

Attending a virtual 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 family and 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 (using a 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.

Please note that medicines which have been validated as eligible for the ultra-orphan pathway follow a different process. A PACE meeting is not held during the initial SMC assessment as SMC is not making a decision at this time. A PACE meeting may be convened during the ultra-orphan reassessment following evidence generation. For further information please speak to the Public Involvement Team.

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 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.

After the PACE meeting, 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.

How do I join a PACE meeting?

PACE meetings are now being held virtually using Microsoft Teams.

If you already have an MS Teams account, select the meeting invite from your calendar or email with the meeting details and papers and click on 'Join Microsoft Teams Meeting'.

You can then choose the audio and video settings you want. Once you have done this, select 'Join now'. This will bring you into the meeting lobby. The meeting organizer will be notified that you're there, and will admit you to the meeting.

Do I need an MS Teams account to participate in the meeting?

You can join a Teams meeting whether or not you have an MS Teams account.

If you don't have an MS Teams account, to join, go to the meeting invite and select 'Join Microsoft Teams Meeting'. A web page will then open, where you'll see two choices: 'Download the Windows app' and 'Join on the web instead'. If you join on the web, you can use either Microsoft Edge or Google Chrome.

Your browser may ask if it is okay for Teams to use your mic and camera. You will need to allow this so you'll be seen and heard in the meeting.

Enter your name and choose your audio and video settings. When you're ready, hit 'Join now'. This will bring you into the meeting lobby. The meeting organizer will be notified that you're there, and will admit you to the meeting.

Do I need a computer or laptop to join an MS Teams meeting?

You can also join an MS Teams meeting using a mobile phone.

If you don't already have the MS Teams app, please download this from your app store. You can then open the app directly from the app store page.

MS Teams will ask if it's okay to use your mic, be sure to allow it so others in the meeting will be able to hear you. You will then be given two options for joining your meeting: 'Join as a guest' or 'Sign in and join'. Please choose 'Join as a guest'. You will be prompted to enter your name and then to select 'Join now'. This will bring you into the meeting lobby. The meeting organizer will be notified that you're there, and will admit you to the meeting.

What time should I join the meeting?

Please join the meeting a few minutes before the start time. Please also make sure that both your camera and microphone are on and you can be seen and heard at this time.

What if I have problems joining?

If you have any problems joining the meeting, please contact the meeting organiser who will be able to assist you.

Who participates 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

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

Whilst 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 across the UK 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.

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.

All 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. 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 patient group 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 provisional PACE meeting date will be set as soon as we begin assessing a submission from a pharmaceutical company. To assist with diary planning and to ensure participation, submitting patient groups will be made aware of this provisional date once their patient group submission has been finalised. We will then 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 usually 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 conventional clinical and economic assessment process and discusses issues such as; how this medicine may address an unmet need.

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 optional 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:

- 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.
- Company PACE statement (from the submitting pharmaceutical company).
- PACE meeting template (blank).

What is the format of a PACE meeting?

The PACE Chair, along with the SMC Public Involvement Team, strive to make each PACE meeting welcoming, supportive and engaging. Each PACE meeting lasts for approximately one hour. **Please keep your camera on and mute your microphone if you are not speaking, for the duration of the meeting.**

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, focusing on the impact of the condition to quality of life and the potential value the medicine could have for both patients and

families/carers. It is very important to be as focused 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 clinical experts 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 meeting statement. This is achieved by participants working through a standard set of questions (you are sent a blank 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 the SMC Committee is the decision-making body and the decision rests with them. The PACE statement will be included in the SMC Committee 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 them 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.

What if I have accessibility requirements?

If you have any accessibility requirements which need to be considered, please let a member of the Public Involvement Team know in advance of the meeting so they can try and make appropriate arrangements for you.

What happens after the PACE meeting?

The draft PACE meeting statement 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 when the medicine will be discussed. 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. Other representatives from your patient group will be able to register to attend the meeting as public observer. The SMC Committee meeting is also held virtually.

Feedback and evaluation

As part of Healthcare Improvement Scotland SMC is committed to continuous improvement. All clinicians and patient groups are encouraged to provide feedback regarding their involvement in PACE. A link to an e-survey is included in the email sent to you with the final PACE statement. 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: his.smcpublicinvolvement@nhs.scot

You may find it helpful to view this [short video](#) of a Patient Group Partner explaining their experience of participating at a PACE meeting.