

Toolkit for Engaging with SMC Appraisals

Hints and Tips for the Pharmaceutical Industry

Developed in partnership with the Scottish Medicines Consortium



The purpose of this document is to offer support and guidance to pharmaceutical companies who are submitting HTA dossiers to the Scottish Medicines Consortium (SMC) for assessment. It contains an overview of the process, links to important support documents and webpages, and the contact details of individuals who are available to assist throughout the submission process.

Scottish Medicines Consortium

SMC provides advice to NHS Boards and their Area Drug and Therapeutics Committees (ADTCs) across Scotland about the status of newly licensed medicines and new indications of existing medicines (licensed from January 2002).

The SMC remit is confined to prescription-only medicines. It excludes vaccines, branded generics, blood products, plasma substitutes and diagnostics. In addition, SMC have recently expanded their definition of out-of-remit to include

- paediatric indications, where the reference adult indication is already SMC approved
- new formulations/presentations of an existing medicine, where that medicine is already approved for the relevant indication(s) and is being marketed at the same (net) price or cheaper.

It is advisable to contact SMC for guidance if there is any uncertainty as to whether these categories apply to a medicine.

Devices that contain a medicine are only assessed if they have been licensed as a medicine by the Medicines and Healthcare products Regulatory Agency (MHRA).

Biosimilars are considered as out-of-remit if the reference product is accepted by SMC [or Healthcare Improvement Scotland (HIS)] for the same indication(s) and in the same population – or if the reference medicine was initially licensed and available prior to 31 January 2002. Full submissions are required for indications and/or populations where the reference product is not recommended by SMC/HIS.

SMC reserves the right to request a full submission, if the introduction of the medicine is anticipated to have a significant impact on NHSScotland resources.

SMC aims to issue advice to NHSScotland on all newly licensed medicines as soon as practical after the launch of the product involved.

SMC – Recent Changes in Process

Several important changes to SMC ways of working were introduced, following the *Review of Access to New Medicines; an independent review by Dr Brian Montgomery* and following SMC's own review of processes. These include:

- **Interim Acceptance:** this additional decision option for SMC committee members was introduced in 2018, initially only for medicines with a conditional marketing authorisation, to help improve access to innovative medicines with high clinical and/or economic uncertainty. It is also now available as an option for medicines included in the MHRA Innovative Licensing and Access Pathway (ILAP) and the MHRA Early Access to Medicines Scheme (EAMS). The New Drugs Committee (NDC) will assess whether the data to be collected will address the key uncertainties, and they advise SMC accordingly. The company is required to submit a revised dossier for reassessment when the additional evidence is available.
- **The Ultra Orphan Pathway:** this pathway was introduced in 2018 to improve access to

medicines licensed for ultra-rare conditions, with high clinical/economic uncertainty. A 'coverage with evidence' approach is utilised. Medicines which are validated as ultra orphan (UO) are required to submit a dossier to SMC (using the specific UO New Product Assessment Form (NPAF)) a Patient Access Scheme (PAS) to the Patient Access Scheme Advisory Group (PASAG) and, following SMC assessment, a Data Collection plan to Scottish Government. The medicine is made available to Scottish patients for up to 3 years whilst the company collects additional data, following which the company must submit an updated dossier, including the new data, to SMC for reassessment. It is at this point that SMC will decide whether to formally approve or not recommend the medicine. To be validated as an UO medicine, the following criteria must be met:

- The condition has a prevalence of 1 in 50,000 or less in Scotland – not the indication
 - The medicine has a Great Britain (GB) orphan marketing authorisation from the MHRA
 - The condition is chronic and severely disabling
 - The condition requires highly specialised management
- **Fast-Track Resubmissions:** this resubmission option is available when, following receipt of a non-recommendation, the company decides to resubmit, **having revised their original PAS only**. The company must resubmit within three months of being informed of the original decision, with SMC aiming to publish their decision within 14 weeks of submission – this is achieved by removing the usual NDC assessment step from the assessment path.
 - **Expansion of Abbreviated Submission Route:** the abbreviated route is now an option for medicines that are second or later in class, if the new medicine costs the same or less or has a limited net budget impact, using acquisition cost only – it is advisable to contact SMC for guidance if there is any uncertainty as to whether a medicine fulfils these requirements.
 - **PAS revision post NDC:** If NDC submit a negative recommendation to SMC, companies have the option of revising their original, or offering a new PAS before the SMC committee meeting. This has been an option available to medicines going through the Patient and Clinician Experience (PACE) process since 2015, and was expanded to include all medicines in 2020.

Hints and Tips - Current Support Mechanisms

Direct Engagement with the SMC

SMC will meet with a submitting company in the following situations:

Before submission: SMC does not routinely meet with companies prior to submission but does offer Early Engagement Meetings to companies when specific requirements are met. These meetings can be requested by completing and submitting an Early Engagement Information Request Form.

Early Engagement Meetings with SMC are available when:

- a company has limited previous experience of engagement with SMC
- and/or aspects of the submission suggest there would be mutual benefit from a meeting, to discuss concerns or issues relating to SMC process or policy at an early stage

Or:

- Where there is a strong suggestion of non-submission and exceptionally high patient need, for example a medicine used for a condition where no other treatment is available

Or:

- When a medicine is in EAMS
- When a medicine is validated as UO

Companies with ILAP medicines will also meet with SMC prior to submission, as part of that process.

After SMC assessment: if the SMC committee decision is not to recommend the use of a medicine, companies can request a meeting with SMC. This takes place usually, but not always after the final Detailed Advice Document (DAD) has been issued to the company and the health boards. A representative of the SMC Executive will meet with company representatives to discuss the assessment and decision, with the aim of assisting the company to identify the key weaknesses/uncertainties in their submission and their next steps.

Indirect Engagement

Before submission: SMC provides very clear, useful and comprehensive advice and process guidance documentation on their website (see below for useful links). In addition, SMC are happy to address company queries – these are submitted to the SMC secretariat in writing. Information on how to submit questions is contained within ***Working with SMC - Guide for Manufacturers***.

During SMC Assessment: Companies have the opportunity address any questions and requests for further information from the assessors before or (more rarely) after the NDC meeting. They are also invited to comment on the NDC DAD (“Company Comments Letter”). Both are important opportunities for companies to assist the SMC in their assessment of a medicine, and the Company Comments Letter is a valuable opportunity to clarify any inaccuracy or misunderstanding of the clinical and/or economic case, to address any weaknesses identified as material by the NDC, to correct any inaccuracies in the DAD, and to re-emphasise *the most important* points in their submission (applying the principle of less is more). The impact that a well-written Company Comments Letter has on a submission should not be underestimated, and the company should take this opportunity in full, regardless of whether a PACE meeting has been requested.

Useful SMC Information Resources

SMC provides detailed guidance on how to make a submission. Below are listed the principal documents/links, to assist access. All these documents/links can be accessed from the [SMC web](#) page. Document specific links are not included in this toolkit as they change each time a document is revised.

The principal guidance document is the ***Working with SMC - A Guide for Manufacturers*** which provides manufacturers with an overview of the SMC remit and associated processes, all within one useful document.

Not all medicines require a submission: Further information can be found in the document ***Guidance on Medicines outwith SMC Remit***.

If you are unsure as to whether SMC will require a submission, or whether to use the full or abbreviated route, SMC will respond to a request for information using the ***Company Information Request Form and Guidance or Contact Us*** [link within the text.](#)

To assist in your submission planning, details regarding timelines, prioritisation criteria and meeting dates can be found following this path from the SMC homepage: SMC>Making a
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submission>Timelines and submission scheduling.

For Full Submissions: The **Guidance on NPAF** provides companies with guidance on how to complete the New Product Assessment Form.

If you consider your medicine to be **Ultra Orphan**, there are links to further information, guidance and the UO NPAF on the Companies page.

If you intend to submit your medicine with a **PAS**: further information, guidance and the required forms are accessible via the Patient Access Schemes link on the Companies page

For Abbreviated Submissions: if you intend to submit an abbreviated submission, guidance and the required template can be found via the Companies page.

For Policy/Process Statements, [use this link](#) : this section contains SMC policy statements relating to modifiers, biosimilar medicines, policy for meetings with manufacturers and other position statements that you may find helpful.

Support from the ABPI

The ABPI offers support for all industry colleagues engaging with the SMC via:

- **ABPI Scotland Office** – *With extensive experience of the NHS, SMC process and associated procedures and providing Industry representation on PASAG. For further information, please contact the ABPI Scotland team: headspeath@abpi.org.uk*
- **The SMC Lead Industry Member**; an experienced pharmaceutical professional, contracted by the ABPI to work with the SMC on process development and continual improvement. They are also a full member of the SMC committee and the chair of the SMC User Group Form. The current lead industry member is Dr. Catriona McMahon and she can be contacted at drcmcmahon@icloud.com
- **The ABPI Scotland Access and Value Group**: Meets on a quarterly basis, focusing on issues related to access to medicines, Health Technology Appraisal (HTA) and specifically the SMC process. *Contact the ABPI Scotland team (headspeath@abpi.org.uk) for more information.*
- **The SMC User Group Forum** – Meets on a quarterly basis and enables direct engagement between the industry and the SMC. The primary focus is on continuous development of, and improvement in SMC processes and, where possible, ensuring that both industry and SMC learn and benefit from practices in other jurisdictions. Industry members of the UGF meet between the main meetings to progress projects and discuss industry-specific issues. *Contact the SMC Lead Industry member (drcmcmahon@icloud.com) for more information*
- **SMC Training sessions and Workshops** – Presenters from the SMC and the industry providing up-to-date advice and guidance on SMC methodology and the process for engagement. *Contact the SMC Lead Industry member (drcmcmahon@icloud.com) for more information*

Hints and Tips – Participating in the SMC Meeting

The purpose of company participation in the SMC meeting is to allow the company to address any outstanding questions that SMC members have and highlight any issues they believe SMC should be

aware of, prior to reaching its decision on advice to NHSScotland.

Before the Meeting:

When preparing for the meeting, it is advisable that the following points are considered:

- Company participants should have an excellent understanding of the medicine under review and the documentation and communications submitted to SMC;
- Company participants should have the ability to respond on cost and clinical effectiveness issues in an accomplished way – e.g. one participant could be senior and strategic and the other technically proficient; it is advisable that both have been intimately involved in the development of the submission.
- Company participants should have excellent communication skills, with the ability to communicate the views of their company under public scrutiny. They should be aware that the audience may include colleagues, competitors, clinicians, patient groups, media, etc.
- Notwithstanding the above, if company participants do not know the answer to a question, they should say so and offer to follow-up with the SMC, if appropriate.
- If a company commits to sending participants, the names pre-notified to SMC should be the people that attend the Committee on the day. Last minute substitutions, especially with more junior staff, should be avoided.

Company participants should ensure they are fully prepared by attending at least one previous meeting to observe the process. In today's virtual/hybrid world, it is possible to book virtual attendance at relatively short notice, but if SMC transitions back to a full face-to-face meeting model, allow plenty of time for applications to be processed as the number of places is limited and demand usually high. To register for a meeting, use the link at the foot of the SMC homepage.

About 10 days before the meeting, the SMC Industry Lead member will email the submitting company (usually the NPAF signatory) to invite their company participants to a briefing session on the morning of the SMC committee. A written briefing will be included in this email.

On the Day of the Meeting:

The process below outlines what can be expected if company participants attend the SMC committee meeting in person. It is expected that this option will become available again, as restrictions are lifted and pressures on the NHS reduce.

Further detail regarding what can be expected if the company participants attend the SMC committee meeting virtually follows this section.

In summary, for in-person attendance:

- On arrival at the meeting venue, company participants are escorted to a room where refreshments will be available, and a member of the SMC staff will provide a briefing. It is not permissible for company participants to approach SMC members during the meeting, the breaks or outside the meeting. Questions should be directed to the SMC Meeting coordinator.
- When the meeting is about to start, company participants will be accompanied to the main meeting room, where they will be directed to seats in the public gallery until their submission is

about to be heard. Thus, most will have the opportunity to observe the discussions preceding their own.

- The Chair of the SMC welcomes everyone to the meeting, highlighting key process points before moving onto the administrative elements of the meeting – welcomes, goodbyes, minutes review etc. The meeting itself is designed to be non-adversarial and the Chair will remind everyone that all questions to the company and patient group participants should be addressed through him. In practice, during the meeting, technical queries about the submission from committee members are directed towards the SMC team and lead presenters in the first instance, who will base their answers on the submission documents and subsequent company comments. Company participants may be invited to answer appropriate questions but are required to not raise points during the discussion.
- When it is time for their submission to be discussed, the SMC Chair will invite the company participants to take seats at the table, usually between the SMC Industry Lead member and another Industry SMC committee member. Patient Group participants will be invited to join the table at the same time. Both sets of participants will be asked to introduce themselves, by pressing the 'speak' button on the microphone on the table directly in front of them
- As stated above, company participants are required to not raise points during the discussion. However, the ABPI member, the SMC Industry Lead and the Industry Medical Director are full participating members and can raise points during the meeting if required. Company participants can alert these members if there is a particular point they wish to have raised. For example, if the committee are having a lengthy discussion on a point that can easily be answered by the company, and the question has not been directed to them, then the industry members can suggest that the company be asked to provide clarification on the point in question.
- If asked a question, be courteous, calm, clear and concise. Remember, if answering a technical question, try to tailor your response to the whole Committee; not all have a technical background.
- After the discussion is concluded, the Chair will invite the patient group participants, followed by the company participants, to make any final points that they feel may have been missed or anything they think requires further clarification. It is very important that companies plan to use this time wisely, and limit the content of their contribution to 3-4 short key points of highest relevance to their submission, focusing on areas where key information requires further interpretation or where clarification is required. This may include answering any question raised during the SMC member discussion that was not answered adequately.
- Thus, company participants must have the ability to listen closely to a complex discussion, and critically choose, in the moment, what to respond to; this is unlike the requirements of company participants at NICE and AWMSG, who need to be able to respond to complex and detailed questions. ***They must also have the confidence to recognise when the company key messages have already been covered in the discussion;*** in this case, company representatives should consider limiting their comment to “we have nothing more to add to what has already been highlighted and discussed”.
- *In summary, as with answering questions, be as clear and concise as possible. Focus on addressing any key points not fully resolved during the deliberations. It is acceptable to provide a key summary point at the end, but be brief. There is no requirement to comment if there are no outstanding issues, so do not feel the need to add anything if it is not necessary. Extraneous commentary that may be perceived as promoting a medicine is **very** counter-productive.*

- After this, company and patient group participants will be asked to leave the table and return to the public gallery; this is the point at which SMC members vote.
- Company Participants may leave the meeting at this point, if they so choose. Alternatively, they can return to their seats and observe the rest of the meeting.
- SMC closed sessions - If SMC members identify a need to have a discussion regarding information that has been identified by the company as confidential, or if there is a need to discuss a potential restriction, the SMC Chair may call a closed session. The company participants will be invited to make any final comments at this stage, as described above, after which they and all public attendees will be requested to leave the SMC meeting room for the duration of this discussion. The closed session will conclude, and members of the public will be invited back into the room as the members will vote on the medicine. Thereafter, the Chair will introduce the next submission. There is no further public discussion regarding the closed session or its outcome.
- At the end of the public section of the meeting, all public observers, including company and patient group participants will be invited to leave the main meeting room. The submitting company will be informed of the outcome of the meeting on the Friday of the same week.

Summary of key differences when attendance is virtual:

Most of the above points remain valid. Plus:

- On joining the virtual meeting, all attendees will be allocated to separate 'rooms' as security checks are run in the background. During this time, your Zoom identifier will be modified by the technical team, to indicate that you are a company participant – usually by the addition of CP before your name. A member of the SMC staff will provide a briefing as you wait for the main meeting to start.
- All participants and observers are requested to remain mute, with videos off, unless participating in a specific session. When participating in a submission, company and patient group participants are invited to 'join the meeting' by turning their videos on. It is requested that microphones remain mute when not speaking eg responding to a question or presenting your *brief* closing summary.
- If company participants have any concerns regarding the meeting, eg an incorrect or non-revised data point being presented, they can notify SMC via the chat box – their chat is directly connected to a member of SMC staff who will notify the Chair of the company's concern. It is recommended that the company also notify the SMC Lead Industry Member of their concern, via text/email, as the chat box is not visible to non-SMC staff.
- When meeting in person, SMC committee members vote on the medicine at the end of each submission; when meeting virtually, members vote on all submissions at the end of the public meeting. As per face-to-face meetings, further discussion on any medicine before voting is not allowed – or indeed after the vote is recorded.
- Company Participants may leave the meeting at the conclusion of their submission, if they so choose. Alternatively, they can turn their videos off, and observe the rest of the meeting.

Hints and Tips – Giving Feedback and Raising Concerns

Feedback from manufacturers is extremely valuable to help the on-going development and improvement of the process. Feedback is collected from both SMC members and industry, after meetings and ad hoc. The combined comments are discussed at the SMC User Group Forum. Where there is significant feedback from multiple companies on a topic, an action plan will be developed and the issue, where possible, will be addressed.

Process-related individual issues and concerns, however, are addressed on a case-by-case basis. Companies should raise such issues with the SMC directly, or if they prefer, with the Lead Industry Member or ABPI Scotland, by email or by phone.

For Further Information

Please contact Dr Catriona McMahon directly: drcmcmahon@icloud.com

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Who we are:

The Association of the British Pharmaceutical Industry (ABPI) represents research-based biopharmaceutical companies, large, medium and small, bringing life-saving and life-enhancing medicines to patients. Our members supply 90 per cent of medicines used by the NHS, and are researching and developing over two-thirds of the current medicines pipeline, ensuring that the UK remains at the forefront of helping patients prevent and overcome diseases.

The ABPI represents all pharmaceutical companies to the SMC, not only ABPI member companies and administers the SMC User Group Forum on behalf of the pharmaceutical industry. ABPI also provides pharmaceutical industry representation on the Patient Access Scheme Advisory Group (PASAG).