

Re-evaluation of SMC decisions

Overview

Introduction

The SMC promotes an open and consultative approach to its methodology and working procedures. Ongoing dialogue with sponsor pharmaceutical companies should minimise the number of occasions when disagreements occur with respect to process or scientific assessment. SMC is committed to rapid, fair and objective assessment of all applications, but occasionally sponsor companies may disagree with the conclusions of an SMC assessment.

SMC has processes for use when such disagreements arise, in two types of situation - one surrounding the **process** by which an SMC decision has been reached, the other surrounding the **evidence** review / scientific conclusions. These are addressed separately below. When the sponsor company seeks another assessment of the evidence base, there are two mechanisms to achieve this - **resubmission** and **independent review**. A resubmission is used where the company has new clinical evidence or economic analysis; the latter may be based on a price reduction or a new or improved Patient Access Scheme. An independent review panel may be convened at the request of the sponsoring company where there are no new data or analyses.

NHSScotland, the pharmaceutical industry and patient groups have collaborated to develop SMC systems and processes for health technology assessment that are well defined but also require some discretion on a case by case basis. Reviews of SMC decisions may occasionally be required. For this to work effectively, all parties should abide by both the spirit and the letter of the arrangements, as set out in overview below. Corresponding standard operating procedures will describe the implementation detail.

Process issues

If a sponsor company believes there has been significant deviation from agreed SMC process in the assessment of an application, this initial concern should be expressed directly to the Secretariat and / or to a senior officer (Chair or Vice-Chair) of SMC or its New Drugs Committee (NDC). It is anticipated that most process-related concerns will be fully addressed and resolved in this way. If concerns cannot be resolved by internal discussion, then the sponsor company

has the option of seeking external judicial review of the process undertaken. This clearly represents exceptional circumstances – in general terms, a legal proceeding to review the administrative action of a public body.

Scientific issues

Companies, in submitting an original application to the SMC, have responsibility to ensure that the data and evidence accurately reflect the efficacy, safety, clinical effectiveness and cost-effectiveness of the medicine. In response, the SMC will apply its agreed process to assessment of all applications. Despite due process being applied, the outcome of the evidence assessment will occasionally provoke disagreement from the sponsor company. Under these circumstances, the company may seek another assessment of the medicine. There are two mechanisms to achieve this, namely resubmission and independent review.

- **Resubmission**

Where there is new clinical evidence, or a new analysis of existing information about a medicine, this may dictate resubmission by the sponsor company. Where this is a complete de novo assessment, all relevant data must be submitted, along with any other supporting documentation, according to the usual SMC process. This resubmission is treated like any other submission to SMC, with full clinical and health economic review followed by consideration at both the NDC and SMC – the usual assessment timelines apply reflecting patient and clinician engagement, if applicable. To reduce workload for sponsor companies and SMC, the resubmission may reproduce the original submission with an appendix, clearly cross-referenced to the original, highlighting new data or analyses on which the resubmission is based. Irrespective of the format of the resubmission (de novo or supplementation of the original), the new information should be evident.

- **Independent review**

Where there are no new data or analyses, the sponsor company may request that SMC convenes an independent review panel (IRP) to reassess the data, analysis and interpretation of the original submission. An IRP may be requested post completion of a full SMC assessment, up to 12 months after publication (provided a resubmission is not underway). If a medicine has been considered by SMC more than once (e.g. a submission and resubmission) then the IRP timescale will refer to the most recent submission.

Overview IRP initiation: summary statement

The company must provide a summary statement to justify and provide clarity on why an IRP is sought, to include confirmation that no new evidence is available and there is no scope for reanalysis of the existing evidence.

IRP composition

The panel asked to undertake the independent review will be appointed by the SMC, on advice from the chairman and secretariat, and will be constituted as follows:

- Chair, who may be appointed from either of the categories below
- Three members (where possible) appointed from an SMC/NDC background (who, by reason of absence, have not previously been involved in the particular submission, including former members of SMC or NDC).
- Four members (where possible) appointed from Scottish NHS Board Area Drug and Therapeutics Committees (or their successors/equivalents) and/or other respected experts in the relevant scientific field, who need not necessarily be working in Scotland.

The quorum shall be set at 50% of the above membership.

Additional attendance

In attendance at the IRP to contribute to the discussion but without voting rights to influence the decision:

- Public partner representative
- Representative of the PACE meeting, if applicable
- SMC assessment team
- Pharmacy assessor, economic assessor and lead assessor
- NHS Central Legal Office representative

In attendance at the IRP as observers, to contribute only by invitation from the IRP chair:

- Chief pharmacist or nominee
- Public involvement co-ordinator
- Representative of the pharmaceutical Industry

In attendance to facilitate the process:

- SMC secretariat

Assessment team

The IRP will be supported by the usual SMC assessment team structure of a pharmacist, health economist and lead assessor, drawn from individuals who have not been involved in the original assessment(s). The SMC secretariat will liaise with the lead pharmacist and lead health economist to identify suitable staff for the IRP assessment team.

Declaration of interests

Declarations will be invited and recorded for all IRP participants. Any interests will influence IRP participation, in line with standard SMC arrangements.

Data review

The IRP will review the relevant submission with the support and guidance of the clinical and health economic assessment teams. No new data can be submitted by the company as part of an IRP. However, the IRP assessment team may ask for clarification from the sponsor company during the review on any issues that arise in relation to the submission.

The previous outputs from NDC and SMC are considered as points of reference only. The IRP assessment team will produce de novo clinical and economic checklists and a detailed advice document (DAD). Where appropriate, the IRP can also consider:

- Patient Group submission
- the Patient and Clinical Engagement (PACE) statement, where a medicine aligns with SMC end of life or very rare conditions criteria
- additional clinical expert input where necessary
- any Patient Access Scheme (PAS) that was included in the initial submission, provided it is still deemed acceptable for NHSScotland by the PAS Assessment Group (PASAG) □ SMC modifiers, where applicable

IRP decision

The IRP aims for decision by consensus. Failing this, a majority vote will determine the IRP position, with a casting vote by the IRP chair, if required.

IRP timeline

The timeline between notification of an IRP request and publication of the final SMC advice is expected to be at least six months, due to the requirement to appoint the chair, convene the panel and implement the process.

Confidentiality

The meeting papers, the deliberations and the output of the IRP are strictly confidential. Members must observe confidentiality from the initial circulation of the papers until publication of the advice on the SMC website. Members will leave meeting papers and any personal notes for disposal after the IRP meeting. The IRP is a closed meeting with a typical interval of three weeks until SMC ratification and another four weeks before advice reaching the public domain, during which time confidentiality must be maintained.

Output

The IRP will report back to the SMC, the submitting company and any company with comparator products referred to in the DAD.

- The SMC will receive the minutes of the IRP meeting and the IRP DAD. The SMC purpose is to confirm that due process has been followed, to ratify the IRP decision and to issue the final guidance on the medicine.
- The submitting company and the manufacturer of any comparator products will receive documentation post IRP, in keeping with standard arrangements post SMC.

Conclusion

The IRP chair will present the findings of the independent review to the SMC in closed session. Assuming ratification there, the advice will be shared with NHS boards / ADTCs with subsequent publication on the SMC website in line with standard procedures and timescales.

Appeal of validation outcome for end of life, orphan and ultra-orphan medicines.

SMC is committed to fair and objective validation of end-of-life, orphan and ultra-orphan status. It is hoped that dialogue with companies will minimise disagreements, but occasionally companies may disagree with the outcome of the validation exercise.

If a company believes the validation has not been conducted correctly this should be raised with the Secretariat.

If a company disagrees with the outcome of the validation exercise for a specific medicine this can be appealed by a request for an independent review of the information originally provided. Key points are as follows:

- the company provides a summary statement to clarify why the validation outcome is being appealed,
- the validation will be repeated by individuals who were not involved in the initial validation exercise,
- conflicts of interest will be handled in line with standard SMC arrangements, and
- de novo summary information will be produced to explain the rationale for the decision reached.

A company can appeal within three months of receiving the initial validation outcome.