Healthcare Improvement Scotland | SMC Advice on new medicines

Working with SMC – A Guide for Manufacturers

April 2017 (updated October 2020)

NHS SCOTLAND

Contents

1. About the Scottish Medicines Consortium (SMC)

The Scottish Medicines Consortium (SMC) was formed in 2001 to benefit patients by providing NHS Scotland with a single source of advice about the value of each new medicine. Before SMC was set up local Area Drug & Therapeutics Committees (ADTC) advised Health Boards on which new medicines should be approved for use in the local area. The introduction of SMC provided a single point of advice and reduced the duplication of effort across Scotland's Health Boards and the differences in availability of medicines between local areas.

1.1 SMC Remit

The purpose of SMC is to assess the comparative clinical-effectiveness and cost-effectiveness of new medicines and accept for use those that clearly represent good value for money to NHS Scotland. SMC has a remit to advise Health Boards across NHS Scotland and their Area Drug and Therapeutics Committees (ADTCs) about the status of all newly licensed medicines and new indications for established medicines. SMC was formed as a consortium of ADTCs, capturing the best of existing practice, experience and skills from across the country, with each Health Board represented in the consortium and participating in its decision-making. SMC has also adopted a cooperative approach beyond clinicians by having senior NHS managers, representatives of the public and the pharmaceutical industry involved in its process.

The SMC process for assessing new medicines in NHSScotland has become more transparent, with SMC meetings held in public since 2014. In 2018 Public Summaries for all decisions were introduced. These, and other changes, to the way SMC operates, have occurred partly as a consequence of the Scottish Government Health and Sport Committee's 2013 review on access to new medicines and the subsequent Montgomery Review of Access to New Medicines, published in December, 2016.

SMC aims to issue its advice as soon as is practical after a new medicine becomes available for use, and therefore requests that companies make submissions as soon as possible after receiving a Committee for Medicinal Products for Human Use (CHMP) positive opinion.

The SMC remit is confined to prescription-only medicines (POMs); it does not assess vaccines, branded generics, blood products (with the exception of anti-bradykinin and C1 inhibitor therapies) and diagnostic drugs. Guidance on the types of medicines that are outwith SMC's remit is available on our website.

In some circumstances an abbreviated submission can be made; this can often be appropriate for new formulations of medicines with a low estimated budget impact. Guidance on when an abbreviated submission might be appropriate can be found on the SMC website. If you are uncertain whether a product is within SMC remit or whether an abbreviated submission is appropriate, an enquiry can be made via a company information request form available on the website.

SMC also has a horizon scanning function that aims to improve financial and service planning within NHS Boards through the provision of early intelligence on new medicines in clinical development. Information on the horizon scanning initiative can be found on our website. In order to ensure that company products are considered in Health Board financial planning cycles, companies are requested to ensure that they enter all relevant data on medicines in phase III clinical development or those that

are three years from being made available to prescribe in the UK onto UK PharmaScan. This will allow SMC to extract most of the required horizon scanning data from this source.

1.2 SMC Organisation

SMC, the organisation, consists of the Executive, professional support staff and two committees.

The Executive's role is to guide the strategic direction of SMC and make decisions on process and policy issues. It consists of the chair, the vice chairs of the SMC and New Drugs Committee (NDC), and members of the SMC senior staff.

The SMC committee is the body that makes the decision as to whether a medicine is accepted for use in NHSScotland, or not. It is made up of around 40 members, some of whom are nominated by ADTCs and others who serve in a personal capacity. All 14 Health Boards are represented and there is a wide mixture of backgrounds to ensure that decisions are made from an appropriately wide societal perspective, not simply from the viewpoint of the clinical evidence. Healthcare managers, public partners and the pharmaceutical industry are all members of SMC and take a full part in its decision-making.

The NDC is smaller committee comprising of clinicians, pharmacists and two pharmaceutical industry members (around 20 members). It has an academic, technical remit and its role is to complete the technical assessment of a company's submission and make a recommendation to the SMC committee. NDC meetings are not held in public.

As an example, the mix of members in 2020 is summarised below, but there will be some changes over time:

Committee Members	SMC Number	NDC Number
Doctors	12	8
Primary care	1	-
Secondary care	11	8
Pharmacists	4	9
Healthcare Management	2	-
Public Partners	3	-
Pharmaceutical Industry	3	2
Health Economist	1	-
Nurse	1	-

Meetings and related timelines

Once a submission is entered into the workflow, an assessment team reviews the submission. This often includes an e-mail exchange of questions and answers with the submitting company. Assessment teams complete both clinical and economic checklists, which, with the original submission and clinical expert comments, go to the NDC, who reviews the evidence and make a preliminary recommendation to the SMC committee. The SMC committee, when it meets to consider the medicine, considers other information, such as patient group submissions, and often takes a broader view than the strictly evidence-based approach of NDC. All meetings are held virtually.

Both SMC and NDC meet monthly, with, a gap of usually six or ten weeks between a medicine being assessed at NDC and then SMC, depending on whether or not the medicine is eligible for the Patient and Clinician Engagement (PACE) process. Timelines are followed closely to ensure that decisions meet the needs of patients, prescribers and the healthcare system. Guidance on the sequence of events and the deadlines for the coming year is available on our website.

Medicines which treat rare and end-of–life conditions are eligible for the more flexible decision making process, involving a PACE meeting. If the NDC advice for these products is 'not recommended', the pharmaceutical company can request that SMC convenes a PACE meeting. This process adds an additional one to three months to the assessment timelines. The benefit is, however that clinicians and patients have a stronger voice in the assessment of these types of medicines and decision making is more flexible. In addition, companies may submit a new or revised Patient Access Scheme (PAS) at this stage in the process, which in turn may avoid some of the resubmissions that would previously have been made.

Discussion of Confidential Information

When assessing each medicine, SMC aims to hold all of the discussion in public (Part 1). On occasions however, there may be a need to hold some of the discussion in a closed session (Part 2) without the presence of the public. This may happen if there is a need to discuss in depth data highlighted by the manufacturer as confidential for commercial reasons or if there is a need to impose an SMC identified restriction. Further details on confidentiality of information are provided in section 3.4 below.

Voting

After the discussion for all submissions has finished, the meeting moves to a closed session (Part 2) and each voting member of SMC casts their vote for each medicine electronically. The outcome is based on a simple majority and the number of votes is confidential. The decision on each medicine is then made known to the committee.

1.3 Professional Support Staff

The two Committees are supported by a team of clinical reviewers made up of pharmacists, health economists, health service researchers and statisticians experienced in critical appraisal, health technology assessment and health economic modelling. For each full submission or resubmission being assessed a team comprising a pharmacist, health economist, health services researcher and an NDC committee member (known as the lead assessor) are allocated to review the company's submission.

The whole organisation is underpinned by a secretariat that provides full administrative and logistical support to the Committees and Assessment Teams and also liaises with the pharmaceutical industry and other external agencies. The work programme and outputs from SMC assessment are all available in the public domain on the SMC website.

1.4 Contact with SMC staff and members

The point of contact for a pharmaceutical company should be the SMC secretariat. The secretariat will be aware of possible upcoming submissions via the horizon scanning process and, as the expected date of marketing authorisation comes closer, will contact the company asking for confirmation of the submission date. This will generally happen at the time the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) issues a positive opinion for the product. At this time the company will be asked to advise the date they intend to make their submission and whether the product could be considered as an end-of-life medicine or orphan a medicine. The submission requirements are different for ultra-orphan medicines – see below for more detail. The secretariat can give advice on submission requirements and timings of submissions. The submission should then be made, as per the Guidance on the New Product Assessment Form, via the secretariat.

At present, members of the SMC professional support staff do not routinely meet with submitting companies – there is no option for a 'scoping meeting'. However if a manufacturer has a specific question, this can be submitted to SMC in advance of the submission, by sending a Request for Information form to the secretariat. If possible the question will be answered.

SMC does offer Early Engagement meetings under specific circumstances: when there is a suggestion that a submission may not be forthcoming and there is exceptionally high patient need, for example a medicine used for a condition where no other treatment is available (including MHRA Early Access to Medicines Schemes medicines); or 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.

SMC aims to issue timely advice, ideally as soon as possible after the product becomes available for prescribing in the UK. Therefore a company is expected to make a submission for a product once it has received a positive opinion from the EMA, CHMP or approval from the Medicine and Healthcare products Regulatory Agency (MHRA). If a submission may be delayed, companies should inform the secretariat as soon as possible after CHMP opinion, stating the reasons for delay and their intended submission timeline.

SMC follows very tight timelines, with an 18-week period for standard submissions or 22-week period for PACE medicines between scheduling the company submission for review and publication of advice. SMC staff will contact companies regarding their submission at set stages throughout the process providing information on the progress of their submission, sharing draft documents about their medicine and sometimes seeking clarification on points of fact.

Companies should be aware that, following submission and before the medicine is considered by the NDC, they will often be contacted by the SMC secretariat for further information, clarification on information already submitted or additional analyses in relation to the health economics component of

the submission. In some cases the company will be expected to provide significant amounts of information within tight timescales.

While the SMC professional support staff are happy to answer questions about a company's submission at other points of the process, the staff cannot comment or give opinions on specific aspects of the evaluation of a submission while the assessment process is underway.

After NDC has considered the submission (NDC meets on the last Tuesday of every month except December) each submitting company will be sent, in confidence, preliminary advice on the Friday following the meeting. The company is given an opportunity to comment on this with a 10 working day deadline for response – see company comments guidance on our website. At this stage there may also be requests for clarification of information submitted or further analysis of information already submitted. Once the company response has been received, it is included in the paperwork for SMC members, alongside the submission.

For end-of–life and orphan medicines, if the NDC advice is 'not recommended' and the company wishes SMC to convene a PACE meeting, the company is asked to submit a PACE statement alongside comments on the NDC draft advice. The company also has the opportunity to submit a new or revised Patient Assess Scheme (PAS) at this time. Further detail on PAS provided below.

After SMC has reviewed the submission, (SMC meets on the first Tuesday of every month), the submitting company will be informed in confidence of the SMC decision, and sent the Detailed Advice Document (DAD), on the following Friday. SMC does not anticipate notification of any further changes after the Company Comments deadline.

NHS Boards are also informed of the advice, in confidence, at this stage. This information will not be made public, however, via the SMC website, until 4 weeks after the SMC meeting. In the intervening period, NHS Boards are expected to prepare for the consequences of the decision.

If relevant, competitor companies are sent a copy of the advice on the Monday of the week following the SMC meeting, to enable them to review statements on their product in the DAD.

If a product is 'not recommended' for use, and the company wishes to consider making a resubmission, a meeting with SMC representatives is recommended. These company meetings are arranged via the Secretariat and are held following publication of the DAD on the SMC website; they normally involve a member of the SMC Executive (usually the vice chairs of NDC and SMC), and a member of the secretariat. It should be noted that individual members of the assessment team are not involved in these meetings. Guidance on meetings with pharmaceutical companies post-SMC can be found on the website.

2. Notes for Manufacturers on Submissions

2.1 Abbreviated submissions

The SMC will consider an abbreviated submission in some circumstances, for example for a new formulation of an established product with a low net budget impact.

Separate guidance on abbreviated submissions is published on the SMC website. Manufacturers should seek confirmation from the SMC secretariat that an abbreviated submission is appropriate prior to making the submission.

2.2 Full submissions

SMC makes recommendations on new medicines to NHS Boards based on an assessment of the clinical and cost-effectiveness within the NHS in Scotland. It is therefore important that manufacturers submit clinical and economic evidence according to the principles and standard outlined in the guidance documents.

The only exception to the requirement for an economic evaluation is where a medicine fulfils the SMC criteria for an abbreviated submission (see above).

The SMC assessment of the likely clinical and cost-effectiveness of a medicine is based on the evidence in the manufacturer's submission. In their submission, the manufacturer needs to demonstrate the case for the clinical and cost-effectiveness of the medicine through a clear, concise, unbiased and robust case to support the application. Each SMC meeting involves around six submissions, therefore it is imperative that manufacturers provide a concise case. Robustness will be judged on the basis of the methodological quality of the case submitted. The application needs to show that the medicine will:

(i) provide additional health benefits that are valued by patients compared to current Scottish practice and that this is at a net cost to the NHS that offers acceptable value in relation to other uses of the same resources,

or

(ii) offer equivalent levels of health benefit to patients at an equivalent or lower net cost to the NHS.

2.3 Positioning within license

SMC has a remit to consider the full indication covered by the marketing authorisation for a new medicine. In some circumstances, however, the company may wish to make a case for the clinical and cost effectiveness of the medicine for a narrower population than that covered by the full licensed indication(s). For example, where the company wishes to make the case for the medicine when positioned for use in a specific patient sub-group in order to maximise its cost-effectiveness.

(i) Where a submission covers only part of the marketing authorisation for a product the submitting company must detail all other aspects of the marketing authorisation that are within SMC remit but have not been covered in the submission.

(ii) Where a submission positions a medicine for use in a sub-group of patients narrower than that covered by the marketing authorisation, the submitting company should ensure that the proposed population for treatment is appropriate and valid within the licensed indication under consideration in the submission.

The manufacturer must state explicitly on the registration page under 1b) that SMC is asked to consider the use of the medicine when positioned for use in a sub-group of the population covered by the marketing authorisation.

2.4 Submissions for medicines for end of life or rare conditions (orphan)

SMC has a special process for the above medicines, primarily related to the ability to request a PACE meeting should the NDC be minded to not recommend the medicine. Companies should therefore read the appropriate guidance on the SMC website. The definitions of orphan/orphan equivalent medicines are based on the full population of the licensed indication irrespective of whether or not the company wishes SMC to consider the product when positioned for use in a sub-population of the licensed indication. The definition of an end of life medicine may be based on a sub-population of the licensed indication where the manufacturer provides adequate justification. In addition to requesting a PACE meeting, the submitting company may also submit a new or revised PAS to improve the cost-effectiveness of their medicine at this stage.

2.5 Submissions for medicines with EMA conditional marketing authorisation

SMC can now accept some medicines on a conditional basis subject to further evaluation. All medicines with EMA conditional marketing authorisation are eligible for this decision option. SMC may issue interim accepted (or interim accepted with a restriction) advice if the committee considers that the additional efficacy and / or safety data requirements in the EMA specific obligations are expected to address the key uncertainties in the evidence presented by the submitting company. The company will be required to provide a full updated submission to SMC when the conditional marketing authorisation is converted to a standard marketing authorisation, typically after 2-3 years. Further information can be found in the appropriate guidance on the SMC website.

2.6 Ultra-Orphan medicines

Following the 2016 Review of Access to New Medicines, the Scottish Government introduced a new pathway to support patient access to medicines for extremely rare conditions – the Ultra-Orphan Pathway. This requires the company to submit their medicine for validation as an ultra-orphan medicine, using the proforma available on the SMC website, which details the criteria against which the medicine will be validated. Following validation, the company can request an Early Engagement meeting with SMC to discuss the challenges within their submission, the uncertainties that they foresee and their proposed submission timelines. Following CHMP positive opinion, the company submits a full submission using the Ultra-orphan New Product Assessment Form (NPAF). The company must also provide a PAS (this is a condition of the pathway). The submission is reviewed by NDC and SMC and an Ultra-orphan Medicines Assessment Report (UMAR) is issued, but no decision on availability in NHSScotland is made. Instead, the company enters into a data collection agreement with Scottish Government, with the aim of exploring and addressing the key uncertainties in their submission. At the end of the data collection period (after approximately 3 years), the company submits for re-assessment, incorporating the new data in their submission. Full information on this pathway and the requirements for inclusion/submission can be found on the SMC website and in Scottish Government guidance.

2.7 Resubmissions

If ‘not recommended’ advice has been issued for a product, and the company wishes to consider a resubmission, they can request, via the Secretariat, a meeting with SMC, with the aim of better understanding why their product was not recommended, thus allowing an appropriate focus for the resubmission.

A resubmission requires new clinical evidence or a new analysis of existing information about the medicine. In most cases the resubmission will follow the same process and timelines as all other submissions. Where possible SMC will ensure that the assessment team involves a pharmacist and an economist who were not involved in the previous submission, but the assessors can be briefed by the original assessor if required. If, however, the only change is a new or improved simple PAS, the company may resubmit using a fast-track process which allows the submission to proceed directly to SMC within a shorter assessment timeline.

3. The New Product Assessment Form (NPAF)

The NPAF provides a template for the evidence to be provided within the company submission. Detailed guidance notes for the completion of the new product assessment form are available on the SMC website. These include a description of the type of information expected to be submitted within each section of the form; an indication, where appropriate, of the expected source of the information; and how the information should be presented.

There is a separate NPAF for ultra-orphan medicines. The detailed guidance notes for the completion of the NPAF is a useful reference as is the supplement entitled 'Submissions for medicines for extremely rare conditions (ultra-orphan medicines)'.

The deadline dates for submitting NPAFs to SMC can be found in a timetable on the website. Incomplete submissions cannot be scheduled for assessment. Once an NPAF has been submitted to SMC no amendments can be made.

Submissions should be concise, but also include all relevant data. The required information is stated for each section of the document and applicants should focus on these requirements and not include information that is not directly relevant to the indication under review. As far as possible, manufacturers should limit the electronic size of the document since it may have to be distributed across servers with varying limits to file size. For guidance, most submissions have a file size of around 1 to 2 megabytes.

The submission should be a stand-alone document. It should focus on information related to the indication for which approval is sought, rather than all available data for the medicine. Appendices may be used for information that exceeds the level of detail requested in the guidance but only when considered essential – they should not present core information. For example it is not acceptable to attach a key study as an appendix and to complete the efficacy section with 'see Appendix X.' In some cases it will be more appropriate to include data as a supporting document, referenced in the text, than as an appendix. SMC also requires completion of an Excel budget impact template for all full submissions. A blank template can be found on the SMC website.

3.1 SMC Review Checklists

The SMC/NDC use checklists as part of their review process, as these improve consistency and aid in supporting an efficient review process. Blank copies of the economics checklist and clinical checklist are made available to industry, via the SMC website. It should be noted, however, that this is provided to aid understanding of the SMC review process. It is not a 'tick-list' for submitting companies i.e. providing all the information on the checklist does not mean that no other information is required. The full NPAF Guidance must be followed.

3.2 Key points on methods

- It is the company's responsibility to clearly demonstrate the case for the cost-effectiveness of a medicine submitted to SMC. If the company does not submit economic evidence according to the principles and standard outlined in the guidance the SMC will be unable to accept the medicine for use in NHS Scotland
- The perspective adopted on costs should be that of the NHS in Scotland and social work.
- The evidence submitted must be assembled systematically and synthesised in a transparent and reproducible way.
- All data used to estimate clinical and cost effectiveness must be presented clearly in tabular form and include details of data sources.
- Clinical and cost-effectiveness needs to be considered over an appropriate time horizon relevant to Scottish practice and patients and all relevant treatment options for the specific patient groups should be compared.
- In general, cost-utility analysis is the preferred form of economic evaluation, with health effects expressed in terms of quality-adjusted life-years (QALYs).
- The SMC considers modelling a relevant framework within which available evidence can be synthesised and estimates of clinical and cost-effectiveness generated.
- The annual discount rate recommended for both costs and benefits is 3.5%.
- Uncertainty surrounding the estimates of cost-effectiveness needs to be included.

Further guidance on methods is provided in the Guidance to Submitting Companies for Completion of the NPAF.

For the assessment of ultra-orphan medicines, the ultra-orphan framework will be used, similar to that used by the National Institute of Health and Care Excellence (NICE) for highly specialised technologies (HST). The QALY will be requested but a wider perspective will be taken on the value of the medicine.

3.3 Key points on references

- All evidence included in the submission should be referenced throughout the NPAF and references should be numbered in the order in which they first appear in the text. Each reference should have only one number that is repeated if it is cited more than once.
- At the end of the submission a list of all references should be provided in the Vancouver style, numbered and ordered strictly in accordance with their numbering in the text. Author/date styles of referencing should not be used. Submissions have been received where listed references did not correspond to the citation in the text, including some with mixed referencing styles. These are unacceptable. Referencing through the use of word processing devices such as footnotes/endnotes is also not acceptable.
- Electronic copies of all references cited in the submission should be sent to the secretariat in a zipped file to be received no later than the monthly deadline for receipt of company submissions. Should the file size exceed 20 MB, please condense into separate files and send each file separately. Each reference should be provided as an individual electronic file and should be in an electronic format that can be searched i.e. Word or Portable Document Format (PDF). Scanned documents are not acceptable other than in exceptional cases where it is impossible to provide a document in a searchable format.

- Full versions of in-house clinical study reports and/or drafts for publication should be provided where these have been used as data sources. These are required for assessors to make factual checks and to gain a comprehensive understanding of relevant study methodology, conduct and results. Synopses and selective extracts are not sufficient.
- On request from the submitting company, SMC will treat data from these sources (that are not otherwise in the public domain) as confidential and the information will not be disclosed in any form to persons or organisations outwith the SMC committee and NDC, SMC clinical and economic assessors and secretarial staff.
- These data will be annotated (by underlining) to indicate that they are confidential in paperwork provided to the SMC committee and NDC, and will be removed from the SMC Detailed Advice Documents that are issued to the NHS and posted on the SMC website.
- While SMC encourages full referencing of the evidence presented, please avoid the inclusion of unnecessary references such as those that duplicate evidence provided by more robust sources.

Further guidance on referencing, including the use of abstracts and posters as sources of information, is provided in the Guidance to Submitting Companies for Completion of the NPAF.

3.4 Confidentiality of Information

SMC is committed to transparency in its decision-making, for this reason confidential information should be kept to a minimum and only data that are genuinely confidential, such as actual numbers should be marked by the company as 'in confidence'. If the medicine is subject to a confidential Patient Access Scheme (PAS), SMC preference is to quote the with-PAS incremental cost effectiveness ratio (ICER) used for decision making at the SMC meeting and to publish this figure in the final DAD.

Information provided in company submissions will only be available to members of SMC and NDC, SMC clinical and economic assessors and secretarial staff. Academic in confidence (AiC) information will also be available to members of the PACE group within the NDC preliminary advice.

Information that is commercial in confidence (CiC) or academic in confidence (AiC) will be annotated by underlining and highlighting in the DAD made available to committee members and will be removed before making the DAD available to the public. During SMC meetings in public, confidential information will be redacted from PowerPoint slide presentations, AiC data may be verbalised unless the company notifies SMC that the data are not theirs and therefore, they cannot grant permission. Should CiC information need to be discussed, a closed 'Part 2' meeting will be held.

Companies are required to state why the data are confidential and the timescale within which they will remain confidential should be detailed within the NPAF. SMC will respect confidentiality, but reserves the right to include data that are already in the public domain e.g. as a published abstract or conference poster. In such cases, SMC will not exceed the level of detail in the published source and the submitting company will have an opportunity to review the Detailed Advice Document (DAD) as part of the routine consultation process, as outlined below. It should be noted that SMC's critique of the clinical and economic evidence as summarised in the DAD is owned by SMC and may not be marked as confidential (excluding information that is genuinely confidential as described above). SMC is committed to adhering to the guidelines agreed with ABPI that appear on the SMC website.

4. SMC decision making

4.1 Where a higher cost per QALY may be accepted

The SMC does not have a formal threshold cost per QALY below which cost-effectiveness would be considered demonstrated. Nor does SMC have a fixed upper limit on willingness- to-pay for a QALY. The cost per QALY is only part of a wider judgement of the value of a new medicine. Where the cost per QALY is relatively high, other factors also play a role in SMC's assessment and may modify the final decision (see below).

4.2 Modifiers

In assessing the relative clinical and cost effectiveness of new medicines, the SMC requires a robust clinical and economic case to be made and for the medicine to demonstrate value for money. In some specific situations SMC may exercise greater flexibility in its decision making to allow consideration of additional factors. These additional factors, known as modifiers, may allow SMC to accept either more uncertainty in the health economic case (or a higher cost per QALY). There are specific modifiers that apply to medicines for EMA designated orphan conditions.

Further information on SMC modifier's policy can be found in the website.

4.3 PACE Meetings

When a PACE meeting has been convened, the output from this meeting, which includes a wider perspective from clinician and patient groups who are experts in this disease area, will be considered by the SMC when making its recommendation. The output from the PACE meeting will be an important factor in the SMC decision.

4.4 Patient Access Schemes

Patient access schemes (PAS) are schemes proposed by pharmaceutical companies to improve the cost-effectiveness of medicines, thereby facilitating patient access. Patient access schemes will be considered by NHS Scotland to facilitate access by patients to medicines that are not, or might not be, in the first instance found to be cost-effective by SMC

PAS schemes are examined by a body separate from SMC. The Patient Access Scheme Assessment Group (PASAG) has been established to undertake an objective and independent assessment of PAS submitted by companies on a national basis.

Manufacturers should submit any PAS at the same time as they are making their submission to SMC. Both submissions must be made via the SMC secretariat. PASAG then reviews and makes a recommendation on the proposed PAS to SMC for consideration alongside the manufacturer's SMC submission. For medicines to treat end-of-life or orphan conditions, if the NDC advice is 'not recommended', the company has the option to submit a PAS at that point, or to modify the current PAS.

The submission of a PAS is a condition for entry into the ultra-orphan pathway.

Full guidance covering submission of a patient access scheme and the SMC approach where a comparator medicine has been accepted for use on the basis of a confidential PAS is available on the SMC website.

4.5 Company attendance at virtual SMC Meetings

Companies have participated in SMC meetings since November 2014. The purpose of their attendance is to allow them to address any questions that SMC members have and provide clarification on any outstanding issues which they believe SMC should be aware of prior to reaching its decision on advice to NHSScotland. It is expected that two participants from the submitting company will attend: ideally the participants will have been involved in the development of the submission and therefore have the ability to respond on cost and clinical-effectiveness issues. Further information regarding company participation can be found in the Toolkit for Engaging with SMC Appraisals. It is recommended that company participants attend at least one previous meeting as a member of the public, to observe the process.

5. Freedom of Information

SMC is part of the Evidence Directorate in Healthcare Improvement Scotland (HIS), a public authority covered by the Freedom of Information (Scotland) Act 2002. Information on how to make a freedom of information request, and on your information rights, can be found on the HIS website.

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