

Attending a Patient and Clinician Engagement (PACE) meeting

Information for participating patient group partners

What is PACE?

PACE (Patient and Clinician Engagement) is a step in the SMC assessment process for medicines for end of life or very rare conditions (called orphan or ultra orphan medicines). It gives patient groups and clinicians a stronger voice in SMC decision making when these kinds of medicines are being considered. The PACE meeting brings together patient group representatives and clinical experts to discuss the severity of the condition and how it impacts on a patient's quality of life and on a patient's family or carers.

Patient group representatives are central to the PACE process. Their role during a PACE meeting is to describe the impact of a condition on quality of life to patients and carers and any improvements the new medicine could bring.

An agreed statement (the PACE template) is generated through discussions at the PACE meeting, a summary of which is then presented at the SMC committee meeting. The full document is included in committee members' papers. This helps SMC committee members to make a fully informed decision about the medicine, which takes greater account of the patient, carer and clinician perspective.

How does PACE work?

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

All medicines are initially assessed by the New Drugs Committee (NDC), who consider the evidence provided by the submitting pharmaceutical company along with clinical expert views.

If the NDC preliminary advice is that an end of life medicine or a medicine for a rare condition is not recommended, then the company is offered the opportunity for a PACE meeting.

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

A summary of the agreed PACE statement is presented as part of the main SMC committee meeting, along with the evidence considered by NDC, the NDC preliminary advice as presented in the detailed advice document (DAD), patient and carer impact quotes provided in patient group submissions, and other relevant information.

Who can participate in a PACE meeting?

PACE meetings are usually chaired by an NDC vice chair and involve the following participants:

- up to two patient/carer representatives, per participating patient group partner organisation
- clinical expert advisors* (nominated through clinical networks)
- SMC pharmacist
- SMC Public Involvement team member
- SMC public partner, and
- lead industry representative for SMC (observer).

*Clinical expert advisors are likely to be consultant level doctors, however clinical nurse specialists and clinical pharmacists can also participate.

While there is no physical representation from the pharmaceutical company at the PACE meeting, the company provides a written statement which is part of the evidence considered by PACE participants.

How are patients and carers appropriately represented at a PACE meeting?

SMC works in partnership with patient groups from around the country to capture patient and carer experiences. We actively seek to source relevant patient groups for every medicine which is assessed, and work with all registered patient groups, from small local support groups to large national voluntary organisations.

To take part in the SMC review process patient groups must first register as an SMC patient group partner. This is very straightforward to do. You complete a simple registration form, providing details about your patient group. This is a one-off process and the details can be updated as required. We will contact you each year to request an update.

Representatives from relevant registered patient group partner organisations are invited to participate in a PACE meeting. It is the responsibility of the patient group partner to ensure the most appropriate representative/s from their organisation attend the meeting. This may be either a member of staff, volunteer, or patient advocate. All participants should have good knowledge of the condition and medicine which is being assessed.

Please note that any participating patient and carer representatives must be actively connected to the patient group, for example, they could be supported by the patient group, be a member of the patient group, or serve in an ambassadorial role.

Do I have to complete any documentation before the meeting?

PACE attendees are required to complete a declaration of interest and code of patient and carer practice forms in advance of receiving the paperwork for the meeting.

You will have completed your patient group submission for the medicine several weeks before the PACE meeting and will have the opportunity to submit an additional patient group PACE statement if you wish.

How many people can participate from my Patient Group?

Up to two representatives from each participating patient group partner organisation may participate in the PACE meeting.

What if I am unable to participate in the meeting?

We strongly encourage participation at a PACE meeting, either in person, or via teleconference. However, we understand that this is not always possible. Patient group information is actively sought and incorporated in advance of the meeting. Therefore, if you are unable to participate personally, your submission will still be included in the PACE meeting papers.

Please inform the Public Involvement team as soon as possible if you are unable to join the meeting.

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

A PACE meeting date will be set as soon as we begin assessing a submission from a pharmaceutical company. We will contact everyone who may be needed for the PACE meeting following preliminary not recommended advice from the NDC and after the company has confirmed that they wish SMC to convene a PACE meeting. You will have approximately one month from this date to prepare for the PACE meeting.

What preparation is needed before a PACE meeting?

The PACE meeting is a structured discussion to describe the severity of the condition and how it impacts on a patient's quality of life and on a patient's family or carers. The meeting explores any potential benefits not already fully captured in the assessment and discusses issues such as; how this medicine may address an unmet need; are there 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.

Patient Group Submissions, along with written statements from participating clinical experts, focusing on the above issues, are included in the PACE meeting papers. You can also provide an additional written Patient Group PACE statement in advance of the meeting, if there are any additional key points which are not included in your Patient Group Submission, or if the Patient Group Partner organisation you are representing has been unable to provide a Patient Group Submission. These will help to inform discussions during the meeting.

Do I receive any paperwork in advance of the meeting?

All participants receive the following confidential meeting papers in advance of the meeting:

- New Drugs Committee (NDC) detailed advice document DAD (any commercial in confidence information will be blacked out)
- patient group submission forms
- patient group partner registration forms
- completed declaration of interest forms
- clinician PACE statements.
- SMC clinical expert responses.

- pharmaceutical company PACE statement (from the submitting pharmaceutical company), and
- PACE meeting template.

What is the format of a PACE meeting?

The chair of PACE, along with the SMC Public Involvement team, strive to make each PACE meeting welcoming, supportive and engaging. Each PACE meetings lasts for approximately one hour.

The chair will welcome all participants and introductions will be made. You will have provided details of declarations of interest in advance, but the chair will ask if there have been any recent updates on the information provided.

The patient group representatives are first on the agenda to participate. The chair will ask you to speak for a few minutes to set the scene as an introduction to the meeting, focussing on the impact of the condition to quality of life and the potential value the medicine could have for both patients and carers. It is very important to be as focussed as possible and some participants prefer to have prompts, bullet points or a short script to talk from.

It is important that you concentrate on quality of life issues which could be improved by taking the medicine compared to current treatment options.

Once you have finished speaking, the chair may ask you to expand on certain points or to clarify information you have shared. The chair will also ask if there are questions from the other PACE participants. The chair will then turn to the clinicians and ask them to speak about the condition from a medical/treatment perspective.

It is not the intention of the meeting to go through your submission, or the clinical and economic case in any detail, as it is more important that the time is used to focus on the key benefits of the new medicine and reach agreement on these.

Discussion and consensus in the meeting informs the development of a structured PACE template. This is achieved by participants working through a standard set of questions (you are sent the template with your meeting papers) which includes how the medicine may help a patient's quality of life and how it could impact on a patient's family or carers.

The pharmacist will record all relevant points. Towards the end of discussions, they will read the key points from the meeting back to participants and note any suggested amendments you may have. Participants will also be asked to highlight what they think are the most important points from the discussion.

Before closing the meeting, the chair will ask if you feel that you have had sufficient opportunity to contribute to the discussion.

The PACE participants are not required to reach a decision on the medicine as SMC is the decision-making body and so the decision rests with them. The PACE statement will be included in the SMC meeting papers and will have a significant influence on the SMC decision.

The key points highlighted by participants will also be summarised and presented verbally at the SMC Committee meeting.

Can I speak to someone about how the meeting works beforehand?

The SMC Public Involvement team is available to support and advise you throughout the PACE process. You are encouraged to contact the Public Involvement team at any time if you have any questions about the PACE meeting. A member of the Public Involvement team will also be present during the meeting to provide any assistance you may require.

We can also arrange for you to speak to one of our PACE mentors. PACE mentors are fellow patient group partners who volunteer to offer support on a one to one basis. All PACE mentors are very experienced in participating in PACE meetings and can help prepare patient group representatives who are new to PACE, providing information and advice based on the mentor's own experience of participating in the process.

What time should I arrive?

Please arrive promptly 10 minutes before the meeting begins.

What will happen when I arrive at the meeting?

On arrival, you will be welcomed by a member of the SMC Public Involvement team who will introduce themselves and answer any questions or queries you may have before the meeting begins.

What facilities are there to accommodate people with disabilities?

Wheelchair users have direct access to the venue from the street. If you are a wheelchair user, have walking difficulties or require use of an induction loop, please contact us so we can ensure appropriate support is in place.

Will refreshments be provided?

Tea, coffee and water will be provided at the meeting.

What happens after the PACE meeting?

The draft PACE template will be sent to all participants for correction of any factual inaccuracies only – it is not an opportunity to add any new information. There is a very tight turnaround for finalisation of this document as it is included in the SMC Committee papers for the next month's meeting. The exact timelines will be explained to you during the meeting.

The final PACE template will also be sent to the submitting company for information.

The Public Involvement team will contact you following the PACE meeting to offer you the opportunity to participate in the SMC Committee meeting, which usually takes place around three weeks after the PACE meeting.

One representative per submitting patient group can participate at the SMC Committee meeting during discussions for the medicine for which they have provided a submission. This must be the named main contact on the patient group submission form. One other representative from your patient group will be able to register to attend the meeting as a public observer, sitting in the public gallery.

Will I be able to claim expenses to attend a PACE meeting?

You can claim reasonable standard class travel to attend a PACE meeting. If you are planning to claim for any travel, this must be agreed with SMC in advance of the meeting. For further details about claiming expenses please speak to the Public Involvement team.

Feedback and evaluation

As part of Healthcare Improvement Scotland, SMC is committed to continuous improvement. The Public Involvement team will send you an online survey link following the SMC meeting, asking for your opinions on the experience of participating in the SMC assessment of the medicine.

We encourage you to provide honest feedback to help us review and continually improve this process.

If you have any questions, please contact the Public Involvement team:

Email: hcis.SMCPublicInvolvement@nhs.net

Telephone: 0141 414 2403