

Attending a virtual SMC Committee Meeting

Information for participating Company Representatives

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 to ensure the best allocation of resources for NHS Scotland.

SMC Committee meetings were previously held at The Merchants House in Glasgow, however meetings were suspended in March 2020 in the early stages of the COVID-19 pandemic. The meetings resumed in August 2020 and are now being held virtually using Zoom. SMC Committee meetings are open to members of the public to observe. Registration is mandatory and must be completed in advance of the meeting, through the SMC website:

<https://www.scottishmedicines.org.uk/about-us/register-for-a-meeting/>

Company representative participation

Company representatives will be invited to participate in a meeting where a full submission or resubmission for one of their products is being considered. There is no obligation for the company to attend and non-attendance will not prejudice the review. The submitting company will receive an invitation to attend the SMC meeting which will include the deadline for company representatives to register for the meeting.

SMC allows a maximum of two company representatives for each medicine under consideration. The role of the company representatives is to respond to specific inquiries and/or comment on any matters of factual accuracy as directed by the SMC Chair.

The company representative should:

1. Be an employee of, or be acting on behalf of the submitting company and ideally have been directly involved in the development of the company's submission
2. Have detailed knowledge of the product under consideration and be able to engage effectively with the SMC committee
3. Have a comprehensive understanding of SMC submission and decision making processes
4. Be able to comment accurately on the product's
 - a. Comparative efficacy
 - b. Comparative safety
 - c. Clinical effectiveness
 - d. Cost effectiveness
5. Agree to be bound by the terms and conditions of SMC's existing confidentiality policy regarding medicines under assessment.

NB: Submitting companies who provide two representatives to attend the meeting may not be granted additional places to attend as a public observer

SMC meetings routinely consider between 5-7 full submissions. As we are unable to specify timings for individual product discussions in advance, the company representatives will be invited to attend from the start of the Committee meeting. Company representatives have the option to leave the meeting after their agenda item has been discussed. They will receive a briefing prior to the meeting and may be asked for feedback following their attendance.

Company representatives will be invited to participate in the meeting at the point where their product is under discussion. The Chair will invite you to introduce yourself to the committee. Once introductions have been carried out, you will be placed on mute and the discussion will commence. You should keep your camera on throughout the discussion of the medicine.

If a committee member has a question that they would like to ask you, they will use the 'hand up' facility to ask permission from the Chair for the question to be asked. If the question is appropriate, the Chair will invite you to answer.

Please do not speak during discussions, unless invited by the Chair. This is to ensure that business is conducted efficiently.

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 thank you and you will then be placed back onto mute and your camera will be turned off again.

In the event of a closed session being required within the meeting, company representatives will normally **be asked to leave** the virtual meeting room although at the discretion of the Chair they may be asked to remain in the room for this part of the discussion to specifically respond to questions from committee members about confidential information in the company's submission.

At the time of the SMC meeting, the New Drugs Committee (NDC) has considered in detail the evidence submitted by the pharmaceutical company who has had the opportunity to respond with clarification, further analysis and comments on any weaknesses identified. SMC will consider NDC's preliminary recommendation together with clinical expert opinion, patient group contributions and, where relevant, the output of a Patient and Clinician Engagement (PACE) meeting. There is no requirement for members to repeat the detailed discussion held at NDC. The company response to the NDC preliminary recommendation is included in the meeting papers and reflected in the presentation given by the SMC team to committee members before the medicine is discussed.

SMC members will consider NDC's preliminary recommendation and seek clarification of any outstanding clinical or cost-effectiveness issues, consider the company response to the preliminary recommendation and take into account societal issues.

The presence of representatives from the submitting company provides a further opportunity for members to raise any outstanding points about the clinical and cost-effectiveness evidence that they feel the company has not adequately addressed in their submission or in the company comments after NDC. New evidence from the company is not admissible at this stage in the process. Company representatives should be aware that there may be no need for questions, if the submission is straightforward and there are no outstanding issues.

Company representatives will not be participants in the discussion on the submission. All questions for company representatives should be directed through the Chair and the company will be invited to respond at the Chair's discretion.

Members should not ask the company to answer questions that directly refer to commercial in confidence information, e.g. value of Patient Access Schemes, but they may ask the company about outstanding issues in relation to the clinical, economic or budget impact information within the submission or supporting documentation.

The submitting company delegates will be invited to respond and provide clarification of any outstanding issues. After all submissions have been discussed, a closed session will take place where members will vote. The decision for each medicine will be announced after the vote.

SMC meeting minutes will contain the names of the companies in attendance, but not the names of the individuals.

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.

When and how are virtual meetings held?

SMC Committee meetings take place on the first Tuesday of each month. The meetings are held virtually on Zoom - prior registration for meetings is mandatory. The meetings run from 12.30pm to 4.30pm (approximately).

If a meeting is cancelled or the time and/or location of a meeting changes, details of this will be published on the SMC website and we will let you know as quickly as possible.

How do I register for a meeting

To attend a virtual SMC Committee meeting you are required to register via the [SMC website](#). Your request to join a meeting will be confirmed the day prior to the meeting and you should retain your confirmation email containing joining instructions. The joining instructions are unique to each attendee and should not be shared with anyone as only one person can join a meeting per unique URL.

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

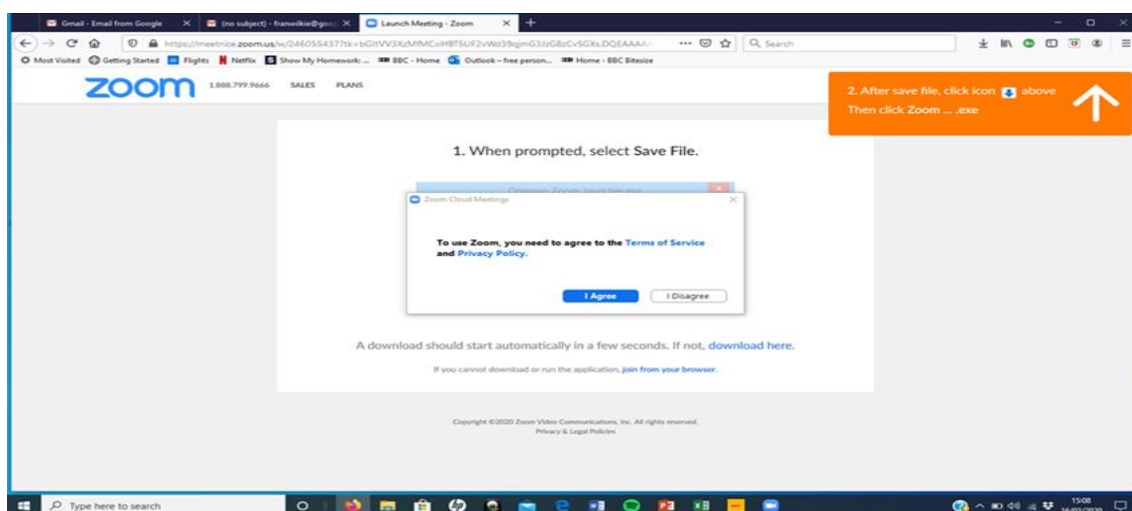
Although the meeting does not commence until 12.30pm, it is essential to join promptly at 12 noon. There are a series of security checks to run whilst attendees are held in a virtual meeting room followed by a number of briefings. If you would like to leave before the end of the meeting, please use the chat function to notify the co-host before leaving

How do I join the meeting?

Please refer to the email you received containing your unique joining instructions.

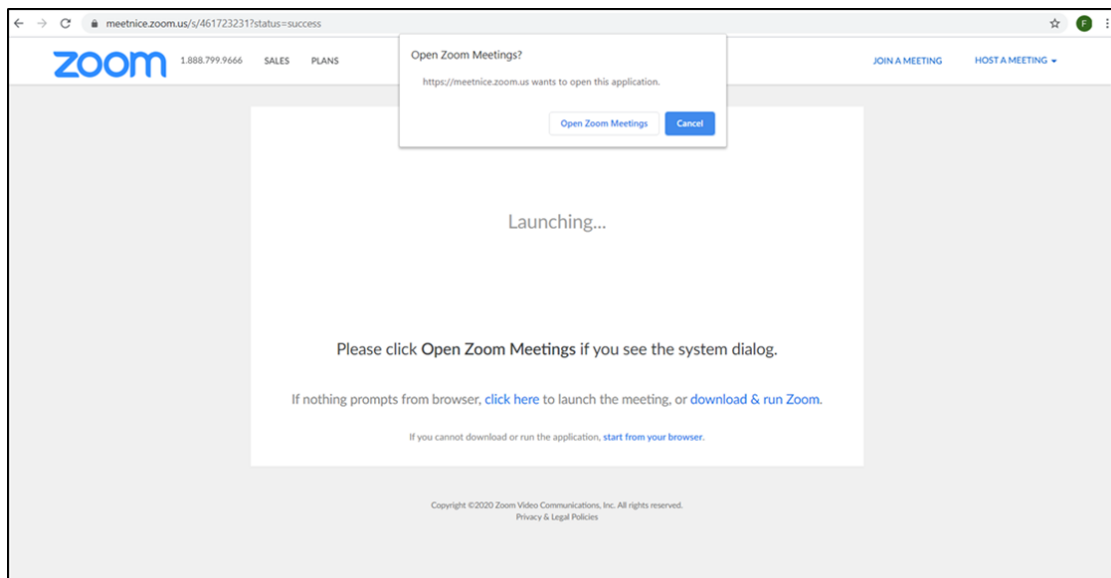
Click on (or copy and paste) the link in your confirmation email into your web browser. If you have not used Zoom before, you will see something similar to image 1. Click to agree to the Terms of Service and Privacy Policy then follow the on-screen instructions to save and run the file.

Image 1:



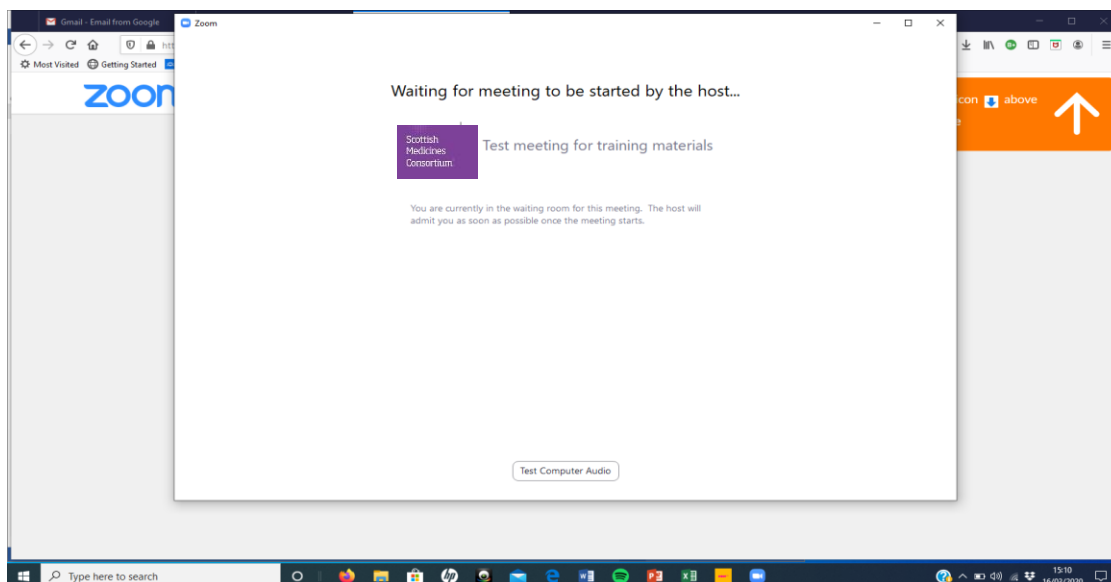
If you have used Zoom before, you should see a screen like image 2. Click on **Open Zoom Meetings**. If you do not see the **Open Zoom Meetings** pop-up box, use the links on your screen to launch the meeting.

Image 2:



Once Zoom opens, you should see a screen like image 3, telling you that you are waiting for the meeting to start. Your host will start the meeting at the appropriate time.

Image 3:

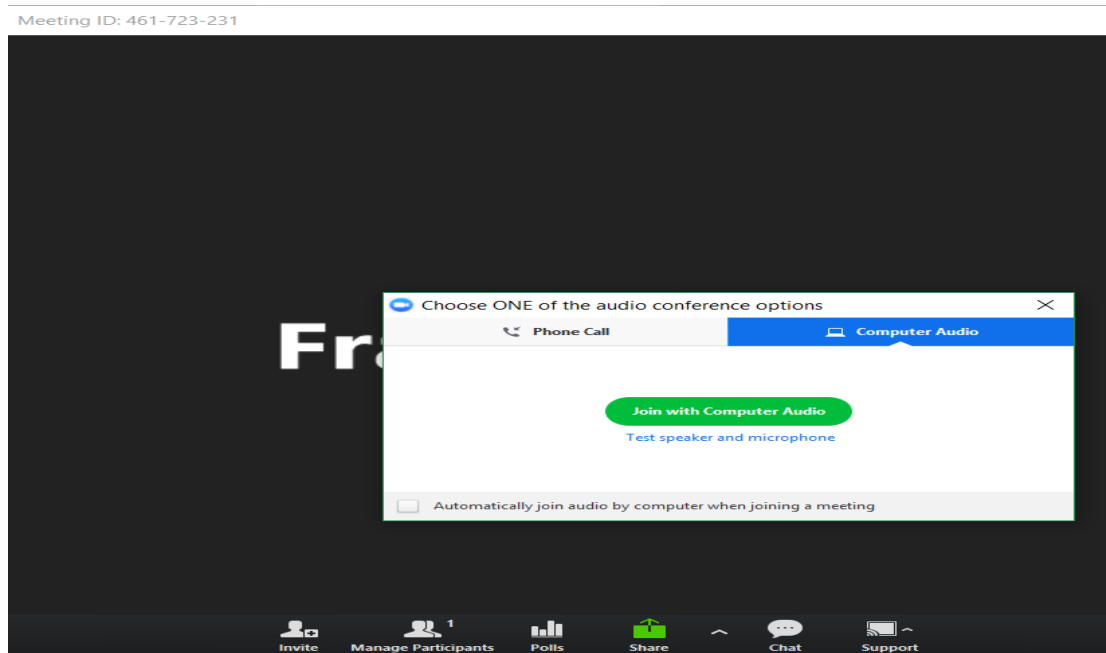


You should now see a screen like image 4. You are in the online meeting, but need to join the audio conference to hear what's being said. The easiest option is to join using your computer's audio. If

you have not used Zoom before and want to check if your computer has a microphone and speakers, click **Test speaker and microphone**.

NB: if you know your computer audio works, skip to image 6.

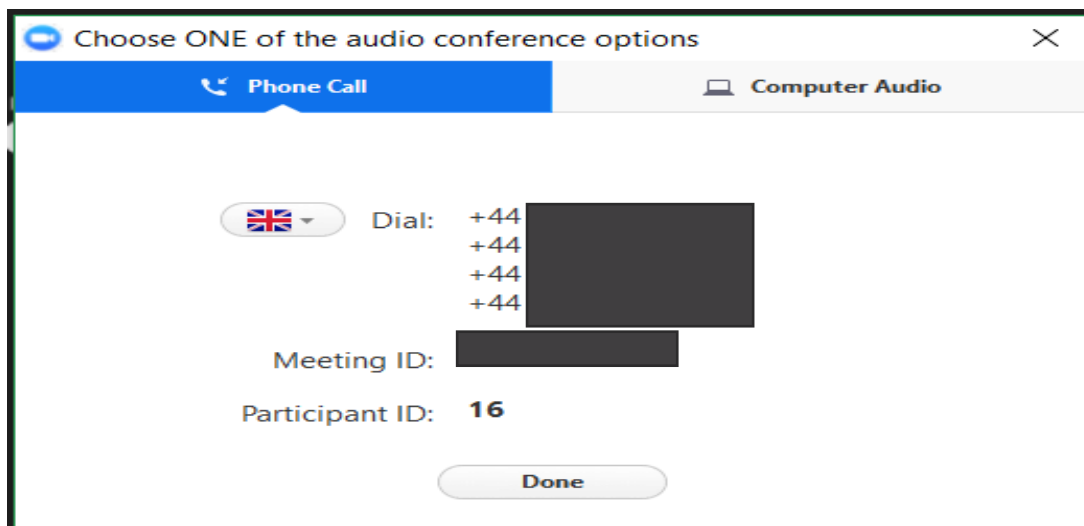
Image 4:



Follow the instructions on screen to test your microphone and speakers. If you hear both a ringtone, and then a replay of you speaking, you'll get a message to say your speaker and microphone 'look good'. Click on **Join with Computer Audio**. If you answered no to either question, you'll get a message saying they've tested – click on **Join Audio by Phone**.

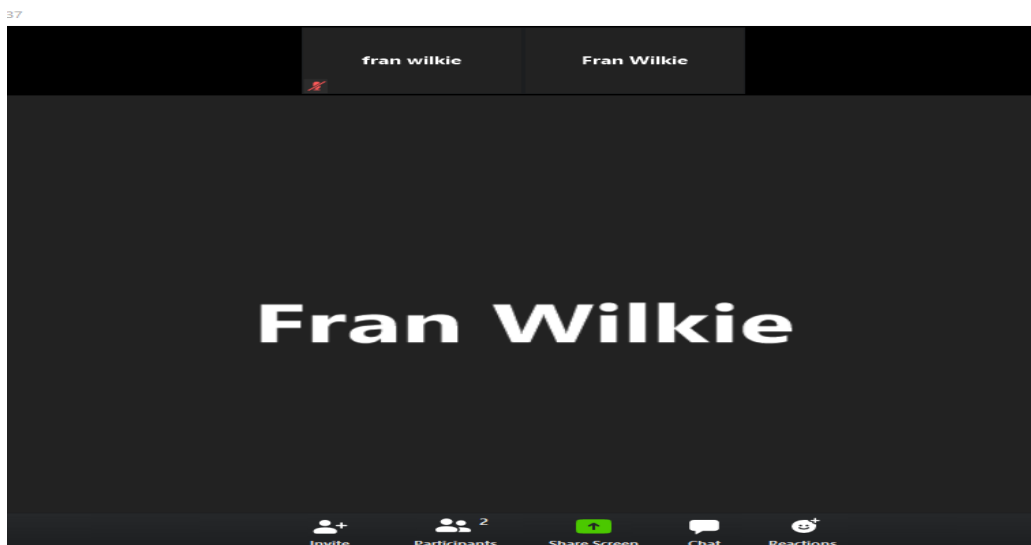
If you need to join using your phone, click on the Phone Call tab at the top of the box. Dial one of the numbers from your phone (image 5). Follow the prompts to enter the **Meeting ID** and your **Participant ID** on your phone's keypad and click the **Done** button. You can change your audio options at any point by clicking on the arrow next to the Microphone icon in the bottom left hand corner of your screen.

Image 5:



The main part of your screen will display whatever the host chooses to share with you (PowerPoint slide, website, etc). An example is shown in image 6. The names of other participants will show along the top of the screen. There is a toolbar at the bottom, although this isn't always visible – move your mouse to the bottom of the screen to make the toolbar display.

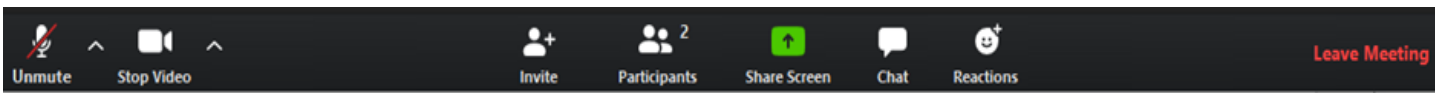
Image 6:



Functions available during the meeting

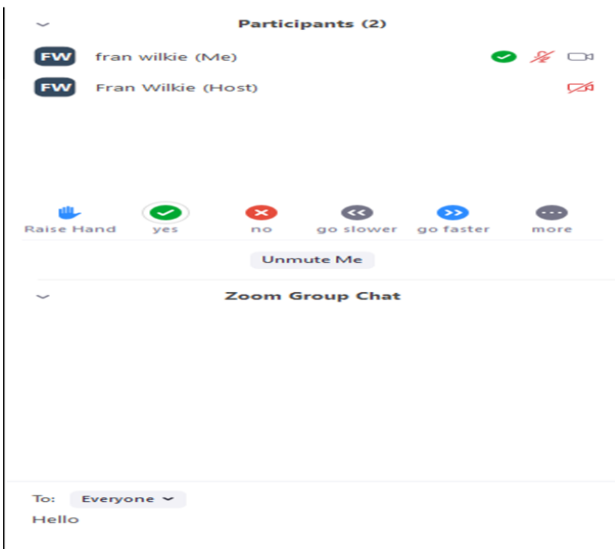
The toolbar is where you can control your interaction with Zoom (image 7). You can change your audio and video settings using the icons on the left hand side. It is important to note however, members of the public cannot speak or ask questions during the meeting. You can click on the relevant buttons to see who else is in the meeting, and to use the chat function (see next slides for more details). You can also leave the meeting.

Image 7:



During the meeting you will only be able to send a direct message to the host or a co-host of the meeting. If you click on the Chat button from the main toolbar, it will open another window (image 8). From here, you can send messages; you type your message at the bottom of the screen. Press return on your keyboard to send the message.

Image 8:



To leave the meeting, hover your mouse at the bottom of the screen to make the toolbar appear. Click on the **Leave Meeting** button.

What if I have accessibility requirements?

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

Who should I contact if I require assistance?

There will be a technical host for the meeting who will ensure everything is working and deal with any unexpected technology issues. Their contact number and email address will be given to all participants so they can be contacted during the meeting. You will also be supported by the ABPI Lead representative who will be on hand via the SMC co-host to provide information and guidance when needed.

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 will happen when I join the meeting?

When you join the meeting at first, you will be placed in a virtual holding room along with the other public observers. You will then be welcomed by the SMC team, who will deliver a technical meeting brief explaining how the meeting will work. When the meeting brief is finished, you will then be placed into another holding room, where a member of SMC will deliver a brief to all participants of the meeting. This team member will provide you with contact details, and be your point of contact throughout the afternoon should you have any queries. When the meeting is ready to commence, all participants will be asked to turn off their microphone and video camera functions and moved back to the main meeting. Please be aware that there may be a slight delay in you joining the meeting, please do not leave the designated virtual holding room until you are moved automatically into the main meeting by the technical host.

What should I do if I have technical issues?

If, during the meeting, you are having difficulty with audibility, technology failure or any other technical issues please use that chat facility or send an email to either the technical host or the co-host who will assist you. They will advise the meeting host who will ensure the chair is aware.

What if I am late for the meeting?

We strongly encourage you to join the meeting promptly, however, if you are going to be late joining the meeting, you will be placed into a virtual holding room until you are admitted into the meeting at an appropriate time by the technical host. If possible, please advise a member of the SMC team if you are going to be late.

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.

Ahead of the meeting you will be sent an agenda which will allow you to follow the order of the committee meeting. SMC committee meetings will use PowerPoint slides during the presentations which replaces the need to circulate redacted detailed advice documents which was done previously at face to face committee meetings.

Who will be at the meeting?

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

The submitting patient group partner representative is also invited to participate in SMC committee meetings to respond to specific queries relating to patient and carer issues and provide points of clarity relating to their Patient Group 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 it 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 there be any scheduled breaks?

Yes, the chair will call regular breaks to avoid virtual meeting fatigue. A longer break may be called if the meeting is likely to last several hours. If you have to leave the meeting at any point, please turn off your camera and make sure your microphone is on mute.

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. Should this happen, you will be placed in a virtual holding room and 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 is not possible as an announcement of the decision in public could have significant commercial risks. When the discussion for all submissions has ended, and the meeting moves to a closed session, the Chair will ask each committee member to record their vote electronically on whether or not to accept the medicine. The votes will be counted and the decision announced to the SMC committee in this closed session.

When will the final SMC advice be published?

On the Friday following the SMC Committee meeting, the submitting pharmaceutical 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.

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. You are not permitted to talk during the meeting and cannot send messages to committee members. If you have any questions you can message a co-host of the meeting; the name of which will be disclosed in a brief at the start of the meeting.

Can I take notes at the committee meeting?

You may take notes, but the use of recording devices are not allowed during the committee meeting. Committee meeting minutes will be published on the SMC website around four weeks after the meeting.

Can I use social media during the meeting?

Live reporting of committee meeting proceedings is not allowed. Anyone seen to be recording/broadcasting during a meeting will be removed from the meeting immediately.

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 observers and participants 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 children attend committee meetings?

Children under the age of 16 cannot attend committee meetings