

Frequently Asked Questions from Clinical Experts

1. What is the Scottish Medicines Consortium (SMC)?

The Scottish Medicines Consortium (SMC) is a consortium of Area Drug and Therapeutic Committees (ADTCs) with representation derived from across NHSScotland. SMC also has representatives from the pharmaceutical industry. There are also public partners whose role is to help ensure the views of the public are taken into account during SMC decision making.

2. What does SMC do?

The Consortium provides advice to all NHS Boards and their ADTCs about the status of newly licensed medicines, new formulations of existing medicines and any major new indications for established products. This advice is given as soon as practical after the launch of the product involved. NHS Boards are advised that no new medicine should be used routinely in their areas until SMC makes a recommendation. These recommendations are made available on the SMC website (www.scottishmedicines.org.uk) which is updated regularly each month. Advice to ADTCs is disseminated in confidence shortly after each meeting, and approximately one month before it is published on the website.

SMC also has a horizon scanning function; the aim of which is to improve financial and service planning within NHS Boards through the provision of early intelligence on new medicines in clinical development.

3. What form does SMC Advice take?

SMC considers the clinical and cost effectiveness of each medicine and issues its advice on the following terms:

- The medicine is accepted for use in NHSScotland
- The medicine is accepted for restricted use
 - restricted to a patient group
 - restricted by prescriber
- The medicine is not recommended for use in NHSScotland

The committee also has the opportunity to accept some medicines on an interim basis subject to ongoing evaluation and reassessment.

A detailed advice document is prepared for release giving reasons for the advice.

Submissions for medicines that are validated as ultra-orphan according to the revised definition will be assessed by SMC and will then be available to prescribers for a period of up to three years while further clinical effectiveness data are gathered. After this period the company will be asked to provide an updated submission for reassessment and SMC will make a decision on routine use of the medicine in NHSScotland.

Health professionals are expected to take due account of SMC advice when exercising their clinical judgement. This recommendation does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

4. How does SMC carry out its assessment work?

SMC meets on the first Tuesday of each month and considers on average six to eight new medicines at each meeting. Its work is supported by a team of economic and clinical assessors, and the New Drugs Committee. The New Drugs Committee (NDC) meets on the last Tuesday of each month.

SMC's assessment process first requires pharmaceutical companies to complete a New Product Assessment Form (NPAF) and supply the necessary supporting data for consideration.

Thereafter, there is a staged assessment process, which briefly, is as follows:

- The submission is first, critically evaluated by an assessment team.
- The team's evaluation then goes forward to NDC, a scientific committee that appraises the clinical and economic case made in the submission and provides draft advice for SMC.
- The NDC draft is shared with the submitting company, allowing them to make comments, for consideration by SMC.
- Medicines validated as meeting end of life and/or orphan/orphan equivalent criteria are eligible for an additional step, patient and clinician engagement (PACE). At the PACE meeting, patient representatives and clinicians describe the impact of a condition on quality of life to patients and carers and any improvements a new medicine could bring. Medicines validated as eligible for the ultra-orphan pathway will be eligible for PACE at reassessment following evidence generation.
- At its monthly meeting, SMC then considers all the scientific evidence, expert opinion, company comments, the output from the PACE meeting (if applicable) and any wider prevailing factors, such as patients' perspective, before issuing their final advice to the submitting company, and NHS Boards/ADTCs.

5. How does SMC carry out its horizon scanning?

Horizon scanning is carried out by a team including pharmacists, health services researchers, finance experts and a project officer.

Horizon scanning information is detailed in an annual report (Forward Look) issued in confidence each October to key Health Board personnel, including Directors of Medicine, Finance, Pharmacy and Public Health. The Directors of Finance and Pharmacy also receive a set of financial spreadsheets that summarise the estimated net budget impact of 'high impact' new medicines. The Forward Look report lists all new medicines expected to reach the UK market within the next calendar year but focuses on those with the potential for 'high impact'. These include medicines with a predicted moderate to high net medicine budget impact for NHS Scotland relative to comparators (i.e. >£500,000 per annum at year five) and those potentially associated with major service implications.

6. Why does SMC need clinical expert advice?

SMC is a large body of some 50 people. Membership includes Health Board Chief Executives, Directors of Finance and Pharmacy, ADTC Chairs, economists, industry representatives, lay members and clinicians from primary, secondary and tertiary care.

It is not practical to include representation from all clinical specialty areas on the Consortium itself. However the robustness of SMC's assessment process depends very strongly on opinion and advice from clinical experts. SMC has therefore established a panel of several hundred clinical experts representing a wide range of specialty and sub specialty areas from across Scotland.

Clinician, as well as patient views, are integral to the PACE meeting, which is held if preliminary NDC advice is 'not recommended'. Clinicians are nominated by clinical networks or special interest groups. The aim of the PACE meeting 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.

Clinical expert advice is an essential part of the horizon scanning processes that provide NHS Boards with intelligence on new medicines in clinical development (including new chemical / biological entities, new indications and new formulations of established medicines) anticipated to enter the UK market in the next calendar year.

Clinical expert advice is also required for the validation process for medicines being considered for entry to the ultra-orphan pathway and occasionally to validate end of life and/or orphan equivalent status for medicines being considered for eligibility for a PACE meeting.

7. How does SMC identify Clinical Experts and invite them to join the Expert Panel?

Clinical experts may be nominated by colleagues or via networks (e.g. cancer networks) or special interest groups. SMC invites nominees to join the panel by completing the necessary engagement forms. To ensure SMC always consults the most appropriate experts available, it is important that experts who agree to join, provide as much detail as possible in terms of their specialty and sub-specialty interests.

8. Does SMC only consult with Clinical Experts in Scotland?

SMC normally consults with Scottish clinicians. However, occasionally it will assess treatments for very rare conditions where there may only be a few patients in Scotland and therefore only limited clinical expertise may be available, or none at all. In those circumstances SMC will approach experts in larger treatment centres based in England and Wales.

9. How does SMC contact Clinical Experts on the panel?

Due to the very tight timescales that SMC works to (please see Question 10 for details of SMC processes and timescales), experts will normally be contacted by email, or occasionally by telephone.

- Contact for assessment work will be made through the SMC Secretariat and there is no requirement to attend meetings.
- Contact for PACE meetings will be made by an SMC PACE coordinator and experts can attend the PACE meeting in person (at SMC, Delta House, West Nile Street, Glasgow) or by teleconference or video conference.
- Contact for horizon scanning activities will usually be made via the Horizon Scanning Pharmacist(s).

10. How do Clinical Experts fit into SMC's assessment process?

As described in Question 4, SMC undertakes a staged assessment process.

In total it takes an average of 15 to 18 weeks from the assessment commencing to the advice being released into the public domain. This is extended by one to three months when a PACE meeting is convened.

Experts are engaged at the beginning of the assessment process, to provide contextual information on current prescribing practice (may include off-label prescribing or unlicensed treatments), disease prevalence, where there is unmet need and where new products may fit into or replace existing treatments. We ask for this information in the form of six generic questions, see appendix 1. This information informs the scientific critique carried out by a team of assessors. Therefore we ask clinical experts to respond with this information within two to three weeks.

As the assessment proceeds, it may be necessary to consult with clinical experts again for advice on specific issues that may have been highlighted by the assessment team, NDC or SMC. These additional requests will be in the form of one or two specific questions, perhaps in relation to a sub group of patients or to check some of the assumptions made in the company submission. Again, due to time constraints (we may be seeking advice to allow SMC to make their final decision) SMC will seek a prompt response.

For medicines validated as meeting end of life and/or orphan/orphan equivalent criteria, a PACE meeting may be convened in the event of preliminary 'not recommended' advice from NDC. The clinicians participating in the PACE meeting may not be the same as those clinical experts consulted during the medicine assessment, as described above. PACE clinical experts are asked to provide answers in advance of the PACE meeting to eight questions which form the clinician template, see appendix 2. In addition they attend the PACE meeting in person or by teleconference/video conference where a consensus PACE statement is agreed.

11. How do Clinical Experts fit into the Patient Access Scheme Assessment Group (PASAG) Assessment Process?

A patient access scheme (PAS) is a scheme proposed by a pharmaceutical company in order to improve the cost-effectiveness of a medicine and enable patients to receive access to cost-effective innovative medicines. PASAG, established under the auspices of NHS National Services Scotland, reviews and advises NHS Scotland on the feasibility of proposed schemes for implementation. PASAG will undertake an independent assessment of the PAS and advise SMC on its feasibility for implementation by NHS Boards in Scotland. The PAS will be considered as part of the cost-effectiveness case submitted to the SMC. If a product has been submitted to SMC with a PAS clinical experts may occasionally be asked to respond to a list of medicine specific questions to assist PASAG. Your responses will be forwarded to the PASAG Secretariat.

12. How do Clinical Experts fit into SMC's horizon scanning process?

For horizon scanning processes, clinical expertise is required to support the Horizon Scanning Team generate estimates of the potential financial and service impact that new developments may have on NHS Scotland. This includes defining the patients or clinical circumstances in which the new product or indication is likely to be used, estimating the number of patients in Scotland likely to receive the new product and considering the potential cost and service impact of the new development. Considerations for identifying high impact medicines during horizon scanning activities are included in appendix 3.

13. How frequently will I be contacted for advice for assessments?

It is difficult to quantify how frequently SMC will contact individual experts. SMC assesses approximately 6 to 8 new medicines/new indications/new formulations each month. As the submissions cover all therapeutic areas, you may be contacted frequently or less often depending on the individual medicines being considered.

Routinely three PACE meetings are held each month and will be for a range of medicines, with many being for cancer.

We aim to have several experts on our Expert Panel for each specialty area so that we can avoid having to contact the same experts repeatedly.

14. What sort of information and advice will SMC ask for?

Please see Questions 10, 11 and 12.

15. Do I have to do further reading or research when providing advice to SMC?

This is a matter for individual experts. If SMC has correctly identified the appropriate experts then more often than not they will have the necessary information at their fingertips (see questions 10, 11 and 12), although in some instances the expert may choose to do some preparatory reading or source information e.g. on local disease prevalence etc. and this is likely to be more important when responding to questions for horizon scanning activities.

Requests for more specific advice may require a little reading or research but SMC would hope that the input required would be relatively minimal.

16. If I provide advice to SMC, will my advice or my identity be made public?

All expert responses associated with SMC assessments are anonymised by the SMC Secretariat before they are included in the meeting papers for NDC, PACE and SMC. The output from the PACE meeting is anonymised and included in meeting papers for SMC. Clinical expert views are also anonymised when included in horizon scanning reports.

For medicines which represent a therapeutic advancement, SGHD/CMO (2012)¹ requires SMC to include, in the SMC Detailed Advice Document, the consensus of opinion of the place that the medicine would have in therapy as provided by clinical experts (where this has been articulated).

However, all information received by SMC may be subject to disclosure under the Freedom of Information (Scotland) Act 2002. Your identity, and response may be disclosable, if requested under the Act.

17. Why do I have to declare interests for each product I am asked to advise on?

Experts' interests can change over a period of time, to ensure an open and transparent process SMC records details of any interests held by all those involved in the assessment of each submission. It is important that clinical expert responses used in SMC assessment of the evidence for a medicine are perceived as being impartial, we are therefore unable to use responses from clinical experts who have a personal specific interest in the medicine under review or a direct competitor.

Declaration of interest for clinicians attending PACE meetings and those providing clinical expert input for medicines considered via the ultra-orphan pathway are noted and experts with declared interests can be involved.

Declarations of interest on specific products are not required when commenting on horizon scanning intelligence / information.

18. I am unsure about my declaration of interest, for example:

Q1	I recruited patients into a company sponsored trial and prescribed the medicine under review but did not receive personal payment, is this a personal interest?
A1	This is a non-personal specific interest unless you are likely to benefit personally in some other way e.g. by being a Chief Investigator or Co-Chief Investigator or a Principal Investigator who is likely to benefit from authorship of a resulting publication.
Q2	I was paid to participate on an Advisory Board for the medicine under review six years ago, does the personal interest still apply?
A2	No because involvement was more than three years ago this is classed as a lapsed personal specific interest. (However, note that a personal specific interest as a result

	of significant involvement in the development of a product, or through authorship of a core publication on the product, never lapses).
Q3	What constitutes a significant involvement in the development of a product?
A3	This includes pre-clinical and clinical development e.g. being a Chief or Co-Chief Investigator of a company funded clinical trial or being paid to provide scientific advice.
Q4	I participated on an Advisory Board for the medicine under review but didn't receive/accept payment, is this a personal interest?
A4	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q5	I participated on an Advisory Board for the medicine under review but passed payment to charity, is this a personal interest?
A5	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q6	I directly advised the Company on their SMC submission but didn't receive payment, is this a personal interest?
A6	Yes as this might reasonably be perceived as possibly affecting your impartiality.
Q7	I was paid to take part on an Advisory Board for the medicine under review but in a different indication, is this classed as a specific interest?
A7	Yes as the interest relates to the same product.
Q8	I received travel expenses from Company X to attend a conference, is this a personal interest?
A8	Such expenses should be declared, however would not be considered as a personal interest unless the expenses were disproportionate.
Q9	I attended a conference sponsored by a number of companies and received travel expenses from my department, do I need to declare an interest?
A9	No.
Q10	I attended a conference satellite meeting in relation to the medicine under review, is this a personal interest?
A10	Not unless disproportionate expenses/hospitality were provided by the pharmaceutical company.
Q11	Company X paid my registration fee to attend a conference, is this a personal interest?
A11	Yes. This would be considered a non-specific interest unless directly related to the medicine under review.

Q12	I have a personal specific interest in a medicine that is a direct competitor to the product under review, should I declare this?
A12	Yes as this also represents a personal interest in the medicine under review.
Q14	I am a SMC clinical expert and have a personal specific interest in the medicine under review, will my responses be considered by SMC?
A14	It is important that clinical expert responses used in SMC assessment of a medicine are perceived as being impartial. SMC is therefore unable to use responses from experts who have a personal specific interest. However experts who have a personal specific interest can be involved with PACE.
Q15	After what time period do interests lapse?
A15	Personal specific interests lapse after a period of three years unless they are as a result of significant involvement in the development of a product, in which case they never lapse. Personal non-specific and non-personal interests normally lapse after 12 months.

19. Will my interests be made public by SMC

SMC may be required to disclose information following a request, under the terms of the Freedom of Information (Scotland) Act 2002 (via a Health Board) (see question 16).

20. Confidentiality

SMC's assessment of a submission remains confidential until it is released into the public domain.

In addition, some of the information that is supplied to SMC by the submitting company, can be deemed to be commercial, or academic-in-confidence. SMC therefore requires assurance that they will not suffer any loss through a breach of confidentiality.

NHS employees acting as clinical expert advisers to SMC are indemnified under their contracts of employment with their NHS Board employers against possible court action arising from their SMC activities. SMC requests that confidentiality is observed in respect of all information shared in relation to the SMC submission and horizon scanning processes and that steps are taken to ensure it is not breached.

For non-NHS employees acting as clinical expert advisers, SMC requests that confidentiality is observed in respect of all information shared in relation to the SMC submission and horizon scanning processes and that steps are taken to ensure it is not breached.

Appendix 1: Six Generic Questions that SMC asks in relation to each submission:

Please answer the questions in relation to the licensed indication/positioning:

1. What prescribing guidelines are available, or in preparation, which could influence Scottish prescribing in the indication under review/positioning proposed by the company?
2. Does the medicine under review fill any unmet need (i.e. used in a therapeutic area where there is currently no satisfactory treatment(s)).
3. What are the current treatments used in Scotland for the indication under review (including non-pharmacological options if relevant)? Please indicate which is the predominant treatment and what is your preferred treatment (if different to predominant treatment).
4. If accepted for use, what treatment is most likely to be displaced by the medicine in the indication under review/positioning proposed by the company?
5. SMC has a role to provide advice on the clinical and cost-effectiveness of new medicines compared to existing treatments. If you have knowledge of this particular new product:
 - Do you consider it to be a therapeutic advancement in the treatment of the indication under review? If so, please explain
 - Describe how it might fit into your treatment plan (e.g. situations where it might be more appropriate).
 - Are there any further issues that might be relevant to introduction of this medicine into clinical practice (e.g. service implications).
6. Disease prevalence: if you have this information, please estimate how many patients are likely to be eligible for treatment with the new product in your Health Board or catchment area and/or in Scotland. (Please specify Health Board or catchment area)

Appendix 2: Standard questions for medicines eligible for patient and clinician engagement (PACE)

1. Severity of the condition

Please describe the impact of the condition on patients, carers and their families and give your assessment of severity.

2. Unmet need

Please outline how this new medicine would address the unmet needs of people affected by this condition.

3. Added value of the medicine for the patient

a. How would this medicine be expected to add value to the patient's wellbeing and experience of care?

Note: Consider impact on quality of life such as the ability to work or continue in education / continue to function, symptoms such as extreme tiredness, pain, psychological distress, also factors such as convenience of the treatment, whether it allows self-care or the ability to maintain independence and dignity, out of pocket expenses. Where possible please provide supporting evidence.

b. How is this medicine better than current treatments?

Note: Consider burden of current treatments, improvements in quality and convenience of treatment, reduction in side effects and reduction in risk of complications. Where possible please provide supporting evidence.

c. Does the medicine have the potential to make a significant and substantial impact on health related benefits? If so, please explain how.

4. Added value of the medicine for the patient's family or carers

Please outline how treating a patient with this medicine might impact on the patient's family or carers. For example, in terms of time for accompanied visits for treatment, requirement for assisting the patient with personal care and support, out of pocket expenses, impact on family life and impact on the carer's ability to work.

5. What is the most appropriate position for the medicine in the pathway of care for the condition? Does this differ from the company's proposed positioning?

Please give your views on how the new medicine is expected to be used in relation to currently available treatments.

6. Are there any important considerations in relation to treatment delivery (e.g. how treatment should be monitored; how long it should be continued; any significant service infrastructure or staffing issues in relation to delivering the treatment etc.)?

Note: Consider the burden of monitoring on patients, carers and healthcare resources.

7. Other considerations

Please note any further considerations not included in the other sections of this form.

8. What are the key factors that would justify this medicine being routinely available in NHSScotland?

Appendix 3: Considerations for identifying high impact medicines during horizon scanning activities

It may be helpful to consider the following points when assessing the likely financial and / or service impact of a medicine for NHS Scotland.

1. Is the medicine a first in class medicine or a medicine that potentially offers a significant improvement in disease management or has an improved side effect profile? This may be particularly relevant where there are currently no real pharmacological treatments or alternatives.
2. Will the medicine be associated with a high cost or a prolonged duration of therapy (e.g. maintenance or preventative therapies, novel or personalised therapies, orphan medicines)?
3. Will the medicine be used in a large patient population (e.g. high volume cancers such as breast, colorectal, lung and prostate)?
4. Will the medicine have significant service implications (e.g. tissue testing required, complex administration, preparation or storage requirements, monitoring requirements, prolonged duration of administration, new clinics required, significant impact on staff time)?
5. Will the medicine be additive to existing therapies (e.g. biologicals, gene therapies, personalised vaccines) and therefore be associated with additional cost and service impact or will it be used instead of an existing therapy (and cost-offsets will need to be considered)?
6. At what stage of the disease process will the medicine be used (e.g. first, second or subsequent line, newly diagnosed patients versus patients with metastatic / advanced disease)?
7. Will the medicine be produced as a new formulation or offer an alternative route of administration with potential benefits for patients (i.e. change from intravenous to oral administration)?
8. Is the medicine being developed for a high profile indication (e.g. media / patient group pressures, political implications)?
9. Will the introduction of the medicine have potential implications for primary care and / or public health (e.g. medicines for prevention of cancer, medicines for obesity or alcohol dependency)?