# Blue text on a black background  Description automatically generatedGuidance to submitting companies:

Question and answer document on economic submissions to the Scottish Medicines Consortium

This document is provided to give general guidance to submitting companies making submissions to SMC and should be read in conjunction with the most recent version of the SMC Guidance to Submitting Companies for Completion of the New Product Assessment Form document available on the SMC website. Following the advice provides no assurance of getting a positive recommendation. Where a submitting company is in doubt about any aspect of the submission requirements, they should contact the SMC Secretariat for guidance.

*Does an SMC submission always require an economic evaluation?*

The fundamental task of the SMC is to recommend whether a medicine should be routinely used in Scotland by understanding whether it represents a good use of NHS resources. SMC conducts various types of appraisals, which it looks to match to the characteristics and circumstances of the medicine under review. The following types of appraisals require a full economic evaluation:

* full submission
* resubmission
* ultra-orphan initial assessment
* ultra-orphan reassessment

In these cases, the submission should compare a medicine’s clinical and cost-effectiveness with the practice that would be displaced. SMC recognises that the clinical data may be less extensive for some medicines, such as those classed as orphan or ultra-orphan. However, evidence to enable the clinical and patient benefits to be compared with costs, over an adequate timeframe, are still essential to inform SMC’s decision making.

When a submitting company can demonstrate that their medicine has a low expected budget impact in Scotland and has similar clinical effectiveness to an existing treatment it may qualify for SMC’s abbreviated submission process. In those cases, a full economic evaluation is not required. Further details on the abbreviated submission process are available on the SMC website.

***Does an SMC submission always require a budget impact assessment?***

Yes. An estimate of the budget impact of the medicine over a five-year time horizon must be submitted with all applications, including medicines within the abbreviated submission process. This information is essential to inform on the net costs (drug costs associated with the new medicine less any subsequent savings in relation to other medicines, adjusted for all anticipated changes to other resources used in NHS Scotland). This information is necessary for the Health Boards to support any implementation decision by the SMC.

***What resources are available to submitting companies to help them complete the economic part of a submission to SMC?***

Specific guidance on the economic evaluation is given in the Guidance for Submitting Companies on Completion of the NPAF document available from the SMC website or from the Secretariat. This deals with each stage of an economic evaluation.

If this does not address an issue, submitting companies can contact the SMC Secretariat for clarification. However, guidance should only be sought on general points about method – SMC cannot become involved in detailed discussions about specific submissions while they are in preparation.

***What is the review process for a submission including an economic evaluation?***

The first stage is that the submission is forwarded to an Economist for review. This has two aspects:

* firstly, to verify that an economic analysis and budget impact analysis have been provided as part of the NPAF, along with the economic model, budget impact template(s) and where relevant a completed Patient Access Scheme (PAS) application form.
* secondly, is the evidence submitted suitable for critical appraisal? The submission form asks submitting companies to state where in their submission certain key guidance points have been addressed (e.g. “on which page does the submission clearly state the costs used to value resource use?”). This checklist will be reviewed for completeness, with a judgement made at the end about suitability to proceed.

The submitting company should be informed of a decision from this stage within ten days of submission. The Secretariat will also add the submission to the agenda for a meeting of the New Drugs Committee (NDC), informing the submitting company of the timetable.

The submissions are then allocated to an Economic Assessor for critical appraisal. The Economic Assessor works in collaboration with a Pharmacist Reviewer, a Health Services Researcher and a Lead Assessor (collectively called the Assessment Team) to consider relevant existing practice in NHSScotland and the submitted evidence. The Lead Assessor is a member of the NDC. To assist this analysis, the Assessment Team usually require access to original articles describing studies and results to validate its relevance to the Scottish setting. Thus, it is helpful to ensure all references in support of the submission accompany the submission.

Written critiques of the clinical and economic submissions are circulated to the NDC two weeks before the meeting, through the detailed advice document (DAD) and summary checklists prepared by the Economic Assessor and Pharmacist Reviewer. At the meeting itself, the Assessment Team give a brief verbal presentation followed by general discussion. The draft recommendation and DAD are then revised in the light of these comments. Note that while SMC meets in public, the NDC meeting is held in private.

***How much detail is required in the economic submission?***

This is difficult to answer and depends upon the nature of the product under consideration, the comparisons that are made, the quality of the clinical evidence available, and so on. The main role of the submission is to provide sufficient evidence for the SMC to judge value in a Scottish setting so it must cover the points set out in the economics checklist. A concise, clearly argued case tends to be more persuasive than a technical case based on a huge amount of detail, except where this is very clearly justified.

***What type of economic evaluation should I use?***

This depends in part upon what the new product is being compared to, the nature and quality of the clinical evidence and so on. The submitting company should be aware that the SMC is trying to assess the value of new medicines in the context of a number of pressures upon the NHS in Scotland. To promote consistency across appraisals, SMC has a preference for generic measures of outcome, such as the quality-adjusted life-year (QALY), over disease-specific measures of outcome, suggesting that the submitting company should give serious consideration to a cost-utility analysis (CUA). This does not mean that CUA is required every time. Some examples of where it could be argued that it is unnecessary are as follows:

* a medicine that extends life in good quality might be assessed using a cost-effectiveness analysis (CEA) with life-years gained as the benefit measure. The good quality of long-term survival would have to have some proof, however, and not merely be asserted in the submission.
* the QALY does not capture the main benefit of the medicine – contraception is one example.
* utility values appear to lack sensitivity in circumstances where other measures suggest health improvements or disease reductions. Again, this should be demonstrated and not simply asserted. SMC would need to be assured that the changes on the non-QALY measures are valued by patients.

One approach is a cost impact study concluding there are net economic costs savings, in addition to the clinical evidence suggesting the medicine is at least as good as the alternative (e.g. a ‘me-too’ drug). This approach clearly has merits but it is not without risk. If the SMC does not agree with some aspect of the calculation of net cost, then this might undermine the claim of net saving. This might delay consideration of the submission or even lead to a judgement of “not recommended,” so this approach (while legitimate) should be used with caution.

The same could be said of a cost-minimisation analysis (CMA). This might be used where a clinical trial shows no difference in the main outcome. However, there may be objective organisational or patient issues that lead SMC to conclude that there are other aspects of benefit beyond the primary outcome selected; again, this might make a simple economic analysis seem inadequate.

In summary, there may be circumstances where a simpler approach than CUA can be used but these should be considered with care by submitting companies. Conversely, submitting a CUA is no guarantee of success.

***Do I have to use Scottish data in the economic submission? Does SMC expect me to commission specific pieces of work for the submission?***

The generalisability of evidence is a key consideration for the SMC. SMC recognises there are limitations on what can be achieved, especially when the product is so close to its launch date. Taking some of the main components of an economic evaluation in turn:

1. Resource use – the SMC would require some reassurance that data used are broadly representative of Scottish patient pathways and clinical practice. Data from elsewhere in the UK are acceptable. Resource use data from other countries or estimated by a panel of experts are regarded with some suspicion and should be avoided if possible, or at least validated for the Scottish setting and included in a rigorous sensitivity analysis.

Costs to value resource use – data on Scottish hospital costs are available on a per diem basis from Scottish Health Service Costs publication. The report covering the period 2022 to 2023 is available from the [Public Health Scotland website](https://publichealthscotland.scot/publications/scottish-health-service-costs/scottish-health-service-costs-summary-for-financial-year-2022-to-2023/files-listing-2022-to-2023/). At the time of preparing a submission, the submitting company should check the Public Health Scotland website to ensure that the latest version is being used.

NHS Reference Costs from the Department of Health are acceptable. Primary care and community costs from the Unit Costs of Health Care publication by Personal Social Services Research Unit, University of Kent, are also acceptable. Other sources of cost data should be clearly explained.

1. Ways to value health gain such as utilities – specifically commissioned studies to support the SMC submission are not needed but in the face of concern about the values elicited from any method, the methodology, sample size and nature of respondents should be made transparent and the values be subject to a rigorous sensitivity analysis.

***If the economic*** ***evidence I have available does not match the*** ***guidance then what should I do?***

The SMC recognises that not every point of guidance will apply to all economic evaluations; equally, there will be times when data requested by SMC are not available. It is easier for the SMC to understand the evidence presented when the submitting company makes a clear statement about why a particular approach was selected in preference to another, or why some data items are not available.

***What does the NDC of SMC particularly value in an economic submission?***

The following comments are intended to assist submitting companies and are not a checklist of points that will guarantee success if adhered to.

Firstly, the SMC’s concerns may pertain to the clinical evidence but sometimes the economic evaluation highlights these issues. For example, a medicine might have shown a statistically significant difference on a disease-specific outcome measure but the economic evaluation raises the question of what value this has to the patient, and hence whether this justifies the proposed cost. It is an advantage if the submission includes results that directly measure improvements in the patient’s quality of life rather than in a proxy measure. SMC places great weight on the patient’s perspective on health gain.

Secondly, a rigorous sensitivity analysis may demonstrate the robustness of the base case result. It is well known that economic evaluations are very demanding in terms of data inputs and at this stage of a product’s life very little is known with certainty. Appropriate use should be made of one-way, scenario, threshold and probabilistic sensitivity analyses.

***How does consideration by SMC differ from consideration by the NDC?***

The NDC looks at the submission first. This group is composed of doctors, pharmacists, nurses, and representatives from industry.. The main task of this group is to exercise critical appraisal skills to assess the strengths and weaknesses of the scientific case as presented by the submitting company. It can only assess the medicine through the information from the submission.

In some circumstances, where the presented clinical and economic cases are particularly strong, the NDC may choose to issue an accepted decision on a medicine they have reviewed. In this case a final acceptance decision will be taken by the SMC Executive, rather than the full SMC committee. This will speed up the acceptance process for the medicine.

In instances where the NDC view that significant uncertainties remain, or that the cost in relation to the estimated health benefits remain high, the submission will progress to a review by the full SMC committee.

The SMC committee has a broader representation and includes the groups above plus patient representatives, academic health economists and staff holding senior leadership roles in the NHS. SMC members receive various documents, including the submitting company’s submission, the completed economic checklist, the summary of product characteristics, collated feedback from Scottish clinical experts,the DAD from NDC and any company comments submitted after the NDC. A member presents the key points, including those from the economic evaluation, and discussion on these and wider issues that that go beyond the scientific arguments is facilitated. SMC then considers its recommendation.

What feedback can I expect and is there a chance for further dialogue with the economic reviewer during the review process?

The SMC communicates the outcomes of the NDC and SMC meetings shortly after they have taken place. After the NDC meeting, the submitting company will have the opportunity to review and comment on the DAD. Where relevant these written comments will be taken into account at the SMC meeting.

There is no direct contact between submitting companies and Assessment Team members within the process. However, Assessment Team members have the opportunity to contact submitting companies for further information or clarification: experience to date has shown the value in this contact. This mainly takes place prior to the NDC meeting and is facilitated via the SMC Secretariat. Submitting companies can contact the Assessment Team if required (for example to highlight any significant errors or omissions that have come to light) but this should be via the Secretariat as well and should preferably be via e-mail so that there is a permanent record for future reference.

Economic Assessors may discuss points about the economic guidance with submitting companies but they will not become involved in discussions about a particular submission prior to its submission.

When the final recommendation on the product is communicated to the submitting company, the DAD will be automatically provided. The economic checklist, providing more detail on the critical appraisal that was carried out on the product up to and including the date of the NDC meeting can be provided upon request.

***If a not recommended decision is made by the SMC committee, is there an opportunity to discuss the decision and any resubmission with SMC?***

Yes. If a not recommended decision is issued, the submitting company can get in touch with the SMC Secretariat to request a meeting. The purpose of such meetings is to give the submitting company general guidance on the principal issues that would need to be addressed in any resubmission. SMC company meetings are attended by a member of the SMC Executive Team and a member of the SMC Secretariat but it should be noted that the Assessment Team who worked on the original submission are not present at the meeting.

***If there is one piece of advice SMC would offer in terms of the submitted economic evaluation having a good chance of being accepted then what would it be?***

The economic evaluation needs a sound basic design, including a comparator that reflects SMC guidance, a benefit measure that reflects SMC guidance and data that are plausible in a Scottish context. If the submitting company does not satisfy the SMC on these basic design points then no amount of complex modelling or sophisticated sensitivity analysis will compensate. However, even if the economic case is well-conducted and robust, the economic evaluation needs to demonstrate that the product offers reasonable value for money to NHS Scotland compared to other uses of scarce NHS resources.

If you have any comments on this document, want to suggest a further question, or want to discuss any point further, then please contact the Secretariat at SMC.