Scottish Medicines Consortium
Update Report 2016

Providing advice about the status
of all newly licensed medicines
www.scottishmedicines.org.uk

Healthcare Improvement Scotland

NHS SCOTLAND

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Contents

Introduction

As part of Healthcare Improvement Scotland, the Scottish Medicines Consortium's (SMC) role is to provide robust, carefully considered advice to NHS boards to ensure beneficial new medicines are available for routine use by the people of Scotland. Following the Scottish Government's review into access to new medicines in 2013, we have undertaken significant changes to our processes which has led to a greater number of medicines being made available for routine use in NHSScotland. This report will look at those changes and their impact.

Helping patients access new medicines: SMC's changing processes

Timeline for changes to SMC processes

September 2011	Patient group petitions submitted to Public Petitions Committee about access to new medicines.
November 2012	Cabinet Secretary for Health and Wellbeing announces the New Medicines Review.
May 2013	New Medicines Review (comprising Routledge and Swainson reviews) published by Scottish Government.
July 2013	Health and Sport Committee review into access to new medicines published.
October 2013	Scottish Government publishes its response to the Health and Sport Committee inquiry report. Cabinet Secretary directs SMC to undertake a review of its approach to evaluating end of life/orphan medicines.
December 2013	SMC's Task and Finish Group, chaired by Professor David Webb, reports back to the Cabinet Secretary.
January 2014	Cabinet Secretary welcomes the report and asks SMC to put the recommendations in place by May 2014.
May 2014	All submissions for medicines used at the end of life and for very rare conditions now eligible for the Patient and Clinician Engagement (PACE) process. First SMC meeting held in public. Introduction of the ultra-orphan framework for considering medicines for very rare conditions.
September 2014	First SMC meeting to consider medicines reviewed under the PACE process.
October 2014	Publication of first decisions on medicines considered through the PACE process.
November 2014	First SMC meeting with direct contribution from invited pharmaceutical company representatives.
December 2015	Health and Sport Committee announce call for evidence on progress since the 2013 inquiry.
January 2016	Scottish Government announces independent review of access to new medicines to be led by former NHS Fife Medical Director, Dr Brian Montgomery.

Transparency and public engagement

To improve the public's understanding of SMC, the New Medicines Review recommended greater transparency in our processes and everyday work. We are committed to being more public facing and have taken the following steps to make our processes more open:

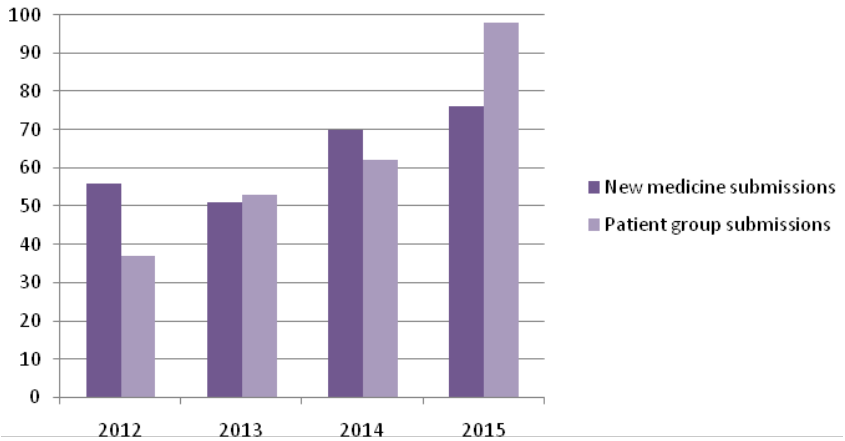
- strengthening patient and public involvement
- meetings in public, and
- engagement with pharmaceutical companies.

Strengthening patient and public involvement

SMC has always sought the views of patient groups on medicines submitted for review so patient opinion can inform our Committee's considerations. To further strengthen patient and public involvement activities, we have recruited a new Public Involvement team. The team has:

- undertaken a review of SMC's Public Involvement work
- set up the Public Involvement Network (PIN), a group representing patient and carer groups who have submitted to SMC. PIN engages with patient groups to ensure the views of patients, carers and the public are captured and used to inform SMC decision-making
- within PIN, set up an advisory group to provide SMC with strategic advice to help continuously improve how we involve patients, carers and members of the public in our work
- developed a new patient group submission form and written a guide for support groups making a submission on a medicine
- held two events for patient groups to encourage engagement with SMC
- offered increased support to patient groups on how to engage with SMC
- provided new and revised public involvement content for the SMC website
- developed new forms and guidance for pharmaceutical companies to provide information to help support patient group submissions, and
- worked to significantly increase the number of submissions from patient groups on medicines under review by SMC - see Figure 1.

Figure 1: Patient group submissions*



* A new medicine submission may have more than one patient group submission

Meetings in public

To help the people of Scotland better understand the work we do on their behalf, the New Medicines Review recommended SMC meetings were held in public. We held our first meeting in public in May 2014.

In total, 603 people have attended SMC meetings (see Table 1 below). Feedback gathered from 161 people who observed meetings and returned evaluation forms between May 2014 and February 2016 showed 82% felt that observing had improved their understanding of how SMC works. This feedback will be used to improve our information for attendees.

While we strive to hold as much of the meeting in public as possible, there will be occasions when the Committee has to discuss an issue in a private session, for example where key information is regarded as commercial in confidence (information that if disclosed may result in damage to a company's commercial interests or intellectual property). To date there have been 11 private sessions from 128 full submissions assessed between May 2014 and July 2016.

Table 1: Breakdown of public observers at SMC meetings, May 2014–July 2016

Observers who registered as:

Patient groups	**94**
Pharmaceutical company representatives (observing only)	**171**
Pharmaceutical company representatives (participating in meeting)	**249**
Members of the public	**60**
Other (for example students, media)	**29**
Total	**603**

Engagement with pharmaceutical companies

To further increase transparency, the New Medicines Review recommended pharmaceutical company representatives attend SMC meetings to answer any questions the Committee may have about their submission. Since November 2014, companies may have two representatives present for each medicine under consideration. Most companies have taken this opportunity and feedback indicates that they find it extremely useful, with 87% of those who provided comment saying that attending was of benefit to their organisation.*

To support pharmaceutical companies' understanding of our new processes and encourage good quality submissions first time round, we held two pharmaceutical industry training events in September 2015 and May 2016. Following positive feedback, we are now planning to hold more events. We are also piloting early engagement meetings with companies that require further guidance on submissions in specific circumstances.

* Out of 68 people who provided feedback

New process for medicines used at the end of life and for very rare conditions

Working with a range of stakeholders, including patient groups, clinicians and pharmaceutical industry representatives, we have introduced more flexible approaches for medicines used at the end of life or for very rare conditions.

What do we mean by medicines used at the end of life and for very rare conditions?

We use the following definitions:

End of life medicine	A medicine used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments.
Orphan medicine	Medicines used to treat very rare conditions are known as orphan medicines. SMC uses the following definition for orphan medicines: "A medicine with European Medicines Agency (EMA) designated orphan status (conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of population irrespective of whether it has orphan status."
Ultra-orphan medicine	Medicines for extremely rare conditions may be known as ultra-orphan medicines. SMC uses this term for medicines used to treat conditions with a prevalence of 1 in 50,000 or less (or a maximum of 100 people in Scotland).

Patient and Clinician Engagement process

To assess medicines for end of life and very rare conditions, we have developed the Patient and Clinician Engagement (PACE) process, an additional step in our process which gives the Committee more flexibility when considering these medicines.

The PACE process involves a meeting which brings together SMC representatives with patient group representatives and healthcare professionals with expertise in the medicine under review. The meeting gathers detailed information which allows a discussion on the benefits of a medicine, including how it can impact the quality of a patient's life. This information may not always be fully captured within the conventional assessment process.

The outcome of the PACE meeting is an agreed statement which is included in the SMC meeting papers and is a major factor in the Committee's decision.

The first decisions taken under the PACE process were published in October 2014.

Ultra-orphan medicines

We have introduced a framework of explicit decision-making criteria for these medicines to emphasise the nature of the condition, the impact of the new medicine and its value for money. This process allows the Committee to consider:

- the wider impact a medicine may have for patients and their carers beyond direct health benefits, and
- the medicine's impact on specialist services and costs to the NHS and Social Care Services.

A PACE meeting can be held for an ultra-orphan medicine if the company requests it.

As well as undertaking the changes described, we have continued our core business of assessing all newly licensed medicines and indications.

Table 2 below gives an overview of all submissions reviewed by SMC since 2012 and illustrates that the acceptance rate has been increasing since the introduction of the new processes.

Table 2: Overview of all submissions reviewed by SMC

	2012	2013	2014	2015	2016 (to July)
Full submissions	42 (43%)	45 (41%)	50 (51%)	63 (56%)	34 (53%)
Resubmissions	11 (11%)	12 (11%)	19 (19%)	12 (11%)	7 (11%)
Abbreviated submissions	16 (16%)	30 (27%)	17 (17%)	26 (23%)	8 (13%)
Non-submissions	28 (29%)	24 (22%)	12 (12%)	11 (10%)	15 (23%)
Total submissions	97	111	98	112	64
Accepted/accepted restricted (all submissions)	51 (53%)	71 (64%)	70 (71%)	86 (77%)	31 (74%)
Not recommended (all submissions)	46 (47%)	40 (36%)	28 (29%)	26 (23%)	11 (26%)
Total decisions	97	111	98	112	42
Combined acceptance rate for orphan/cancer medicines advice published between Nov 2011-Oct 2013		48%			
Total medicines considered through new assessment processes	Not applicable	Not applicable	(from October – December) 6	33	19
Medicines accepted/ accepted restricted following new processes	Not applicable	Not applicable	(from October – December) 4 (67%)	23 (70%)	11 (58%)
Medicines not recommended following new processes	Not applicable	Not applicable	2 (33%)	10 (30%)	8 (42%)

Outcomes summary

Patient group submissions	Patient group submissions have increased from 37 (52% of new medicine submissions) in 2012 to 96 (78% of new medicine submissions) in 2015.
Public attendance at SMC meetings	603 people have attended SMC meetings in the public gallery since May 2014; 82% of those surveyed (161 respondents) stated that observing had improved their understanding of how SMC works.
Company representative attendance at SMC meetings	249 representatives from pharmaceutical companies have attended SMC meetings since November 2014 to provide points of information and answer questions on invitation from the chair; 87% of those surveyed (62) stated that attending was of benefit to their organisation.
New medicine submissions activity	Total new medicine submissions to SMC have remained in the range 97–112 per annum from 2012 to 2015. The overall acceptance rate was 53% in 2012 and 77% in 2015.
PACE process influence on acceptance rate	57 PACE medicines have been assessed by SMC from October 2014–July 2016. The overall acceptance rate was 75%. This compares with an acceptance rate for orphan and cancer medicines of 48% between 2011 and 2013 (pre PACE).

Next steps

A strong element of partnership working was involved in developing these new processes: patient groups, clinicians, and the pharmaceutical industry all helped to shape the way we now produce advice. Since we introduced these changes in 2014, patient access to effective new medicines across Scotland has increased and we are pleased with the progress that has been made in a short time. Our thanks go to all those who have helped us to develop our processes and who continue to engage with the work of SMC.

We are committed to reviewing these new processes in order to drive continuous improvement. In line with this, we made a submission to the Health and Sport Committee's access to new medicines progress update inquiry. Our chairman, Professor Jonathan Fox, and Healthcare Improvement Scotland Chief Executive, Angiolina Foster, also appeared at the Committee's inquiry evidence session, alongside Shona Robison, Cabinet Secretary for Health, Wellbeing and Sport, and Dr Rose Marie Parr, Chief Pharmaceutical Officer for Scotland.

We have also submitted evidence to the independent review of access to new medicines which is currently being led by Dr Brian Montgomery. The review was announced by the Scottish Government in January 2016 and is expected to report in the summer.

You can find out more about our work on our website: **www.scottishmedicines.org.uk.**

You can read and download this document from our website. We are happy to consider requests for other languages or formats. Please contact our Equality and Diversity Advisor on 0141 225 6999 or email contactpublicinvolvement.his@nhs.net

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