PACE – Patient and Clinician Engagement

This factsheet is to help explain what to expect from the Patient and Clinician Engagement (PACE) process, part of the Scottish Medicines Consortium assessment process for new medicines. This information is for anyone who may be able to help us by taking part in PACE. Our Public Involvement Team is available to help guide and support you through the PACE process.

About the Scottish Medicines Consortium

The Scottish Medicines Consortium is part of Healthcare Improvement Scotland. Our role is to provide advice to the NHS in Scotland about the clinical and cost-effectiveness of new medicines. This includes:

- How well the medicine works.
- Which patients would benefit from receiving the medicine.
- How well the medicine works and how safe it is to use compared to currently used treatments.
- How taking the medicine affects the quality of a patient’s life.
- How much the medicine costs compared to the other treatment options.

We review new medicines, new ways to use existing medicines, and new formulations of existing medicines. Most new medicines have to be approved by the SMC before doctors are able to use them routinely in the NHS in Scotland.

Each assessment is carried out by our team of pharmacists and health economists, who evaluate the evidence provided by the pharmaceutical company which has produced the medicine. The results of this evaluation are then carefully looked at by our New Drugs Committee (NDC), which considers only the scientific evidence, and writes a detailed advice document (DAD). This document is presented and discussed at the SMC meeting.

We also gather information from patient groups and the voluntary sector about how people are affected by the condition and the impact of the new medicine on patients and their carers. This information is also presented and discussed at the SMC meeting.

SMC has around 40 members who are mostly volunteers. Membership is made up of key experts from every Health Board area in Scotland. This includes: doctors, pharmacists, senior managers from Health Boards, public partner members as well as representatives from the Association of the British Pharmaceutical Industry (ABPI). The wide mixture of backgrounds helps to make sure that decisions are made from a broad perspective, not simply from a clinical viewpoint. SMC considers all the evidence and decides whether or not to approve the medicine for use in NHS Scotland, and any conditions for use. The process usually takes around 18 weeks to complete.

For more detailed information regarding the assessment process please see our website at: www.scottishmedicines.org.uk
What is PACE?

PACE is a stage in the SMC assessment process. It can be used to allow a more flexible approach to considering medicines for either end of life treatment\(^1\) or very rare conditions (called orphan or ultra orphan medicines)\(^2\). The main part of the PACE process is a meeting which brings together patient representatives and healthcare professional experts. The purpose of the PACE meeting is to gather detailed information which will allow 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.

When is PACE used?

It can be used when the New Drugs Committee (NDC) is not able to recommend a medicine from review of the scientific evidence. The information gathered during the PACE meeting is collated and then presented at the main SMC meeting. This helps the SMC committee to make a decision that takes greater account of the patient and clinician perspective.

How does the process work?

Pharmaceutical companies are asked to say in their submission to SMC whether the medicine is for end of life care or for a very rare condition. They are asked to provide evidence for this.

The medicine is then evaluated by the New Drugs Committee in the usual way. If the NDC advice is not recommended, or if it is accepted with restrictions, the pharmaceutical company that produces the medicine can ask for a PACE meeting.

There is also an opportunity at this time for the company to offer a new or revised Patient Access Scheme aimed at making their product better value for the NHS in Scotland.

Information gathered during the PACE meeting will then be presented as part of the main SMC committee meeting, along with the NDC Detailed Advice Document and other relevant information.

Who can take part in a PACE meeting?

The following representatives are invited to take part in the PACE meeting:

- Patient and/or carer representatives from the relevant patient groups (up to two representatives per meeting patient group).
- Clinical expert advisors (nominated by clinical networks - up to three representatives per meeting).
- SMC Public Partner.
- SMC Public Involvement Team member.
- SMC New Drugs Committee member.

Where there is no obvious patient group for a specific medicine (e.g. for very rare conditions) we work with Rare Diseases UK and the Genetic Alliance to ensure that the interests of patients and carers are represented as fully as possible. On some occasions where we have been unable to source a patient/carer representative, a representative from Rare Diseases UK or the Genetic Alliance has been asked to attend PACE to represent the patient/carer voice.

If a patient group or voluntary organisation is not registered with these organisations, then the SMC Public Involvement Team will contact organisations who represent the particular patient group.

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\(^1\) End of life medicine is used to treat a condition at a stage that usually leads to death within three years with currently available treatments.

\(^2\) Orphan medicine is used to treat a condition which affects less than 2,500 in 5 million people. Ultra-orphan medicine is used to treat a condition which affects 1 in 50,000 people or less.
The meeting are chaired by the New Drugs Committee vice-chair. Those taking part in the meeting will include a public partner and a member of the Public Involvement Team. We work with managed clinical networks throughout Scotland to identify suitable clinical expert advisers. These are likely to be consultant level doctors, however, when appropriate, we have also invited clinical nurse specialists or clinical pharmacists to attend PACE.

There is no physical representation from the pharmaceutical industry at the meeting but the manufacturer of the medicine under review is able to send in a short statement to be considered at the meeting.

**Declarations of Interest and Confidentiality**

Those who take part in the PACE meeting must declare any conflicts of interest to ensure the transparency of the meeting. A confidentiality agreement must also be signed as information provided for the PACE meeting must remain confidential.

Occasionally SMC is asked to provide details of any interests held by participants in meetings that contribute to the assessment process. SMC will never issue any information that reveals personal medical information about a patient, however under Freedom of Information requests we are obliged to reveal details of any interests held by employees, office bearers and/or board members of patient groups.

**What preparation is needed before a PACE meeting?**

The PACE meeting involves going through a standard set of questions which includes how the medicine helps a patient’s quality of life and how it impacts on a patient's family or carers. The group discusses issues such as unmet need, severity of the condition, specific patient groups that may benefit more from the use of the medicine and where in the patient pathway the medicine could most appropriately be used. You can see the full list of questions discussed [here](#).

If a voluntary organisation submission for the medicine has already been forwarded to SMC then this is included in the PACE meeting papers. Expert advisers also have the option of completing a short statement focusing on the above questions prior to the meeting if they wish. Either way, it is important that you gather evidence to support the above issues before coming along to the meeting. Concentrate on quality of life issues which could be improved by taking the medicine compared to current treatment options, such as:

1. The ability to continue work or education.
2. The management of symptoms such as: pain and extreme tiredness.
3. Helping relieve psychological distress.
4. Convenience of how and where the treatment is received.
5. The ability to self-care or maintain independence and dignity.

There may already be evidence available to support the possible impact of a medicine on a patient’s life. We will need a short statement highlighting key issues before the meeting. Where possible, we will use information already supplied through a voluntary organisation submission.

**Our Public Involvement Team is available support and advise you on ways to prepare for the meeting. You will be able to meet with a member of the team, who can go over the requirements of PACE and help further explain what to expect from the process.**

**How much time will I have to prepare for the PACE meeting?**

A PACE meeting date will be set as soon as we have scheduled a submission from a pharmaceutical company. We will then contact everyone who may be needed for the PACE meeting. We will confirm whether the meeting is needed following negative advice from the New Drugs Committee and after the company has confirmed that they wish SMC to convene a PACE meeting (around nine weeks after submission date). You will have one month from this date to prepare for the PACE meeting, although if you wish to submit a short statement (described above) we will need this two weeks before the meeting.
When will the PACE meeting take place?
PACE meetings take place on the second Tuesday of each month in the SMC offices in Glasgow.

What happens during the PACE meeting?
The chairperson of the PACE group will guide everyone through the standard questions. There will be a discussion for each question and the views of all participants will be noted.

A summary of the discussions will be completed in the format of a template and the content agreed by group members.

After the PACE Meeting
The completed PACE group template is included in the SMC meeting papers for the medicine alongside the NDC Detailed Advice Document, company comments, voluntary organisation submission(s) and any new or revised Patient Access Scheme submission.

The information from the PACE group is a major factor in the SMC committee’s decision on whether they are able to accept the medicine.

Those who attended the PACE meeting can register to attend the SMC meeting where the medicine will be considered, as a member of the public gallery.

If you would like any further information please don’t hesitate to contact our Public Involvement Team on: 0141 414 2403 or email: hcis.SMCPublicInvolvement@nhs.net