Attending a Scottish Medicines Consortium Meeting - Information for Members of the Public

This factsheet is for members of the public who have registered to observe a Scottish Medicines Consortium (SMC) meeting. We welcome your attendance at these meetings. We hope that it will help you to understand how the SMC works in striving to meet the needs of the people of Scotland, in relation to the availability of medicines. The following information may be useful to you so that you know what to expect from the meeting.

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 they can be prescribed in the NHS in Scotland.

Each assessment is carried out by a team of pharmacists, health service researchers and health economists, who evaluate the evidence provided by the pharmaceutical company which has produced the medicine. The evaluation is then reviewed 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 about how the medicine affects quality of life for patients and their carers. This information is also presented and discussed at the SMC meeting.

SMC has around 25 members mainly comprising clinicians and others from the Health Boards in Scotland. These include doctors, pharmacists, and senior managers. The Committee also has public partner members as well as representatives from the Association of the British Pharmaceutical Industry (ABPI). The wide mix 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

Attending an SMC meeting

SMC meetings are open for members of the public to attend. This supports our commitment to openness and transparency. We hope that it helps people to understand the way in which we look at all available evidence before making a recommendation on whether or not we are able to approve a medicine for use in the NHS in Scotland.

There will be up to 25 members of the public attending the meeting with a maximum of two representatives per submitting pharmaceutical company and two representatives per submitting patient group. If the meeting is oversubscribed, priority will be given to members of the public and patient groups.

Following the suspension of SMC, NDC and Patient and Clinician Engagement (PACE) meetings in the early stages of the COVID-19 pandemic, NDC meetings resumed at the end of June 2020, followed by PACE meetings early July 2020 and SMC meetings resumed from August 2020. All three meetings have resumed, initially, on a virtual basis with NDC and PACE using MS Teams and SMC committee meetings using Zoom.

Virtual meetings are very different than face to face meetings and can take time to get used to. In addition to this information document about SMC meetings, attendees to meetings will also be sent an agenda and a Virtual Meetings Protocols & Etiquette document.

When and where are meetings held?

SMC meets 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.

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

Although the SMC committee 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. You are expected to stay for the entire committee meeting, but if it is necessary to leave the meeting early please let a co-host of the meeting know you are leaving. (Functions available during the meeting on page 7 explains how to do this).

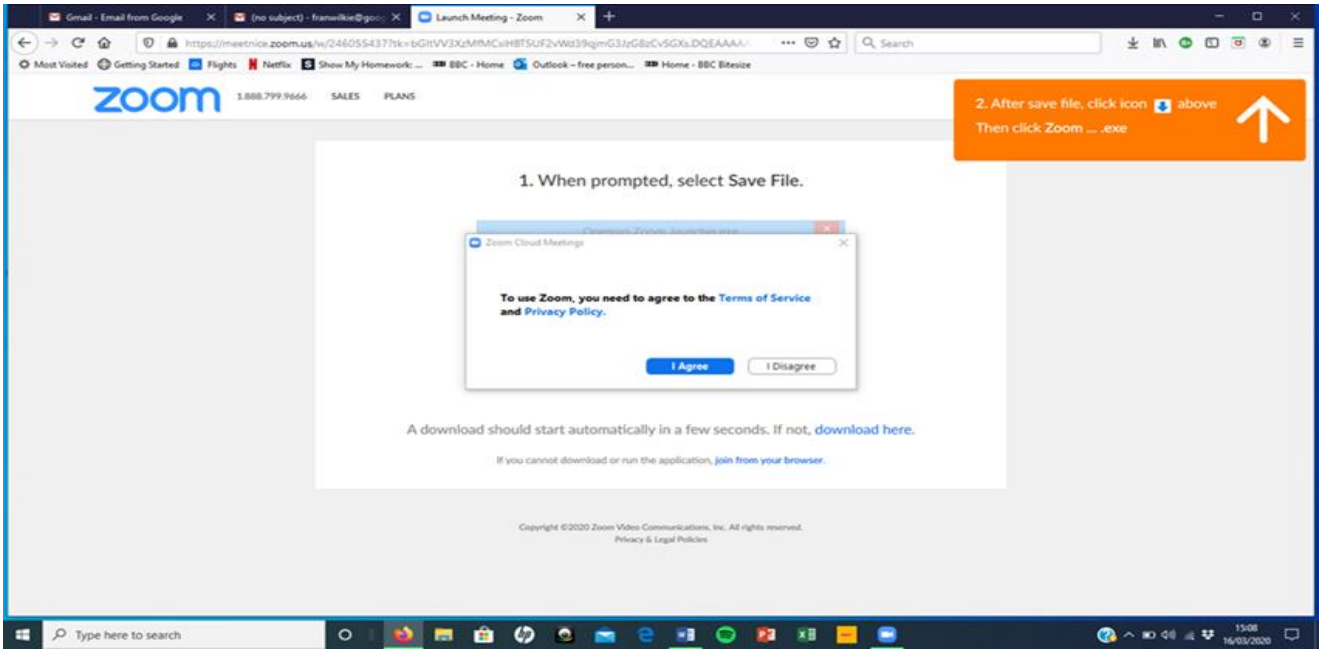
Registering to join a meeting

To attend a virtual SMC committee meeting you are required to register via the SMC website, preferably one week in advance of the meeting. Your request to join a SMC 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 will happen when I join the meeting?

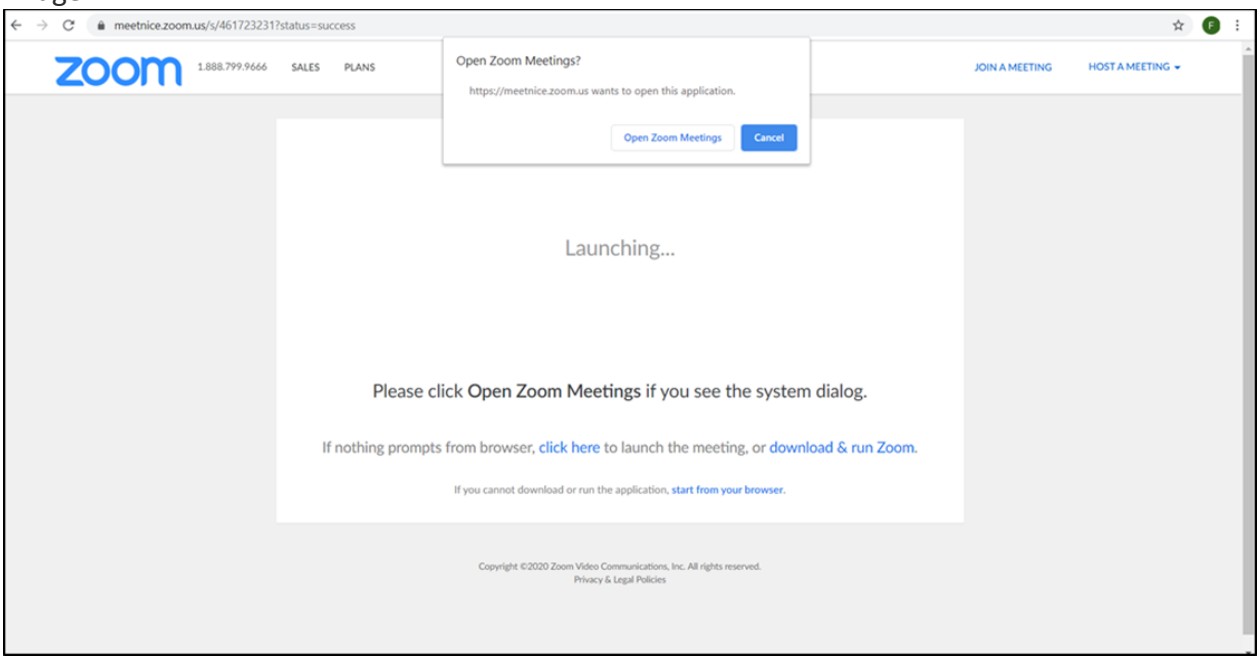
Using your unique joining instructions to join the meeting at 12noon. Click on (or copy and paste) the link in your confirmation email into your web browser. If you have not used Zoom before, you will see something similar to image 1. Click to agree to the Terms of Service and Privacy Policy then follow the on-screen instructions to save and run the file.

Image 1:



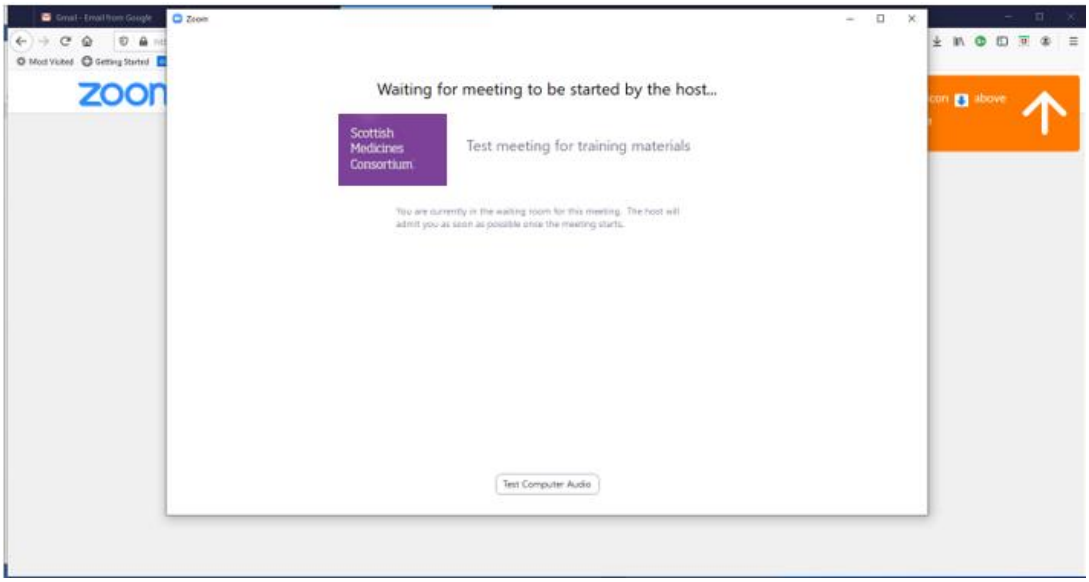
If you have used Zoom before, you should see a screen like image 2. Click on **Open Zoom Meetings**. If you do not see the **Open Zoom Meetings** pop-up box, use the links on your screen to launch the meeting.

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.

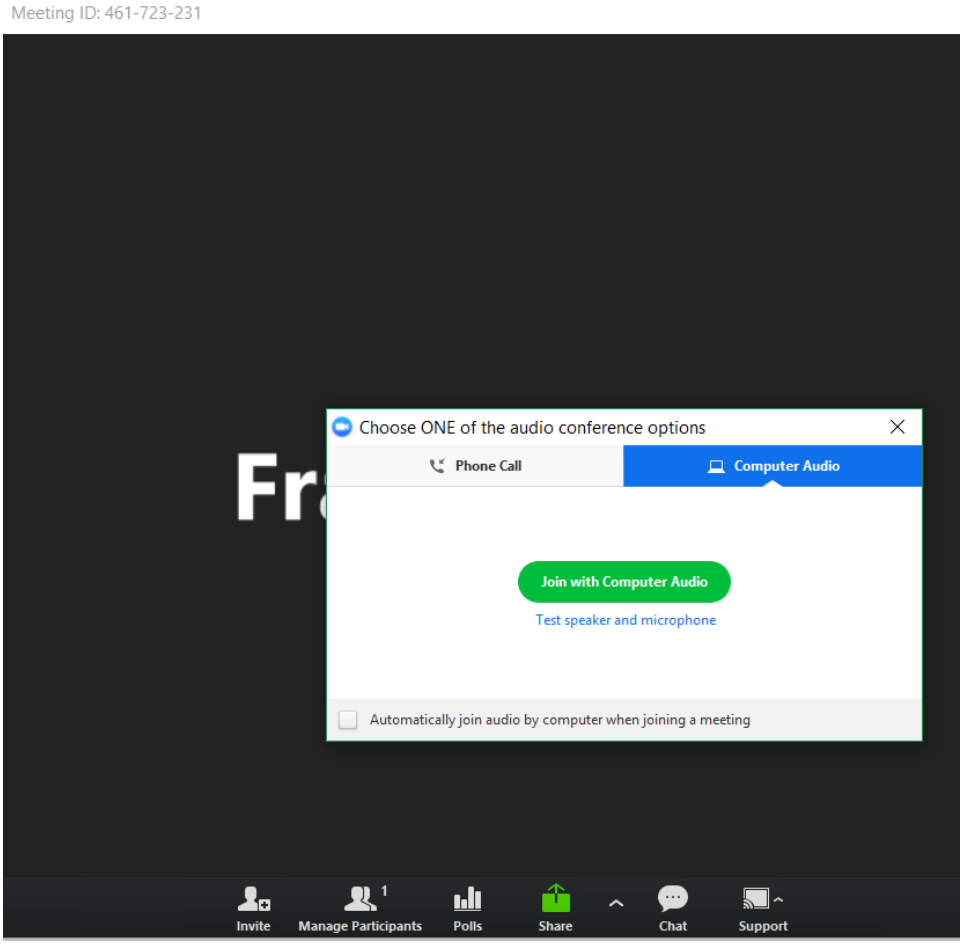
Image 3:



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.

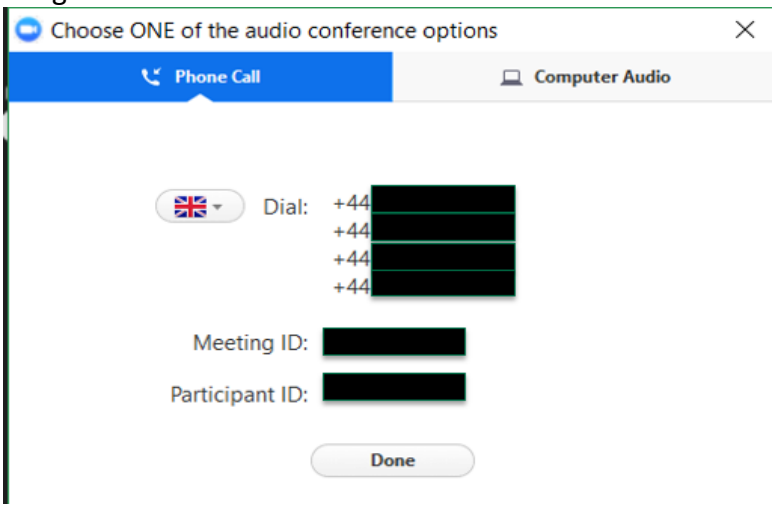
Image 4:



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:



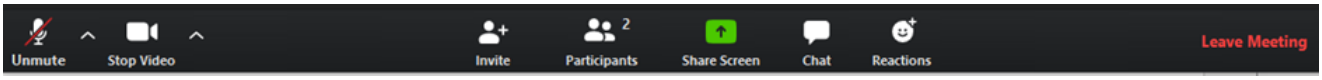
The main part of your screen will display whatever the host chooses to share with you (PowerPoint slide, website, etc). An example is shown in image 6. The names of other participants will show along the top of the screen. There is a toolbar at the bottom, although this isn't always visible – move your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

Image 6:

Functions available during the meeting

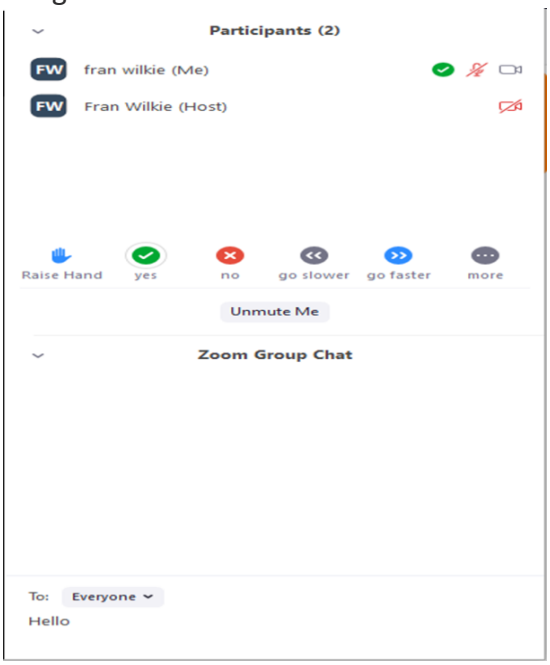
The toolbar is where you can control your interaction with Zoom (image 7). You can change your audio and video settings using the icons on the left hand side. It is important to note however, members of the public cannot speak or ask questions during the meeting. You can click on the relevant buttons 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.

Will papers be provided for public observers to follow the committee meeting?

SMC usually considers around six medicines at each meeting. As papers for each submission are hundreds of pages in length and contain information the submitting pharmaceutical company has identified as confidential (both commercial and academic), we are unable to issue these to public observers.

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 were previously provided at face to face committee meetings.

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 committee will be in attendance. Submitting pharmaceutical company representatives and patient group representatives will also participate in the meeting. Invited observers may also be present.

What information is assessed at the meeting?

The SMC meeting is the final part of the assessment process. For each medicine being considered, Committee members will discuss and consider all of the evidence. This includes: the submission from the pharmaceutical company, the Detailed Advice Document, patient group submissions, the views of clinical experts in Scotland and the output from a PACE meeting, if one was held.

PACE is a process for review of end of life medicines and medicines for rare conditions (known as orphan or ultra orphan medicines). More information can be found on our website.

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.

How long will the meeting last?

The chairperson 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.

Will I be able to listen to all the discussions?

We are fully committed to holding our 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 product 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. 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 chairperson may declare, or be asked by a committee member to declare, a closed session, allowing detailed discussion of this confidential material. You will be moved to a virtual breakout meeting room temporarily while this takes place.

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 chairperson 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 all submissions has ended, and the meeting moves to a closed session, the chairperson 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?

The SMC assessment is summarised in a document called a Detailed Advice Document (DAD). This is sent to the submitting company on the Friday following the SMC meeting, in confidence, advising the company of SMC's decision. NHS Boards are also informed of the advice, in confidence, at this stage. The advice is made public four weeks after the meeting when it is published on the SMC website. This four week period allows NHS Boards to prepare and, where relevant, comparator companies to review statements on their product in the DAD.

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. Members of the public 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; you will be given this person's name 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 is not allowed during the committee meeting. 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 the public to respect the importance of committee members being 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?

Live reporting of committee meeting proceedings is not allowed. If you are found to be broadcasting the proceedings via any media you will be asked to leave.

Can I conduct a research study on the committee meeting and/or SMC?

If you have registered to attend a meeting, and also wish to conduct a study on the committee meeting and/or our processes, please contact the SMC secretariat. You will need to provide details

on the purpose and context of your study, the information you plan to gather during the meeting and this will then be passed to the SMC Executive for consent. You will be informed of the decision by email. If it is not possible for you to conduct your research study you will still be able to observe the meeting; however, you will not be allowed to conduct any research at the meeting. If you no longer wish to attend the meeting, please inform the SMC secretariat as soon as possible, to allow your place to be offered to someone else.

What will happen if a public observer tries to disrupt the committee meeting?

We expect that everyone who joins a meeting will respect the work of the committee and will not cause any disruption. If anyone causes a disruption, the meeting will be stopped and the chairperson may insist that the individual leaves before restarting.

Can children attend committee meetings?

Children under the age of 16 cannot attend committee meetings.

Are there regulations for members of the press registering to attend a meeting?

A member of the Healthcare Improvement Scotland communications team will attend meetings when members of the press are present and provide an appropriate briefing.

Are there other categories of observers?

SMC staff, external representatives (e.g. from NHS Boards) or invited guests may attend meetings with the permission of the SMC Chairperson.

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

Please inform a member of the SMC secretariat as soon as possible if you are unable to attend the meeting. There are a limited number of public places available to attend meetings and by sending your apologies with as much notice as possible your place can be given to someone else.

If you have any other questions regarding attending the SMC meeting please don't hesitate to get in touch with our public involvement team at: hcis.smc-mip@nhs.net

Commonly used terms explained

Below is a list of terms commonly used during an SMC meeting, along with an explanation of what they mean:

Area Drug and Therapeutics Committees (ADTCs): Responsible for providing advice to NHS Boards on all matters affecting effectiveness, safety and economy in the use of treatments to help meet the health needs of each local Health Board population.

Association of the British Pharmaceutical Industry (ABPI): The trade association for more than 70 companies in the UK producing prescription medicines. Its member companies research, develop, manufacture and supply more than 80 per cent of the medicines prescribed through the NHS.

Comparator Company: A company that has either the same or similar product available for treatment.

Cost Consequence Analysis (CCA): A form of economic evaluation in which the outcomes (of which a variety of measures are normally presented) are reported separately from costs.

Cost Utility Analysis (CUA): A method of cost-effectiveness analysis that uses the quality adjusted life year (QALYs) as a measure.

Detailed Advice Document (DAD): Contains the summary of information about a product that SMC has assessed.

End of life medicine: A medicine used to treat a condition at a stage that usually leads to death within three years with currently available treatments.

European Medicines Agency (EMA): Responsible for the protection and promotion of public health, through the evaluation and regulation of medicines (until Dec 31st 2020).

Formulary: A list of medicines approved for routine use in a Health Board.

Health and Sport Committee: Examines the Scottish Government's health policy, the NHS in Scotland and sport.

Healthcare Improvement Scotland (HIS): A Scottish Health Body which supports healthcare providers in Scotland to deliver high quality, evidence based, safe, effective and person-centred care; and to make sure those services to provide public assurance about the quality and safety of that care.

Health Technology Appraisal/Assessment (HTA): Examines the safety, clinical effectiveness, cost-effectiveness, organisational implications, social impact, legal and ethical considerations of the application of a health technology which is usually a drug, medical device or clinical/surgical procedure.

Horizon scanning: The process of identifying new medicines or new uses of existing medicines that are expected to be licensed in the near future and estimating their potential impact on patient care.

Incremental Cost effectiveness ratio (ICER): The difference in costs divided by the difference in benefits.

Medicines Appraisal: The structured evaluation of the properties and effects of a medicine, ideally with consideration of its clinical effectiveness and cost effectiveness when used for the specified indication.

The National Institute for Health and Care Excellence (NICE): Responsible for deciding what medication and treatments should be available on the NHS in England and Wales.

New Drugs Committee (NDC): Considers the scientific evidence on new medicines, and provides preliminary recommendations to SMC on the introduction of these medicines in Scotland.

New Products Assessment Form (NPAF): Provides a template for the evidence required by SMC to make recommendations to NHS Boards and Area Drug and Therapeutics Committees.

Office of Fair Trading (OFT): The UK's consumer and competition authority, which aims to make markets work well for consumers.

Off-label: Use of a medicine outside the terms of its official European licensing permissions.

Off-licence: See off-label.

Orphan medicine: Medicine for conditions affecting fewer than 2,500 people in a population of 5 million or a medicine to treat an equivalent size of population irrespective of whether it has designated orphan status.

Patient Access Scheme (PAS): A scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a drug and enable patients to receive access to cost-effective innovative medicines.

Patient Access Scheme Assessment Group (PASAG): Assesses proposed Patient Access Schemes (PAS) in NHS Scotland.

Patient and Clinician Engagement (PACE) Meetings: A part of the SMC process of assessment of medicines that comes in when the NDC view is that a certain medicine cannot be recommended for use in NHS Scotland. Treatments that will be eligible to be referred to a PACE meeting must come under the status of end of life, orphan or ultra orphan. The aim of the PACE group is to describe the added benefits of the medicine from both patient and clinician perspectives, that may not be fully captured within the conventional clinical and economic assessment process.

Public Involvement Network (PIN) Advisory Group: A subgroup of the SMC which makes recommendations to on the development of public involvement opportunities and ensures that the patient/carer perspective is reflected in SMC decisions.

Patient Group: Patient focused organisations which provide comments from patients and carers, and provides this information in the form of a submission of evidence to SMC regarding a particular medicine under consideration.

Peer Approved Clinical System (PACS): Replaces the Individual Patient treatment Request system for using medicines not approved for regular use in the NHS and gives clinicians a bigger say in approval for treatments.

Voluntary Branded Medicines Pricing and Access Scheme (VPAS): A voluntary agreement between the UK Government and the Association of the British Pharmaceutical Industry (ABPI) which allows pharmaceutical companies to set their own prices for branded prescription medicines, but with rules placed upon overall profit.

Quality Adjusted Life Year (QALY): A measurement that takes into account how much a treatment both lengthens and improves the quality of a patient's life. A QALY is calculated mathematically by multiplying the number of additional years of life achieved by a treatment by a measure of the quality of life.

Scottish Antimicrobial Prescribing Group (SAPG): Co-ordinates and delivers a national framework to improve the quality of antimicrobial prescribing and management in Scotland.

Scottish Intercollegiate Guidelines Network (SIGN): Develops evidence based clinical practice guidelines for the NHS Scotland.

Single Technology Appraisal: A single technology appraisal covers a single technology (e.g. a medicine) for a single indication.

Submitting Company: A company which submits a treatment that it manufactures to SMC for assessment of whether it will be accepted for use in NHS Scotland.

Ultra-orphan medicine: To be considered as an ultra-orphan medicine all criteria listed should be met:

- the condition* has a prevalence of 1 in 50,000 or less in Scotland,
- the medicine has an EMA orphan designation for the condition and this is maintained at time of marketing authorisation,
- the condition is chronic and severely disabling, and
- the condition requires highly specialised management.

** SMC uses the description of the condition within the European Medicines Agency's (EMA) Orphan Maintenance Assessment Report (OMAR) as a reference (or the description within the original orphan designation if the OMAR is not available).*

Submissions for medicines that are validated as ultra-orphan according to this definition will be assessed by SMC and will then be available to prescribers for a period of up to three years while further clinical effectiveness data are gathered. After this period the company will be asked to

provide an updated submission for reassessment and SMC will make a decision on routine use of the medicine in NHSScotland.

User Group Forum (SMC UGF): A subgroup of SMC for members of the pharmaceutical industry to consider issues related to SMC's HTA processes.