The Scottish Medicines Consortium (SMC) is part of Healthcare Improvement Scotland. We advise the 14 NHS boards in NHSScotland on the clinical and cost effectiveness of all new medicines, based on early health technology assessment of a submission from the sponsor pharmaceutical company.

In 2013, the Scottish Government conducted a review on patient access to new medicines. As a consequence, SMC was asked to implement a series of recommendations to increase transparency, give patients and their representatives a greater role, and increase access to new medicines. We outline here the changes made and their impact to date.

Methods

The key changes implemented were:

- appointing a public involvement team
- conducting a stakeholder review of key processes in public involvement work
- establishing a Public Involvement Network group to advise SMC on best practice in public involvement
- holding SMC meetings in public
- introducing more flexible processes for assessing for medicines for end of life and rare conditions
- developing a new framework for assessing ultra-orphan medicines, and
- involving pharmaceutical company representatives in discussions about their submission.

Aims/Objectives

The aims of the project were to:

- give the public a stronger voice in the assessment of medicines for end of life and rare conditions
- increase transparency of SMC processes
- develop a refreshed process for patient group submissions on new medicines
- proactively engage with patient groups
- develop a more flexible process for considering medicines to treat end of life and rare conditions – the Patient and Clinician Engagement (PACE) process, and
- establish processes for holding SMC meetings in public.

Results

- SMC meetings now held in public. Private sessions to discuss commercial in confidence information kept to a minimum.
- Increased number of patient group submissions (see Figure 2).
- 48 end of life/orphan medicines assessed with input from the new PACE process (August 2014 –April 2016); 35 accepted for use and 13 not recommended.
- Pharmaceutical company representatives at SMC meetings since November 2014.
- Following the appointment of the public involvement team, SMC works more closely with patient groups.
- Early experience suggests changes are increasing transparency, giving patient groups a stronger voice in decision-making and leading to an increased acceptance rate for medicines used at the end of life and for very rare conditions.

Patient and Clinician Engagement Process

The aim of the PACE process is to explore the added benefits of the medicine, from patient, carer and clinician perspectives, that may not be fully captured within the conventional clinical and economic case.

The PACE meeting involves a round table discussion with patient representatives and healthcare professional experts focusing on how the medicine can:

- add value to the patient’s wellbeing and experience of care (for example, ability to work, impact on quality of life, symptom control), and
- add value for the patient’s family and/or carers (for example, impact on family life, impact on the carer’s ability to work).

The output from the PACE meeting is a consensus statement, provided to all committee members and presented at the meeting. This has a major influence on the SMC decision.

Historical data on acceptance rates show that over the period 2011-2013, over 50% of both orphan and cancer medicines were not recommended for use. An analysis of decisions on medicines considered under the PACE process from September 2014–February 2016 shows that 30 medicines (75%) have been accepted and 10 (25%) not recommended.

Conclusions

We have worked closely with key stakeholders, including patient groups, clinicians and the pharmaceutical industry, to introduce these changes. So far, experience suggests that we are meeting the desired objectives of increasing transparency and giving patients and their representatives a stronger voice in the decision-making process. Our analyses of data from the first year since the PACE process was introduced show an increased acceptance rate for end of life and orphan medicines. We will continue to develop and improve these changes over time.

References:


End of life - a medicine used to treat a condition at a stage that usually leads to death within 3 years with currently available treatments

Orphan - 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

Ultra-orphan - a medicine used to treat a condition with a prevalence of 1 in 50,000 or less (100 people or less in Scotland)

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