



An evaluation of how SMC has engaged with its key stakeholders and shaped medicines use across NHSScotland

Summary Report



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Summary Report

Prepared by the SMC Evaluation Project Team

This work was undertaken by the National Medicines Utilisation Unit, Information Services Division, NHS National Services Scotland in collaboration with the Scottish Medicines Consortium.

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Introduction

The Scottish Medicines Consortium (SMC) was established in October 2001 to ensure that NHSScotland Area Drug and Therapeutics Committees (ADTCs) and NHS boards have consistent, robust advice on the clinical effectiveness and cost-effectiveness of new medicines, at an early stage in the life-cycle of the product.

The remit of the SMC is to provide advice to NHS boards and their ADTCs across Scotland about the status of all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002). Advice is made available as soon as practical after the launch of the medicine. NHS board ADTCs advise clinicians not to prescribe a new medicine prior to the publication of SMC advice. The SMC is a consortium of stakeholders from ADTCs with additional members from the Association of the British Pharmaceutical Industry (ABPI), NHSScotland management and public partners (groups representing patients' views).

This evaluation investigates how SMC has impacted on and engaged with its key stakeholders and examines how SMC advice has shaped medicines use across NHSScotland.

Methods of study

Stakeholders

Impact on ADTCs' role and function

This involved:

- a review of reports describing the experiences, approaches and processes of ADTCs before and after the establishment of the SMC at defined time points (2000, 2002, 2003–2004).
- a structured review in 2006–2007 of publicly available information on ADTCs and an ADTC workshop (≈60 participants) in 2007 that focused on sharing best practice.

Engagement with stakeholders

This involved:

- **public partners:** a postal questionnaire in 2006 to public partner organisations (n=154) followed by a telephone follow-up survey of non-responders¹. A total of 93 responses were received. In addition, qualitative interviews (n=15) with a representative sample of public partners were undertaken.
- **ADTCs and pharmaceutical industry:** two workshops were held separately in 2006–2007 for ADTCs (≈60 participants) and pharmaceutical industry (≈100 participants) to explore the successes, challenges and potential for improving engagement between SMC and ADTCs/pharmaceutical industry.

SMC advice

The SMC issues three categories of advice: 'accepted for use', 'accepted for restricted use' and 'not recommended'. Between January 2002 and December 2005, the SMC issued advice on 207 medicines. All medicines were examined to look for availability of national utilisation data and where selection may allow potentially meaningful interpretation in the absence of patient level data. This resulted in the identification of 20 medicines that were 'not recommended' by SMC and 54 medicines that were 'accepted for use' or 'accepted for restricted use' for which data were available.

Usage data for primary care medicines were obtained through the Prescribing Information System for Scotland (PRISMS). For hospital medicines, usage data were obtained from hospital pharmacies and manufacturers. A 'medicine profile' was developed for each of the 74 medicines. The profile included: the SMC advice; a description of the epidemiology of the indication for the medicine; NHSScotland medicines use over time, annotated with key milestones; a comparison of the actual versus estimated manufacturer's budget impact; and potential factors that may be influencing medicines use within NHSScotland. A qualitative review of the

¹ This study was commissioned from the Scottish Centre for Social Research (ScotCen).

medicine profiles was undertaken to identify potential factors to explain the patterns of medicines use.

Further analysis was undertaken in two areas. Firstly, a sample (n=28) of medicines was reviewed to assess the reliability of budget impact estimates combined with a focus group to gain an understanding of how NHS boards use this information. Secondly, a detailed case study was undertaken of etanercept for psoriatic arthritis in adults (designated by SMC as a unique medicine) involving a review of adherence of NHS boards to the SMC etanercept protocol and an assessment of the use of etanercept.

Key findings

Stakeholders

Impact on ADTCs' role and function

Before the inception of SMC (in 2000), some NHS boards had well-developed approaches to the evaluation of new medicines and all NHS boards had a Drug and Therapeutics Committee. In 2000, NHS boards had no standardised definition of a 'new medicine' and there was evidence of variation between ADTCs in membership, medicines reviewed, skills and processes. By the end of 2002 (first SMC advice April 2002), some NHS boards had adapted their activities to manage SMC advice and others were in the process of doing so.

In 2003–2004 all NHS boards had mechanisms in place to manage SMC advice and some ADTCs had developed categorisation systems for medicines assessed by SMC, to provide clarity for prescribers and to accommodate evolving formulary systems. The role of ADTCs in monitoring medicines use was recognised, and available data were exploited where resources permitted.

By 2006–2007 there was evidence of continued evolution by ADTCs with –

- consistency across ADTCs of medicines considered and a changing focus of ADTCs from evaluation to assessment of local implications and implementation
- integration of SMC advice within local formulary systems
- continued development of the scope and type of information available publicly
- increasing use of information technology to provide more timely communication with prescribers, and
- development of medicines use monitoring mechanisms.

Engagement with stakeholders

ADTCs: The SMC was recognised by ADTCs across NHSScotland as the single source of timely advice about new medicines for local formulary management and financial planning processes. Challenges for NHS boards remain around medicines introduced before the establishment of the SMC. Suggested improvements focused on succession planning for SMC membership and on sustained effective communication with the public and media to develop an understanding of the relative roles and responsibilities of the SMC and ADTCs in managing the introduction of new medicines.

Public partners: Awareness of SMC and its processes by public partners was limited, with 41% of public partners indicating that they were aware of SMC itself and 33% aware of its patient involvement processes and website. Encouragingly, those who had engaged with SMC had a generally positive view of their involvement.

Pharmaceutical industry: The SMC was viewed by industry as having a robust and transparent decision-making process. The pharmaceutical industry considered that it has been recognised as a key partner. Challenges remain around the perception of variation in how NHS boards implement SMC advice and in maintaining effective communication between industry representatives on the SMC (and its subcommittees) and the wider pharmaceutical industry. Suggested improvements included earlier access to the economic checklist, continued development of systems for implementation of SMC advice across NHSScotland, and continued dialogue with other health technology assessment organisations.

SMC advice

The 74 medicine profiles prepared were used to quantify medicine use before and after SMC advice, to identify and explain some of the patterns in medicines use and to examine budget impact information. In addition, a detailed case study was undertaken of etanercept for psoriatic arthritis.

Use before and after SMC advice

SMC advice was issued within 6 months of launch for 81% of medicines that were subsequently 'accepted for use' or 'accepted for restricted use' and for 65% of medicines that were subsequently 'not recommended'. Before SMC advice, for those medicines used predominantly in primary care a total of £1million on the SMC 'accepted for use' or 'accepted for restricted use' medicines and £1.4million was spent in NHSScotland on the SMC 'not recommended' medicines. In the context of a cumulative spend in the primary care drugs bill, over the study period (2002–2003 to 2005–2006) of £3.7 billion this expenditure was small and may in part be explained by processes in place in NHS boards to enable access to medicines not included in the local formulary. Approximately £1million was spent in NHSScotland in 2005–2006 (0.1% of the primary care drugs bill) on 10 medicines that remained 'not recommended' throughout the period of investigation.

There were insufficient robust utilisation and expenditure data for a number of the hospital medicines preventing meaningful assessment of overall expenditure on these medicines both before and after SMC advice.

Factors influencing medicine use

Review of the medicine profiles identified a number of factors that may explain some of the patterns of medicines use (Table 1). These factors are useful in understanding the challenges in the assessment, uptake and monitoring of new medicines in NHSScotland.

Table 1: Factors that may help to explain patterns in medicines use

(a) SMC 'not recommended' advice for primary care medicines

Factor	Observation
Delay between UK launch of medicine and initial SMC advice (> 9months)	There was a pattern of increasing use of the new medicine the further the SMC advice was issued from the launch date.
Limited use relative to alternative treatments	Use of a new product was minimal in the context of overall expenditure or volume of alternative treatments for the clinical condition.
No alternative licensed products	At the time of launch there was no other licensed product available for the indication of this product.
Influence of pharmaceutical industry marketing strategy	The clinical community indicated that the industry marketing strategy had a significant impact on the usage of the product.
Variation in advice issued by national bodies to NHS boards and clinicians.	The lack of consistent clinical guidance impacted on usage, which did not decline on issue of SMC advice.
Lack of engagement of relevant clinical experts in early stages of SMC	There was no decline in medicine use on issue of SMC advice as a result of lack of clinical engagement within the assessment process.

(b) SMC 'accepted for use' or 'accepted for restricted use' advice for primary care and hospital medicines

Factor	Observation
Limitations of data obtained from NHS boards and manufacturers	Extracting data from hospital and industry systems was challenging and resulted in incomplete data for several hospital medicines within the study.
Challenges in interpreting data for 'restricted use' medicines	Due to the absence of patient level data, it was not possible to identify whether the medicines use reflected the SMC restriction(s).
Availability of alternative treatment(s) for a clinical condition	For a clinical condition, where other treatments already exist, variation in prescribing of a new medicine between NHS boards may be clinically appropriate.

Budget impact

The comparison of manufacturers' budget impact estimates with actual expenditure (n=28) highlighted variation. Initial analysis identified a series of factors that may have contributed to this variation: restrictions in the SMC accepted advice that were not reflected in the manufacturer's budget impact estimate, causing overestimation of the budget impact; new safety information that may have affected product uptake; unclear market penetration estimates or errors in calculation of estimates which made the manufacturer's estimate less robust and lack of hospital utilisation information making expenditure data incomplete. It was, therefore, not possible to meaningfully compare the manufacturers' estimates with the actual expenditure in NHSScotland. Further critical review of a subset of these submissions (n=20) highlighted issues with the information provided by the manufacturer; the most common issues including clinical trial drop-out rates either not stated or not supported by the data presented, and no rationale given for the product uptake rate. A key theme was, however, that most of the submissions had multiple issues.

The focus group discussion with senior NHS board employees identified four key themes: budget impact information is an important part of the preparatory work for the managed entry of new medicines; the information is often locally adapted with the involvement of clinicians; clarity on derivation of the estimates would be beneficial to NHS boards; and a standard presentation format for the information within the SMC Detailed Advice Document (DAD) would improve the usefulness to NHS boards.

Case study – etanercept for psoriatic arthritis

Analysis of data on utilisation of etanercept from hospital pharmacy departments, lead clinicians and manufacturers identified different and significant issues with each of the data sources. It was concluded that there was not a clean and relevant dataset to perform a quantitative assessment of the utilisation of etanercept for psoriatic arthritis in NHSScotland.

Adherence to the SMC etanercept protocol identified that the majority or all NHS boards met the protocol criteria relating to: patient inclusion/exclusion criteria; provision of patient information; local arrangements for pharmacy supply; stopping rules; collection of local information on utilisation, though the information set varied between NHS boards; and safety monitoring through reporting of adverse effects. The audit identified that no single Scottish centre to collect data on clinical effectiveness had been established and that guidance on local organisation structure had only been partially implemented in the majority of NHS boards.

Conclusions

The SMC, which issued its first advice in April 2002, has influenced the managed entry of new medicines in NHSScotland. This evaluation programme sought to explore how SMC had impacted on and engaged with its key stakeholders and to examine how SMC advice has shaped medicines use across NHSScotland. The successes to date, current challenges and potential future direction are:

Successes

- SMC strives to provide early advice following launch of a medicine.
- Available data show that medicines use prior to SMC advice is small in the context of overall medicines use and expenditure.
- SMC has good engagement with ADTCs and the pharmaceutical industry, which place a high value on the work of SMC.
- Budget impact information provided within the SMC Detailed Advice Document is valued and used by NHS boards to facilitate local financial planning.
- ADTCs have adapted and evolved in response to SMC advice, changing focus from primary evaluation to local implementation and monitoring of medicines.
- The SMC etanercept protocol, issued to support national implementation, has largely been followed by NHS boards.

Challenges

- Effective engagement with public partners remains a challenge, compounded by the absence of a national register of public partner organisations.
- Monitoring of the use of medicines following SMC advice is limited by the lack of robust national hospital medicines utilisation information, from the NHS or industry, and also by the absence of patient level data in both primary and hospital care, which inhibits interpretation where medicines have multiple indications.
- Estimation of the budget impact of new medicines remains problematic due to the many factors which can impact on the uptake of a new medicine and the absence of a consistent approach in this area.

Future direction

The evaluation provides direction for an evidence-based plan to develop further the assessment, implementation and monitoring of new medicines in NHSScotland. In particular:

- the factors identified from the medicine profiles provide a number of areas where action can be taken which may further facilitate the effective use and monitoring of medicines
- the issues identified with budget impact estimates provide a basis for discussion with the SMC User Group to develop a more consistent approach in this valued area of work, and
- the information gathered from public partners on how to improve effective engagement can inform the future work of the SMC Patient and Public Involvement Group (PAPIG).

Additional Information

The following full reports are available on the SMC website in addition to the completed medicine profiles for those medicines where robust medicines use data are available:

- Evaluation of the SMC's impact on and engagement with stakeholders
- SMC 'not recommended' advice – an investigation of medicines use across NHSScotland
- SMC 'accepted for use' and 'accepted for restricted use' advice - an investigation of medicines use across NHSScotland
- Measuring adherence of NHS boards to SMC advice for 'unique' treatments
- An evaluation of manufacturer's budget impact estimates with resource use over time in NHSScotland.

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