treating and preventing illness and because of the large amount of resources spent on them. For example, in 2001, £6.8b was spent on prescription medicines in the UK in primary care.¹ In Scotland, this translated to £750m in primary care, equating to 60 million prescriptions.²

Effective assessment can help ensure that medicines are used wisely. In Scotland we are continuing to evolve evaluation systems where the prime focus is on providing patients and their clinicians with up-to-date information to enable the right medicine to be chosen, in the right dose, at the right time and for the right reasons.² This article focuses on two of these national organisations, the Scottish Medicines Consortium (SMC), and the Scottish Intercollegiate Guidelines Network (SIGN).

SMC

What does it do? The SMC (part of the NHS in Scotland, "NHSScotland") was established in October 2001 to provide advice to the 15 NHS Boards across Scotland and the area drug and therapeutics committees (ADTCs) on the status of:

- All newly licensed medicines
- All new formulations of existing drugs
- Major new indications for established products

Each year approximately 40–60 new medicines are licensed for use in the UK, with additional new formulations and new indications bringing the total to about 100. Having a national system for assessing new products, formulations and indications

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allows standardised advice to be given across Scotland. It also promotes collaboration between ADTCs, avoiding unnecessary duplication of effort.

The SMC aims to issue advice as soon as possible after the launch of a product. The co-operation of the pharmaceutical industry is crucial in achieving this. Among the reasons why such co-operation has been forthcoming is that the system is beneficial to pharmaceutical companies in that they can make one submission to a single organisation, thereby simplifying the process to get their new products, formulations and indications reviewed in Scotland. Co-operation also stems from the fact that most of the research and development work involved in bringing a medicine to the market is undertaken jointly between the pharmaceutical industry and clinicians working in the NHS. The Scottish Executive Health Department (SEHD) has recently issued new guidance on joint working between NHSScotland and the pharmaceutical industry.³

The membership of the SMC is wider than that of many ADTCs and includes clinicians (eg, doctors, pharmacists and nurses), economists, lay members and representatives from NHS management, the Association of British Pharmaceutical Industry and patient organisations.⁴ Since 2003, SMC (and SIGN) came under the umbrella of NHS Quality Improvement Scotland (which incorporates the work previously undertaken by the Health Technology Board for Scotland and the Clinical Standards Board for Scotland) in a reorganisation to support close working between Scottish bodies involved in quality improvement.

How does it operate? When a new medicine is produced, the SMC assesses it to find out:

- How effective it might be
- Which patients would benefit from it
- What it costs
- Whether it is more effective than the treatments being used at present

Panel 1: SMC guidance development process

1. Submission of new medicine form

2. Assessment review

3. Assessment report submitted to New Drugs Committee

4. Recommendation report to SMC and applicant company

5. Report and final advice sent to NHS boards, drug and therapeutics committees and applicant company

6. Publication of final advice on website

The New Drugs Committee is a working group of the SMC (whose members includes pharmacists)

- Whether it is worth investing NHS money to prescribe it

The SMC process is set out in Panel 1. There are three categories of final advice:

- Accepted for general use
- Accepted for restricted use
- Not recommended for use

Those medicines categorised for general use include drugs where alternative drug treatments already exist and where local formulary management systems will make local recommendations on use. The restricted category applies when the advice restricts the use of the medicine beyond the licence to a defined group of patients and/or a group of clinicians, often specialists working in hospitals. An example is the use of imatinib for

chronic myeloid leukaemia under the direction of haematologists and oncologists. Advice is issued to NHS boards and ADTCs one month in advance of being published on the SMC website. The complete process from submission to publication takes 12 weeks.

Current workload and future plans Over the period May–October 2003, 82 products were assessed by the SMC, with 22 being accepted for general use, 36 being accepted for restricted use and 24 not being recommended.

A strengthened role for the SMC has recently been defined.⁵ As part of this, during 2004, new drugs will be categorised as:

- Unique drugs for specific conditions which, if approved by SMC, will be introduced into NHSScotland to an agreed national programme
- Drugs for conditions where alternative drug treatment already exist which, if approved by SMC, implementation will be subject to local NHS board decision

In addition, the SMC is to develop a horizon scanning system to identify at an early stage high impact, high cost innovative drugs and develop a national implementation plan for NHS Scotland. The aim is to have these drugs provided to meet clinical need within three months of publication of SMC advice. All NHS Boards will need to follow the national implementation plan.

SIGN

What does it do? SIGN was formed in 1993 with the prime objective to improve the quality of health care for patients in Scotland by reducing variation in practice and outcome by developing and disseminating national clinical guidelines that contain recommendations for effective practice based on current evidence. The membership of the SIGN council includes physicians, pharmacists, nurses, dentists, allied health professionals, patients, health service managers, researchers and social services professionals.

How does it operate? SIGN takes a topic approach, therefore including products that are already licensed, rather than just new medicines, formulations and indications. Any individual or group can propose a topic for consideration by the SIGN council. The programme (which currently covers 20 topics) is chosen on the basis of burden of disease, existence of variation in practice and the potential to improve outcome. The criteria for selecting topics is shown in Panel 2.

SIGN guideline development uses explicit methods based on three key principles:

- A systematic review is done to identify and critically appraise the evidence
- Recommendations are explicitly linked to the supporting evidence

Panel 2: Criteria for selection of SIGN topics

- Areas of clinical uncertainty (ie, wide variation in practice or outcomes)
- Conditions where effective treatment is proven and where mortality or morbidity can be reduced
- Iatrogenic disease or interventions carrying significant risks or costs
- Clinical priority areas for the NHS in Scotland, and strategic aims*
- The perceived need for the guideline, as indicated by relevant stakeholders

**Clinical priority areas are currently coronary heart disease and stroke, cancer and mental health. The strategic aims of the NHS in Scotland are currently improving health and tackling inequalities, developing primary and community care and reshaping hospital services*

- Development is carried out by multidisciplinary, nationally representative groups

These principles have remained consistent since SIGN was first established, but the detailed methods based on them (described in the 50th guideline, known as “SIGN 50”)⁶ have evolved to take account of new developments and new types of evidence.

The process used to develop guidelines is set out in Panel 3. The timescale for development, once the topic has been selected, is 24–36 months. On completion, the guideline is published on the website and disseminated to NHSScotland for local implementation. SIGN works closely with other guideline developers across the world and shares information where possible.

Current workload and future plans So far, SIGN has produced 75 guidelines, with more recent topics ranging from the management of harmful drinking and alcohol dependence to the management of colorectal cancer. The way in which SIGN develops guidelines continues to evolve, with ongoing work focusing around how best to incorporate cost-effectiveness considerations and use consensus methods.

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CONCLUSION

The SMC (www.scottishmedicines.org.uk) and SIGN (www.sign.ac.uk) are two resources available within NHSScotland. SIGN provides comprehensive topic-based guidance, focusing on areas where there are known established variations in practice of clinical care and the SMC provides guidance at the point of marketing of new drugs, formulations and indications. Each organisation is professionally led, valued by the health care community and produces guidance that has been successfully adopted at a local level. Pharmacists are integral at all stages in the processes of these two key organisations.

For the SMC, the challenge throughout 2004 is to identify and develop feasible national plans for the “unique category” drugs. For SIGN, the challenge remains the continued development of new guidelines and the updating of published guidelines. Both organisations need to maintain the difficult balance between achieving local ownership and ensuring national consistency. That way, the information they produce will support clinicians and patients in getting the right medicines, in the right dose, at the right time and for the right reasons.

Panel 3: SIGN guideline development process

1. Selection of guideline topics
2. Composition of the guideline development group
3. Systematic literature review
4. Formation and grading of recommendations
5. Consultation and peer review
6. Publication and dissemination
7. Implementation
8. Review