

Attending a Scottish Medicines Consortium (SMC) meeting

Information for participating Patient Group Partners

SMC Committee Meetings

As part of Healthcare Improvement Scotland, SMC's role is to provide robust, carefully considered advice to NHS Boards, to ensure new medicines, which are clinically and cost effective, are available for routine use by the people of Scotland.

The SMC Committee meeting is the final stage of the SMC medicine appraisal process. The committee is made up mainly of clinicians and managers from across NHS Scotland, along with specially trained members of the public (called Public Partners) and the pharmaceutical industry. The Chair of SMC is a practising NHS clinician.

The meeting has a formal tone and occasionally may involve difficult discussions on new medicines and the best allocation of resources for NHS Scotland.

SMC Committee meetings are open to members of the public to observe. Registration must be completed in advance of the meeting, through the SMC website: www.scottishmedicines.org.uk

Patient Group Partner Participation

One representative per submitting patient group is able to participate at the SMC committee meeting, during discussions for the medicine for which they provided a submission. Their role is to answer questions from committee members, relating to patient and carer issues, and provide points of clarity relating to their Patient Group submission, as required. This must be the named main contact on the Patient Group submission form and this person must have an in-depth understanding of the information provided on the form. For joint Patient Group submissions, one representative per named registered Patient Group Partner is able to participate. 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. However, they will not be able to join you at the committee table to participate in discussions.

Please note that for medicines which the SMC New Drugs Committee's (NDC) preliminary advice is accepted, there will be a more concise presentation of the evidence. As there are few uncertainties about the medicine, it is also unlikely that many questions will be asked during discussions.

What information is assessed at the meeting?

The assessment process starts several months before the committee meeting, when the pharmaceutical company makes its submission for a new medicine. Each new medicine submission is analysed by pharmacists, health economists and clinical experts before it is discussed by the New Drugs Committee (NDC). The NDC focuses on the clinical and cost effectiveness of new medicine. After the NDC meeting the submitting company is given an opportunity to comment on the preliminary advice. At the SMC meeting you will hear the outcome of the NDC discussions in a presentation from an NDC member. If the medicine is for an end of life or very rare condition, you will also hear a statement from the Patient and Clinician Engagement (PACE) meeting. This will be followed by a presentation by a member of the SMC Public Involvement Team, who will present a collated summary of all Patient Group submissions for the medicine.

There are usually between five and seven full medicine submissions considered at each committee meeting.

What is my role as a participating patient group representative?

At the start of the meeting you will be seated in the public gallery. At the beginning of discussions about the medicine for which you provided a submission, the Chair will invite you to join the committee table. You will be seated beside a member of the Public Involvement Team, to whom you will have been previously introduced. This person is there to support you throughout your time at the committee table. The Chair will ask you to introduce yourself at the start of discussions.

If a committee member has a question regarding patient or carer impact that they would like to ask you, they will ask permission from the Chair for the question to be asked. If the question is appropriate, the Chair will invite you to answer. It is very important that you have an in-depth knowledge and understanding of your Patient Group submission to SMC, as questions asked by committee are likely to be directly related to this.

Please do not speak during discussions, unless invited by the Chair. This is to ensure that business is conducted efficiently. Committee members may not need to ask questions about the information in your Patient Group submission. Some of the discussions may be very technical in nature. You are not expected to have a working knowledge of, for example, the health economics around the medicine for which you have made a submission, or to comment on them.

When consideration of the medicine is coming to an end, the Chair will ask you if you are content with the accuracy of discussions and if you would like to provide any additional points of clarity relating to the medicine. **You are not permitted to add any new information at this point, unless it is to provide clarity on a particular point or to answer a specific question.** When all discussions about the medicine are finished, the Chair will ask you to return to the public gallery, before committee members vote*.

*** Please note that medicines which are being assessed for the first time using the ultra-orphan pathway follow a different process. SMC is not making a decision at this time, therefore following discussions about the medicine there is no vote. For further information please contact the Public Involvement team.**

What if I am unable to attend the meeting?

We understand that it is not always possible for patient groups to send a representative to attend the SMC Committee Meeting. Patient Group information is actively sought and incorporated in advance of the meeting. Therefore, if you are unable to attend personally, your submission will still be included in the members' meeting papers, presented by the Public Involvement Team, and will form a key part of the decision making process.

Who will be there to help me?

One of the SMC Public Involvement Team will be available to provide information and guidance to you in advance of the meeting. They will also introduce themselves to you before the meeting starts and sit alongside you at the committee table. If you are unsure of any aspect of your role or contribution to the meeting please let a member of the team know and they will assist you.

What time should I arrive and do I need to stay for the entire meeting?

Please arrive promptly at 12noon. If you are not present for the start of the meeting you must wait for an appropriate interval to enter the meeting room. If you would like to leave before the end of the meeting please wait until the designated break.

What will happen when I arrive at the meeting?

On arrival, you will be welcomed by a member of the SMC secretariat, who will explain how the meeting will work. This person will be your point of contact throughout the afternoon and will deal with any queries you may have. A public attendees' room within the meeting venue is provided for you to use before the SMC meeting and during the break.

One of the Public Involvement Team will also introduce themselves at this time and be able to answer any questions you may have.

Will committee papers be provided for the committee meeting?

Each committee member is issued with extensive supporting paperwork for each submission. This includes a detailed analysis of the clinical and cost effectiveness of the medicine, along with all Patient Group submission forms, Patient Group Partner registration forms, and feedback from expert clinical advisors. It also contains information the submitting pharmaceutical company has identified as confidential, so we are only able to provide it to members of SMC Committee.

You will be supplied with an information pack containing a draft copy of the summary assessment for each medicine, with any academic or commercial in confidence information blacked out.

This pack must not be taken from the meeting room and must be returned to a member of the SMC secretariat when you leave the meeting.

Will refreshments be provided?

Tea, coffee and water will be provided before the meeting and during the break. Water is also available in the SMC meeting room. You are welcome to bring refreshments/lunch into the public attendees' room.

Who will be at the meeting?

In addition to the SMC Committee members, members of SMC staff involved in running the meeting and supporting the Chair will also be in attendance. Invited observers may also be present.

The submitting manufacturer is also invited to participate in SMC committee meetings to respond to specific queries about the clinical and health economic evidence for their submission.

SMC Committee meetings are open for members of the public to register to attend.

How long will the meeting last?

The Chair will outline the agenda for the day at the start of the meeting but is difficult to know how long it will take to discuss each medicine or when a meeting will end. The presentation and discussion of each medicine usually takes around 30 minutes, although this is variable.

Will I be able to listen to all the discussions?

SMC is fully committed to holding its meetings in public and we would like as much of the meeting as possible to take place with the public present. However, on occasion part of the discussions for a specific medicine may require a closed session. This is mainly because we have a legal obligation to maintain the academic and commercial confidentiality of any information identified as such by the submitting company. This is standard practice in all health technology assessment organisations in the UK. Public disclosure of this information could negatively impact a company's commercial interests (e.g. share prices) or the academic interests of a research or professional organisation. The Chair may declare, or be asked by a committee member to declare, a closed session, allowing detailed discussion of this confidential material. You will be asked to leave the meeting room temporarily while this takes place, and go to the public attendees' room. You will re-join the meeting when the confidential discussion has been completed.

Some submissions have a Patient Access Schemes (PAS), where the company makes the medicine available to NHS Scotland through a scheme that generally involves a confidential discount on the price of the medicine. We are not allowed to discuss details of the PAS in public, so the Chair may call for a closed session to discuss the specific details of a PAS.

Will the decision about the medicine be announced at the committee meeting?

This isn't possible as an announcement of the decision in public could have significant commercial risks. When the discussion for each submission has ended, the Chair will ask each committee member to record their vote on whether or not to accept the medicine on a voting paper. The votes

will be counted and the decision announced by the SMC Chair in a closed session later in the meeting. You will not hear the decision on the day of the meeting.

When will the final SMC advice be published?

On the Friday following the SMC meeting, the submitting company is sent a summary document informing them, in confidence, of SMC's decision. NHS Boards are also informed of the advice, in confidence, at this stage.

Submitting Patient Group Partners are provided with the SMC decision, under embargo, five days before the information is made public. This is in strict confidence and is to enable you to prepare any advisory services you may provide for patients and carers.

The decision is not made public until approximately four weeks after the SMC meeting when it is published on the SMC website. This period allows NHS Boards to prepare and, where relevant, comparator companies to review statements about their product in the advice.

Can I talk to members of the committee?

The role of SMC members is to make an independent assessment of the evidence. It is very important that no one tries to influence an individual committee member during the meeting, the breaks or outside the meeting on any topics that are under discussion. Patient group representatives are required to use the public attendees' room before the meeting and during the break.

Can I take notes at the committee meeting?

You may take notes, but the use of laptops or other electronic devices is only allowed to reference documents while you are sitting at the committee table and must be switched off at all other times. Committee meeting minutes will be published on the SMC website around four weeks after the meeting.

Can I quote or report what is said at a committee meeting?

This is a public meeting and what members say can be quoted after the meeting. We rely on a full and frank exchange of views to carry out our work and members of the committee will debate the evidence thoroughly. We ask Patient Group Partners to respect that it is important that committee members are able to speak freely without concern that they may be misquoted or that what they have said is taken and reported out of context.

Can I use social media during the meeting?

The use of mobile phones, and recording or live reporting of committee meeting proceedings, is not permitted during the committee meeting.

What facilities are there to accommodate people with disabilities?

Wheelchair users have direct access to the venue from the street. However, due to the venue's building regulations set by the fire service, there are limits on the number of people with mobility problems we can accommodate at meetings. If you are a wheelchair user or have walking difficulties, please contact the SMC secretariat so we can ensure appropriate support is in place.

The committee meeting room is fitted with an induction loop for people with hearing impairment. Please let us know in advance if you need to use it.

Can children attend committee meetings?

Children under the age of 16 cannot attend committee meetings.

Do I need to let you know if I am no longer able to attend a committee meeting?

Please let the Public Involvement Team know as soon as possible if you are unable to attend the meeting.

Will I be able to claim expenses to attend the meeting?

You are able to claim reasonable standard class travel to attend the 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 & evaluation

The Public Involvement Team will send you an online survey link following the meeting, asking for your opinions on the experience of participating in the SMC meeting. We encourage you to provide honest feedback to help us review and develop this process.

If you have any questions please contact the Public Involvement Team:

Email: hcis.SMCPublicInvolvement@nhs.net

Telephone: 0141 414 2403

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