



Evaluation of the SMC's impact on and engagement with stakeholders



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Scottish Medicines Consortium Evaluation Programme

Evaluation of the SMC's impact on and engagement with stakeholders

Executive Summary and Full 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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Executive summary

Introduction

The Scottish Medicines Consortium (SMC) is a consortium of stakeholders from NHS boards and their Area Drug and Therapeutics Committee (ADTC) with representatives from the Association of the British Pharmaceutical Industry (ABPI) and public partners. This report provides a description of how the establishment of SMC has impacted on NHS board ADTCs in their assessment of new medicines over time and also the views of the key stakeholders (ADTCs, public partners and pharmaceutical industry) in relation to SMC engagement past, present and future.

Methods

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 was sent 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.

Key findings

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

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

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.
- Development of medicines use monitoring mechanisms.

Engagement with stakeholders

Table 1 (page 6) provides a summary of the views of the three key stakeholders (ADTCs, public partners and the pharmaceutical industry) in 2006–2007 in relation to stakeholder engagement by SMC using three key themes: successes, challenges, and potential for further improving the engagement process with SMC.

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 had 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.

Table 1: Scottish Medicines Consortium (SMC) engagement with key stakeholders in 2006–2007

	Area Drug and Therapeutics Committees (ADTCs)	Public partners	Pharmaceutical industry
Successes of engagement with SMC	<ul style="list-style-type: none"> - Reduction in ADTC workload in the evaluation of primary evidence. - Effective, transparent engagement. - Standardised approach to new medicines. - Timely, independent advice. - Assists financial planning. 	<ul style="list-style-type: none"> - Current SMC processes quite successful where understood by groups. 	<ul style="list-style-type: none"> - Robust, transparent processes. - Timely decisions, globally recognised and referenced. - Increased uniformity across Scotland. - Reduced delays in patients getting access to medicines. - Pharmaceutical industry recognised as a partner in introduction of medicines.
Challenges of engagement with SMC	<ul style="list-style-type: none"> - Variation in understanding of SMC processes. - Submissions not always made to SMC. - Medicines licensed before SMC was established are not assessed. - Time commitment required as a member of SMC. - Process for nominations for SMC membership. - Clarity for media and patients of the role of local formularies 	<ul style="list-style-type: none"> - Limited awareness at the time of the survey of the SMC (41%), its website and process for submissions (33%). - Not informed by SMC when relevant medicines would be assessed (66%). - Limited support, guidance and feedback from SMC. 	<ul style="list-style-type: none"> - Variations in application of SMC advice in NHS boards. - Lack of implementation process for SMC advice in some NHS boards. - Lack of awareness of the formal mechanism for companies to contact industry representatives on SMC. - Lack of independent assessors. - Short timescales for pharmaceutical companies.
Improving engagement with SMC	<ul style="list-style-type: none"> - Mechanism to increase awareness of SMC process, and implications of recommendations. - Evaluation of selected 'high cost' medicines that were licensed before the SMC. - Improvements to the website. 	<ul style="list-style-type: none"> - Increase knowledge of the SMC assessment process (59%). - Email to inform groups that a medicine relevant to public partners is being considered (58%). - Inviting groups to attend SMC and provide support. 	<ul style="list-style-type: none"> - Mechanism to encourage dialogue between SMC clinical experts and pharmaceutical industry. - Availability of the economic checklist earlier in the process. - Inclusion of 'accepted' medicines in formularies. - Collaboration with National Institute for Health and Clinical Excellence (NICE) and other groups to reduce duplication of effort. - Regular conferences.

Conclusions

This investigation has demonstrated a clear evolution in the process underpinning the introduction of new medicines by ADTCs across NHSScotland. The SMC is now accepted as the single source of timely advice about new medicines by ADTCs, with a high level of confidence in its recommendations, resulting in substantial reduction in local ADTC evaluation of primary evidence. Work at NHS board level has moved from primary evaluation to assessment of local implications and implementation. However, local assessment of the place of a new medicine where clinically similar alternative treatments are already available to prescribers does lead to appropriate variability, and this needs to be understood.

Effective engagement with public partners remains challenging for the SMC. At the time of the study, a significant number of public partners were unaware of the SMC, its website or the SMC process for public partner submissions. Improvements have focused on identifying effective systems to alert groups to forthcoming medicines of interest and a continuing programme to raise awareness of the SMC and the role for public partners in its processes.

SMC engagement with the pharmaceutical industry is described as robust and transparent, with its decisions seen as timely and recognised globally. Better communication, largely within the industry, and earlier release of some parts of SMC documentation are seen as potential improvements in the process.

Full report

Introduction

The remit of the Scottish Medicines Consortium (SMC) is to provide advice to NHS boards and their Area Drug and Therapeutics Committees (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). This advice is made available as soon as practical after the launch of the medicine.

SMC's assessment process first requires pharmaceutical companies to complete a New Product Assessment Form (NPAF) and supply the necessary supporting data for consideration. Thereafter, there is a staged assessment process, which includes internal evaluation of the submission followed by presentation to the New Drugs Committee (NDC), a scientific committee, which appraises the clinical and economic case made in the submission and provides draft advice for SMC. The NDC draft is shared with the submitting company, allowing them to make comments for consideration by SMC. At its monthly meeting, SMC then considers all the scientific evidence, company comments, public partner group submissions and any other factors, before issuing its final advice to NHS boards and ADTCs, with a copy to the submitting company. The advice is released into the public domain approximately one month later.

To evaluate the overall impact of the SMC on medicines utilisation in Scotland, it is necessary to assess SMC's engagement with its stakeholders. The SMC is a consortium of stakeholders from NHS boards and their ADTCs with representatives from the Association of the British Pharmaceutical Industry (ABPI) and public partners.

This report provides a description of how the establishment of SMC has impacted on NHS board ADTCs in their assessment of new medicines over time and also presents the views of the key stakeholders (ADTCs, public partners and pharmaceutical industry) in 2006–2007.

Chapter 1: Area Drug and Therapeutics Committees

Background

Across Scotland, NHS boards have established Area Drug and Therapeutics Committees (ADTCs). These committees have evolved variable roles and remits, to meet local needs, but common to most is activity centred on the evaluation of new medicines to support their safe and effective use by prescribers and the local population.

The establishment of SMC in October 2001 drew upon this expertise, with representation from each of the ADTCs. The aim was to reduce duplication of effort by providing a “single and timely source of advice about all new drugs, new formulations and new indications”.

ADTC chairs are asked to nominate potential new members for SMC and NDC to the SMC Executive Group which identifies replacements for members leaving the committee. The term of office is for an initial three-year period.

Effective engagement with ADTCs is central to the success of the SMC. Consequently a two-stranded approach was taken to this part of the evaluation: first to understand what impact SMC has had on the role and functions of ADTCs over time, and second to summarise the views of current ADTC members across Scotland in relation to the SMC past, present and future.

Method of study

To investigate the impact and engagement of the SMC on NHS board ADTCs' two separate strands of work were undertaken:

A) Impact on ADTCs' role and function – a review of reports describing the experiences, approaches and processes of ADTCs before and after the establishment of the SMC at defined time points was undertaken. The published reports reviewed were:

- Year 2000: The results of an MPH project to identify how new medicines were evaluated in the year 2000, before the SMC existed.¹
- Year 2002: The results of an MSc project to identify how new medicines were evaluated in 2002, after the first few months of the SMC.²
- Year 2003–2004: Key themes identified from the full report and seven individual NHS board reports, produced following a review of the use of medicines in hospitals by Audit Scotland.³

In addition, in 2006–2007, a review of ADTC processes was undertaken using a semi-structured data collection form based on key themes identified in consultation with the SMC evaluation reference group.

Evidence used included, where available, ADTC websites, electronic formularies, minutes of ADTC/formulary meetings and relevant local databases. Data were available for 11 NHS boards. This was followed in June 2007 by a workshop (sharing best practice) at an NHSScotland ADTC conference, attended by over 60 delegates, which explored how SMC advice was implemented, communicated and monitored within NHS boards.

The evidence gathered for each time period was collated using key themes to illustrate the impact of SMC on the role and function of ADTCs over time within NHS boards.

B) Engagement with ADTCs - A second workshop (engagement of the SMC with ADTCs) was held at the June 2007 conference to identify:

- Areas where engagement between the SMC and the ADTCs had been successful.
- The issues which may have hindered engagement between the SMC and the ADTCs.
- Possible ways of improving engagement between the SMC and the ADTCs.

The output from this workshop, repeated twice to enable all delegates to contribute, comprised notes of the discussions documented by the workshop facilitators and members of the SMC evaluation project team, who acted as observers. The materials were analysed to identify key themes.

Key findings

A) Impact on ADTCs' role and function

Before SMC, there was no national source of advice about new medicines close to their market launch. Previously, in 1993, NHS boards had been tasked with establishing Drug and Therapeutics Committees (DTCs [Scottish Executive MEL 1993]) but as no detailed guidance was given on structure or role of the DTCs, this had to be developed locally. By 2000, all NHS boards had a DTC.

Table 2 (page 13) provides a profile of the changing processes and approaches of ADTCs, summarised by key themes, over the period 2000 to 2006–2007.

In 2000, NHS boards had no standardised definition of a 'new medicine', ranging from awaiting a clinician request to more proactive identification of medicines (some to all) close to market launch. There was evidence of variation between NHS board ADTCs in: membership disciplines and skills; level and extent of evidence evaluated; decisions made; and extent of communication and dissemination to prescribers. Evaluation and monitoring were identified as difficult due to limited resource and data availability on medicines usage.

SMC first issued advice in April 2002. By the end of 2002, some NHS boards had adapted their activities to manage SMC advice and were beginning to look to wider roles. Others were still developing systems to

manage the volume of advice from SMC. However, there was evidence of greater consistency in decision-making where processes existed.

The Audit Scotland report, examining hospital practice in 2003–2004, demonstrated that all NHS boards had mechanisms in place to manage SMC advice and some NHS board ADTCs had developed categorisation systems for medicines assessed by SMC, to provide clear messages for prescribers and to accommodate evolving formulary systems. ADTCs' role 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.
- Development of medicines use monitoring mechanisms.

B) Engagement with ADTCs

Table 3 (page 15) summarises the views of delegates who attended the NHSScotland ADTC conference in June 2007. These are presented under three key headings: successes in engagement, difficulties with engagement and improving engagement.

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, which continue to require local evaluation to respond to the clinical needs of patients. Suggested improvements focused on succession planning for SMC membership and on sustained effective communication (in collaboration with ADTCs) 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.

Conclusions

This investigation has demonstrated a clear evolution in the evaluation and implementation of new medicines by ADTCs across NHSScotland. The SMC has served to give a definition to 'new medicine' and as a result has increased the consistency of medicine introduction. The SMC is widely accepted as the single source of timely advice about new medicines by ADTCs, with a high level of confidence in its recommendations, resulting in reduction in local ADTC evaluation of primary evidence. Work at NHS board level has moved from primary evaluation to assessment of local implications and implementation. However, local assessment of the place of a new medicine where clinically similar alternative treatments

are already available to prescribers does lead to appropriate variability, and this needs to be understood.

Areas for improvement mainly focused on succession planning for SMC membership and sustained effective communication with stakeholders and the media.

References

1. Timoney A. MPHSc Thesis: Evaluating new drugs in NHSScotland. University of Glasgow. 2001.
2. Black C. MSc Thesis: Evaluation of the Impact of the Scottish Medicines Consortium on Medicines Management in Scotland. University of Aberdeen. 2003.
3. Audit Scotland. A Scottish prescription: managing the use of medicines in hospitals. July 2005.

Table 2: Area Drug and Therapeutics Committees (ADTCs) – Impact of the Scottish Medicines Consortium (SMC) on roles and function from 2000 to 2006–2007

Theme	2000	2002	2003–2004 (Hospital practice focus)	2006–2007
Medicines reviewed	<ul style="list-style-type: none"> - No single standard working definition of a 'new medicine' - Number of 'new' medicines evaluated within a NHS board varied from 3-91 per year 	<ul style="list-style-type: none"> - Definition moving to 'medicines reviewed by SMC' but some still responding to clinician request, if medicine not in SMC work programme 	<ul style="list-style-type: none"> - New medicines where defined as SMC advice - All NHS boards could describe an internal process for managing SMC advice 	<ul style="list-style-type: none"> - All SMC advice considered by ADTCs but also continuing assessment of medicines launched pre SMC on clinician request
Structures and processes	<ul style="list-style-type: none"> - Trust DTCs were merging to form ADTCs - Variation in evidence gathering and critical appraisal skills training and application - Variation in committee membership with patchy critical appraisal, economic and finance input 	<ul style="list-style-type: none"> - Not all ADTCs had established processes for SMC advice - ADTCs met more frequently and had wider membership but economic, finance and public input remained low - Evidence used was mainly SMC plus local clinical experts, but still some ongoing assimilation and evaluation of primary research sources 	<ul style="list-style-type: none"> - Two approaches by NHS boards: implement all advice or; note all advice but initiate local implementation on clinician request - SMC advice main source of evidence for local review - Some movement towards unified system with single NHS board ADTC 	<ul style="list-style-type: none"> - Different structures for implementation of SMC advice existed in NHS boards. Some with dedicated subcommittees for formulary updating and resource groups for financial and service planning - Local organisational restructuring and managed clinical network developments requiring ADTCs to continually adapt and evolve - Continuing evidence of lack of finance, economic and public membership of ADTCs. Additional challenges of engaging certain clinician specialities - NHS board ADTC representation on SMC varied substantially in number and position held within local structures

Table 2 continued

Theme	2000	2002	2003–2004 (Hospital practice focus)	2006–2007
Implementation	<ul style="list-style-type: none"> - Variable strategies including clinician feedback, formulary inclusion (paper/electronic), bulletins - Some referral to other committees for expensive medicines 	<ul style="list-style-type: none"> - Communication mainly via formulary and paper bulletins. Some use of e-formularies but internet/intranet access in hospital difficult for prescribers 	<ul style="list-style-type: none"> - Implementation involved local needs assessment and resource implications (rarely beyond medicine costs) and referral in some NHS boards to medicine resource groups - Local decision-making categorisation evolving, eg add to formulary, add to specialist list, not preferred, etc - Many NHS boards had developed joint formularies (primary care/hospital) - Staff had increasing access to web-based formularies with more rapid updating 	<ul style="list-style-type: none"> - Clear statements of intent on implementation of unique medicines - SMC advice on orphan drugs continued to pose challenges to NHS boards - Formulary management well established but ensuring responsiveness was increasing resource burden - Evolution of formularies from list of medicines to clinical guidance / treatment pathways as a broader prescribing support tool - Not all formularies were publicly available on the internet - Variation in the ease of identifying NHS boards decisions from clear tabulation of outputs to a need to research ADTC minutes
Evaluation and monitoring	<ul style="list-style-type: none"> - Challenging due to resources available (manpower and data) 	<ul style="list-style-type: none"> - Some ADTCs moving focus to include evaluation of implementation strategies, others struggling to manage output from SMC 	<ul style="list-style-type: none"> - Monitoring usage of new medicines was beginning to be recognised as an important function of ADTCs (under way in some NHS boards) - Hospital data generally come from pharmacy stock control systems, and are reported to ADTCs and senior management committees 	<ul style="list-style-type: none"> - Use of national and local medicines use data (limited in hospitals) to monitor high cost medicines, non-formulary medicines and budget impact estimates was identified in NHS boards to varying degrees - No systematic aggregated patient level data to support examination of clinical effectiveness - Little evidence of local evaluation of the impact of changing processes
Evidence of consistency	<ul style="list-style-type: none"> - Variation in decisions made on new medicines 	<ul style="list-style-type: none"> - Greater consistency in decisions made between NHS boards 	<p>Evidence that approved for use/restricted use SMC advice would not necessarily lead to a medicine being included in the formulary due to local decision-making categorisation, principally where alternatives existed</p>	<ul style="list-style-type: none"> - Most stated that SMC not recommended medicines would not be added to formularies - Continuation of local decision-making categorisation was evident

Table 3: Engagement of Area Drug and Therapeutics Committees (ADTCs) with the Scottish Medicines Consortium (SMC) – ADTC member views in 2007

Success in engagement	Difficulties with engagement	Improving engagement
<ul style="list-style-type: none"> - The SMC has reduced the workload of ADTCs in evaluation of primary evidence - The SMC engages effectively and transparently with its stakeholders, and has resulted in a standardised approach to new medicines across Scotland - Advice issued by the SMC is timely and used as a catalyst in financial planning - The membership of the SMC is representative of the geographical boundaries of Scotland - The SMC has international recognition and credibility - The processes used by the SMC are transparent and robust - The SMC is independent 	<ul style="list-style-type: none"> - There are variations in the level of understanding of SMC processes by prescribers and the media - Pharmaceutical companies (members and non-members of ABPI) do not always make a submission to the SMC - Medicines licensed before the establishment of the SMC are not assessed by the SMC - There is a need for succession planning - It can be difficult for members of the SMC/NDC to travel to meetings - There are differences in how nominations are obtained in NHS boards for membership of SMC/NDC - There is confusion in some areas about whether a medicine accepted by the SMC should be added to the local formulary - A clearer steer is needed for unique medicines 	<ul style="list-style-type: none"> - There should be a mechanism to increase awareness of the SMC process, and the implications of recommendations, among prescribers, patients, the media and the general public - Evaluation of selected 'high cost' medicines that were licensed before the SMC - Improvements to the website

Chapter 2: Public partners

Background

From the establishment of SMC it was recognised that the assessment process would benefit from having a direct input from patients and carers. Consequently, two lay members, now known as public partners, joined the SMC – a third was subsequently recruited. Recruitment of public partners to the SMC is via advertising through the SMC website and other relevant bodies, ie NHS Quality Improvement Scotland, Scottish Health Council, Voluntary Health Scotland and directors of public involvement within NHS boards. A short-list is drawn up from applications received and an appointment made through an interview process.

To take the public involvement agenda forward, the Patient and Public Involvement Group (PAPIG) was formed. This group comprises membership from public partners, pharmaceutical industry, NHS board representatives from SMC and the SMC executive group. PAPIG's role includes promoting and monitoring public awareness and involvement in the work of SMC and presenting a summary of the patient/carer perspective, supplied by public partners, at SMC meetings.

The Scottish Centre for Social Research (ScotCen) was commissioned to evaluate the process of submissions from public partners to the SMC in March 2006.

Public partner submissions form the main method of involving patients, carers and the public in the work of SMC. The main aims of the research were to:

- Ascertain the reasons for the variation in response from public partners.
- Examine why some public partners have made submissions whereas others have not.
- Identify the views of public partners and key stakeholders in relation to the impact of public partner submissions on actual SMC practice.
- Determine how best to maximise the opportunity for patient and carer voices to be heard in the future in order to inform SMC's strategy.

Method of study

A mixed methods approach was used as follows:

- In-depth qualitative interviews were held with key stakeholders (n=4) between April–May 2006 to aid development of research instruments.
- A postal questionnaire survey was undertaken of patient interest groups (n=154) between May–June 2006. Only 22 responses were received.
- A telephone follow-up survey was conducted of the 132 non-responders between July–August 2006. A total of 93 completed responses were received to both the postal and telephone surveys out of a total of 104 groups who reported that they would consider it part of their remit to offer advice on medicines.

- In-depth qualitative interviews were held between August–October 2006, with representatives of public partner groups who had and had not made previous submissions to SMC (n=15).

Key findings

The main findings were:

- Only 41% (n=39) of respondents reported that they were aware of the SMC at the time of the survey, with only 33% (n=31) aware of the SMC website and the process for public partner submissions set up by SMC.
- Two-thirds (n=62) of groups were unable to state whether the current SMC process for public partner submissions was successful or not, probably reflecting the lack of engagement that public partners had experienced with the SMC and its assessment process. However, a majority of those who felt able to respond perceived that the current process was at least quite successful.

Table 4 (page 18) presents additional findings under three key headings: barriers to making submissions; facilitating factors to making submissions; and modifications to the submission process.

The single major barrier identified was the lack of a proactive alert system to inform public partners when a relevant medicine was to be assessed. Support with understanding the submission process for public partners (including possibly the opportunity to attend SMC meetings as observers), completing the necessary documentation and providing feedback following the SMC decision would be welcomed.

Conclusions

Effective engagement with public partners remains challenging for the SMC. At the time of the study, a significant number of public partners were unaware of the SMC, its website or the SMC process for public partner submissions. Improvements focused on identifying effective systems to alert groups to forthcoming medicines of interest and a continuing programme of awareness of the SMC.

Table 4: Engagement of public partner groups with the Scottish Medicines Consortium (SMC) – 2006

Barriers to making submissions' (difficulties with engagement)	Facilitating factors to making submissions (improving engagement)	Modifications to the submissions' process (improving engagement)
<ul style="list-style-type: none"> - The major single barrier to making submissions reported during the survey was that the SMC did not directly inform groups that relevant drugs were coming up for assessment (66% (n=61)), but 48% (n=45) also reported that they did not understand the current system fully. Over 20% (n=20) of groups also said that there was a lack of support and guidance from SMC. - Public partners also tended to report a lack of feedback from the SMC. In particular, the lack of feedback given when groups had made submissions was criticised, as groups had no idea whether they were completing the forms in the manner required by SMC or if their submission had influenced the SMC decision in any way. 	<ul style="list-style-type: none"> - 59% (n=55) of groups thought that knowledge of the SMC assessment process would assist patient interest groups to make submissions. Also, 58% (n=54) of respondents called for an email alert to be sent from the SMC when a medicine relevant to a public partner group or groups was being considered. - 47% (n=44) of respondents said that groups would be more likely to submit to SMC if they believed that public partner submissions actually influenced the SMC decision. - A majority of groups also reported that patient interest groups would be more likely to make a submission to SMC if they thought that the medicine being assessed would benefit their patients. 	<ul style="list-style-type: none"> - The SMC engaging with public partner groups more, and attempting to raise its profile through informal meetings, seminars and newsletters, etc. - The SMC alerting groups directly when relevant drugs are about to be assessed. - The SMC providing more support and guidance for groups throughout the process, for example, by naming a member of staff and providing contact details so that groups can seek advice directly. - The SMC providing more feedback, especially after the submission has been presented, pointing out the strengths and weaknesses of the submission, ways in which it might be improved in the future and, if possible, the influence it brought to bear on the assessment of the medicine. - The SMC inviting public partner groups to attend SMC meetings to make the processes involved more transparent.

Chapter 3: Pharmaceutical industry

Background

The Scottish Medicines Consortium (SMC) engages with the pharmaceutical industry through the Association of the British Pharmaceutical Industry (ABPI), which is the trade association for more than 75 companies in the UK producing prescription medicines.

Three representatives from the ABPI sit as full members of the SMC. Representation from the pharmaceutical industry is also present on the NDC. Recruitment of these members is facilitated through ABPI which co-ordinates the advertisement, review and appointment process.

There is also an SMC user group forum which comprises membership from: ABPI and non ABPI companies; NDC; SMC executive group and the SMC internal evaluation team (pharmacist and health economist). The SMC user group forum's key function is to ensure effective communication with the pharmaceutical industry including review of SMC processes which may affect the submission and approval process for a new medicine.

The report summarises the views of pharmaceutical industry representatives who attended a joint SMC/ABPI conference in 2006, which included examination of stakeholder engagement by SMC past, present and future.

Method of study

The SMC in collaboration with the ABPI organised a one-day conference in November 2006, attended by over 100 delegates from the pharmaceutical industry (ABPI and non-ABPI members) across the United Kingdom. The conference consisted of presentations and workshops.

The focus of the presentations were:

- a) To provide delegates with a general overview of the SMC evaluation project.
- b) To inform delegates on how to make and improve submissions to the SMC.
- c) To provide delegates with an overview of the horizon scanning work.

A workshop was organised to identify:

- a) Areas where engagement between the SMC and the pharmaceutical industry has been successful.
- b) The possible difficulties which may have hindered engagement between the SMC and the pharmaceutical industry.
- c) Possible ways of improving engagement between the SMC and the pharmaceutical industry.

The output from the workshop, repeated twice to enable all delegates to contribute, comprised notes of the discussions documented by the workshop facilitators and members of the SMC evaluation project team, who acted as observers. The materials were analysed to identify key themes.

Key findings

Table 5 (page 20) summarises delegates' discussion at the workshop under three key headings: successes in engagement, challenges in engagement, and potential for improving engagement with SMC.

The SMC was viewed by industry as having robust and transparent processes, which provide timely information that is globally recognised. The pharmaceutical industry considered that it had been recognised as a key partner, and had supported the development of a decision-making process that is "fairer and simpler in comparison to other similar organisations". 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.

Conclusions

The pharmaceutical industry considered that it had been recognised by SMC as a key partner, which has shaped robust and transparent processes, providing timely information that is globally recognised. Challenges identified and improvements proposed include: increased clarity around NHS board processing of SMC advice; effective communication between industry members on SMC and the pharmaceutical industry; and earlier access to the economic checklist.

Table 5: Engagement of pharmaceutical industry with the Scottish Medicines Consortium (SMC) – Industry member views in 2006

Success in engagement	Difficulties with engagement	Improving engagement
<ul style="list-style-type: none"> - The SMC has introduced transparent and robust processes for the introduction of new medicines in Scotland - The SMC's decisions are globally recognised and referenced - The SMC's decisions are timely and have resulted in a more informed process at level (ADTC) - The SMC's submission process and decision-making is fairer and simpler in comparison to other similar organisations - The SMC has increased uniformity across Scotland and reduced delays in patients getting access to medicines - In general, the SMC process has reduced the work involved in making submissions to different NHS boards in Scotland 	<ul style="list-style-type: none"> - There is a perception that there are variations in the application of SMC advice at NHS board level - The lack of an implementation process for SMC advice in some NHS boards is seen as a stumbling block to the introduction of new medicines - There is no formal mechanism through which pharmaceutical companies can contact the ABPI representative sitting on the SMC - The absence of independent assessors in comparison with the National Institute for Health and Clinical Excellence (NICE) is also of concern to pharmaceutical companies - The period given to companies to comment on recommendations from the NDC is short and impacts on the resources of pharmaceutical companies especially where new evidence is being obtained from the company's headquarters 	<ul style="list-style-type: none"> - There should be a mechanism to encourage dialogue between clinical experts from the SMC and pharmaceutical industry when there are differences of opinion - The economic checklist should be made available earlier in the process, ie closer to the issue of the draft SMC Detailed Advice Document (DAD) - If possible, medicines accepted for use should be included in formularies - ADTCs could be more consistent in their implementation of decisions by organising themselves into regional/geographical groups - The SMC should collaborate with NICE to avoid duplication of effort - Conferences should be organised regularly to discuss lessons learnt and improvements that could be made

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