Attending a Scottish Medicines Consortium Meeting

Information for Members of the Public

This factsheet is for members of the public who have registered to come along and observe a Scottish Medicines Consortium (SMC) meeting. The SMC welcomes 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 doctors are able to use them in the NHS in Scotland.

Each assessment is carried out by our team of pharmacists and health economists, who evaluate the evidence provided by the pharmaceutical company which has produced the medicine. The results of this evaluation are then carefully looked at 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 Interest 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 40 members who are mostly volunteers. Membership is made up of key experts from every Health Board area in Scotland. This includes: doctors, pharmacists, senior managers from Health Boards, public partner members as well as representatives from the Association of the British Pharmaceutical Industry (ABPI). The wide mixture 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 have been open for members of the public to attend since May 2014. 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 drug for use in the NHS in Scotland.

There will be up to 20 members of the public attending the meeting with a maximum of two people per organisation. If the meeting is oversubscribed, priority will be given to members of the public and patient groups.

You will receive the agenda for the meeting along with this factsheet. Please print both and bring them with you to the meeting.

When and where are meetings held?
SMC meets on the first Tuesday of each month. The meetings are held in **DoubleTree by Hilton Glasgow Central: Cambridge Street, Glasgow, G2 3HN**. 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?
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. You are expected to stay for the entire committee meeting, but if it is necessary to leave the meeting early please leave during the break.

What will happen when I arrive at the meeting?
On arrival, you will be welcomed by the SMC Meetings Coordinator, who will explain how the meeting will work. The Meetings Coordinator will be your point of contact throughout the afternoon. He or she will deal with any queries you may have. A public attendees' room within the meeting venue is provided for you to use before and during the SMC meeting.

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.

You will be supplied with an information pack containing a draft copy of the New Drugs Committee (NDC) assessment for each medicine with company sensitive information blacked out. The NDC is the committee which carries out the initial review of the evidence on the medicine at a meeting held around five weeks before the SMC meeting.

This pack should not be taken from the meeting room and must be returned to the SMC Meetings Coordinator at the end of the meeting.

Will refreshments be provided?
Tea, coffee and water will be provided and there is a cafe onsite. You are welcome to bring refreshments / lunch into the public attendees' room but not into the SMC meeting room itself.

The following must be followed during the meeting

- All mobile phones, laptops and tablets must be switched off for the duration of the meeting.
- Audio and video recording, photography and the use of social media during the meeting is not allowed. Anyone seen to be recording/broadcasting during a meeting will be asked to leave immediately.
- Food and drink are not allowed within the meeting room.
- Members of the public cannot speak or ask questions during the meeting.
- You should keep your belongings with you at all times in case of an emergency.

This is in accordance with Section 1 (2) Public Bodies (Admission to Meetings) Act 1960.

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. Invited observers may also be present.

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

Patient and Clinician Engagement (PACE) is a new process for end of life medicines and medicines for rare conditions (know as orphan or ultra orphan medicines). More information can be found on our website.

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?
The 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 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 asked to leave the 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 each submission has ended, the chairperson 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 to the SMC committee in a closed session following the meeting.

It must be stressed that the fact that the decision is made in private does not delay patients' access to medicines.

When will the final SMC advice be published?
The SMC assessment is summarised in a document called a Detailed Advice Document (DAD). On the Friday following the SMC meeting, the submitting company is sent the DAD informing it, in confidence, of SMC's decision. NHS Boards are also informed of the advice, in confidence, at this stage. The DAD is not made public until four weeks after the SMC 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?
You will be allocated a separate room from committee members for use before and during the break. If you have any questions the SMC Meetings Coordinator will be able to help you.

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.

Can I take notes at the committee meeting?
You may take notes, but the use of laptops or other electronic 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 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?
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 SMC processes, please contact the SMC Meetings Coordinator. 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 SMC's 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 Meetings in Public Coordinator 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 comes to 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.

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 Meetings Coordinator so we can ensure appropriate support is in place. Parking facilities are available, if booked directly from the Glasgow City Hotel in advance, although spaces are limited.

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.

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. For media enquiries, contact Caroline Foulkes on 0131 623 4705.

Are there other categories of observers?
SMC staff, external representatives (e.g. from NHS Boards) or invited guests may attend SMC 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 the SMC Meetings Coordinator as soon as possible if you are unable to attend the meeting. There are a limited number of public places available to attend SMC meetings and by sending your apologies with as much notice as possible your place can be given to someone else.

Feedback & Evaluation
The SMC Meetings Coordinator will send you a SurveyMonkey link following the meeting, asking for your opinions on the experience of observing the SMC meeting. We encourage you to provide honest feedback to help us review and develop this process.

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:

All Wales Medicines Strategy Group (AWMSG): Provides advice on strategic medicines management and prescribing to the Welsh government.

Applicant 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.

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.

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.

Individual Patient Treatment Request (IPTR): A process by which a patient may receive a medicine when SMC has yet to issue advice on the medicine or if SMC has issued "not recommended" advice for the medicine. This is being replaced by the Peer Approved Clinical System (PACS).

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.

Overarching Medicines Technology Group (OMTG): Makes sure guidance issued by Healthcare Improvement Scotland is consistent and that opportunities for joint working are identified.

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 new 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.

Patient and Public Involvement Group (PAPIG): 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 Interest 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.

Pharmaceutical Price Regulation Scheme (PPRS): 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.

Ultra-orphan medicine: A medicine used to treat a condition with a prevalence of 1 in 50,000 or less (or around 100 people in Scotland).

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