

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 review. 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 all newly licensed medicines, all new formulations of existing medicines and new indications for established products (licensed from January 2002).

The SMC remit is confined to prescription-only medicines. It excludes the assessment of vaccines, branded generics, blood products, plasma substitutes and diagnostics. 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) or the European Medicines Agency (EMA).

With regards to biosimilars, SMC considers these medicines 'out of remit' when the reference product has already been accepted by SMC or Healthcare Improvement Scotland (HIS) for the same indication(s) and in the same population or was initially licensed and available prior to 31 January 2002. Full submissions are required for indication(s) and/or populations where the reference product is not recommended by SMC/HIS. However, SMC reserves the right to request a full submission in the event that it is anticipated to have an impact on NHS Scotland resources¹.

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 in 2014, following the Scottish Government's response to the Scottish Parliament's Health and Sports Committee inquiry into access to new medicines in Scotland. These are outlined below

1. Meetings in public - SMC meetings are held in public with the aim of offering all stakeholders and members of the public the opportunity to better understand how evidence is assessed, interpreted and discussed and how evidence and consultation comments from patient groups, health charities, pharmaceutical companies and clinicians inform how recommendations are made. To ensure that as much of the discussion as possible is held with the public present, a new system was introduced whereby a paper-based and anonymous voting process takes place for every medicine, after each submission is considered. The decision is announced *to the SMC committee only* in a closed session following the main meeting. Additional closed sessions may occasionally be necessary, for example when a legal obligation to maintain academic or commercial confidentiality prohibits discussion in public or if there is a need to discuss potential restrictions to use e.g. a sub-group of patient population.

2. Pharmaceutical company representation - Pharmaceutical company representatives are invited to attend and contribute to their company's submissions at SMC meetings, (full submission or re-submissions only), to respond to specific queries and be able to provide clarification on any outstanding issues.

3. Medicines used at the end-of-life and for very rare conditions – SMC introduced more flexible approaches for the evaluation of medicines used at the end of life and for very rare conditions,

¹ https://www.scottishmedicines.org.uk/About_SMC/Policy_statements/Biosimilar_Medicines

including a broader decision-making framework for ultra-orphan medicines than was previously applied (see below for guidance), the opportunity to request a Patient and Clinician Engagement (PACE) meeting (companies submitting an orphan, ultra-orphan and/or end-of-life medicine with a negative NDC recommendation), and the option to introduce a PAS at a later time-point in the process than was previously permitted, when the SMC's New Drugs Committee delivers a negative recommendation for their product.

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 – see below – but is currently piloting Early Engagement Meetings with companies. These meetings can be requested by completing and submitting an Early Engagement Information Request Form ([link](#)), returning it to gillian.halpin@nhs.net

SMC is concerned that demand for pre-submission meetings may outstrip capacity, so access to Early Engagement Meetings is limited during the pilot. The current guidance for Early Engagement highlights that a meeting is encouraged when:

- a. Intelligence suggests a submission may not be forthcoming and where there is exceptionally high patient need, for example a medicine used for a condition where no other treatment is available.
- b. A company has had limited previous experience of engagement with SMC and/or aspects of the submission suggest there would mutual benefit from a face to face meeting, to discuss concerns or issues relating to SMC process or policy at an early stage.

One area where SMC is open to early engagement, whether face-to-face as part of the pilot or in writing (see below) is with regards to submissions for products that are part of the MHRA's Early Access to Medicine Scheme.

After SMC assessment: if the decision is to not-recommend the use of a medicine companies can request a meeting. A representative of the SMC Executive (usually a New Drugs Committee (NDC) chair or vice-chair and a member of the secretariat) will meet with company representatives to discuss the submission with the aim of assisting the company in deciding their next steps.

Indirect Engagement

1. **Before submission:** SMC does not routinely meet with companies prior to submission, as SMC provides comprehensive advice and process guidance documentation on their website (see below for useful links). Any queries can be submitted to the SMC secretariat in writing. Information on how to do this is contained within the Working with SMC - Guide for Manufacturers – again, see below.
2. **During SMC Assessment:** Companies have the opportunity to comment on the New Drugs Committee (NDC) Detailed Advice Document (DAD) (“Company Comments”), in addition to answering any further questions from the assessors before or after the NDC meeting. This is an important opportunity for companies to clarify any inaccuracy or misunderstanding of their clinical and economic case, to address any identified weaknesses, to correct any inaccuracies in the DAD, to point up any modifiers that may apply and to re-emphasise *the most important* points (applying the principle of less is more). The impact that a well-written Company Comments reply has on a submission should not be underestimated. 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 also be accessed from the [SMC web page](#)

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 process within one document – this document can be found [here](#).

Not all medicines require a submission: Further information can be found in the document ***Guidance on Medicines outwith SMC Remit*** this document can be found [here](#).

To assist in your submission planning, [detailed product assessment timelines are available here](#)

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*** - this document can be found [here](#).

For Full Submissions:

The ***Guidance to Manufacturers on NPAF (October 2016)*** provides companies with guidance on how to complete the New Product Assessment Form - this document can be found [here](#).

If you consider your medicine to be Orphan, Ultra-Orphan, or End-of-life, the following may be useful; ***Guidance for Manufacturers: Supplement for Medicines for End of Life and Vary Rare Conditions (November 2015)*** - this document can be found [here](#).

If you intend to submit your medicine with a patient access scheme: [Documentation and Guidance Notes Required for completion of a Patient Access Scheme](#)

This [link](#) will take you to the SMC webpage for PACE.

A recent change in SMC process for ultra-orphan medicines involves the reformatting of the NDC DAD into the Ultra-Orphan DAD post PACE meeting. The company will receive the traditional format following the NDC meeting but will receive the revised DAD prior to their attendance at the SMC meeting. The Ultra-Orphan format incorporates the PACE outputs throughout the document, hence why SMC cannot share the final format at the time of NDC.

For Abbreviated Submissions:

If you intend to submit an Abbreviated submission, guidance and the required template can be found [here](#).

For Guidance following Non-Recommendations and other important topics

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

For medicines that are non-recommended following a submission including a PACE statement, for guidance on resubmissions click [here](#)

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 Forum. 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 in Edinburgh, focusing on issues related to access to medicines, Health Technology Appraisal (HTA) and specifically the SMC process. The meetings are held at the ABPI Scotland Offices, *Crichton House, 4 Crichton's Close, Edinburgh EH8 8DT* 0131 523 0496 | +44 (0) 7850 312430
- **The SMC User Group Forum** – Meets on a quarterly basis (in Glasgow) and enables direct engagement between the industry and the SMC. Focus is on improving SMC processes. Industry members of the UGF usually meet between the main meetings (in London or by t/c if an in-person meeting is not possible or necessary) to progress projects and discuss industry-specific issues. The meetings are usually held in the SMC offices, *Delta House, 50 West Nile Street, Glasgow, G1 2NP*
- **SMC Training sessions and Masterclasses** – Presenters from the SMC and the industry providing up-to-date advice and guidance on SMC methodology and the process for engagement
- **Members training series** – Regular planned and by request events to inform and update members on topics of interest

Hints and Tips – Participating in the SMC Meeting

As stated above, company participation in the SMC meeting is a relatively new (November 2014) procedure and is evolving as experience and confidence in the process is gained.

The purpose is to allow the company to address any outstanding questions that SMC members have and highlight any outstanding issues of which they believe SMC should be aware of prior to reaching its decision on advice to NHSScotland.

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

- ☐ Company participants must have an excellent understanding of the medicine under review and the documentation and communications submitted to SMC;
- Company participants must 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.
- ☐ With this in mind, early experience suggests that good communication in English is essential, though the Committee do appreciate that some companies may rely on their global offices to offer this level of input and support.
- ☐ 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.
- ☐ Company participants should ensure that are fully prepared by attending at least one previous meeting to observe the process; allow plenty of time for applications to be processed as demand for the limited number of places is usually high.

- ❑ 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.

The SMC Industry Lead member will email the submitting company with a written briefing on what the company representatives can expect at the meeting. In addition, participants will be invited to an industry-specific face-to-face briefing immediately before the SMC briefing session.

In summary:

- ❑ 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 at 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.
- ❑ 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. The process is designed to be non-adversarial. Company participants will be asked to introduce themselves, by pressing the 'speak' button on the microphone on the table directly in front of them and the Chair will remind everyone that all questions to the company should be addressed through him. Any 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 asked not to 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.
- ❑ When answering questions, 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 manufacturer 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”.

- ② *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*
- ② After this, company participants will be asked to leave the table and return to the public gallery; this is the point at which SMC members vote.
- ② **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.
- ② At the end of the public section of the meeting, company participants will be invited to leave the main meeting room. They will be informed of the outcome of the meeting on the Friday of the same week.
- ② The Lead Industry SMC member will contact submitting companies by email the week following the SMC Committee meeting, requesting written feedback regarding the process and the meeting. In addition, companies who receive not recommended advice for their product will receive a briefing document that outlines potential next steps.

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 both after meetings and ad hoc, usually topic specific. 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.

Next Revision date: September 2019

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).