



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Guidance to submitting companies: responding to New Drugs Committee (NDC) preliminary advice

Company comments guidance

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www.scottishmedicines.org.uk

After the New Drug Committee (NDC) meeting has taken place, the submitting company is asked to comment on the NDC detailed advice document (DAD) for their medicine. This stage of the process is generally referred to as “Company Comments” by the Scottish Medicines Consortium (SMC) and the submitting company.

This document is a general guide on issues which should be considered when compiling a response to the NDC DAD and what information submitting companies should provide within their Company Comments.

1. Focusing the response

In order to provide a robust response to the NDC DAD for consideration by the SMC, the Company Comments document should be focused and concise. The NDC DAD will have outlined the main issues or weaknesses in the clinical and economic evidence within the “Clinical Effectiveness” and “Health Economics” sections of the document respectively. The health economics section will generally present the weaknesses in order of priority, but it should be noted that on occasion the multiple issues outlined could be equally important, or have a cumulative impact, on the decision uncertainty and thus each should be addressed. In addition, where an indirect comparison has informed the economic case, then weaknesses with the indirect comparison may be described in the clinical effectiveness section of the NDC DAD.

It is important that these issues are addressed in the response. When responding to a particular weakness in the NDC DAD, be it a clinical effectiveness or health economics issue, it is advisable to quote or make clear which weakness or text is being addressed, as well as referencing the relevant page number of the NDC DAD.

We welcome additional information that can reduce the uncertainty or limitations within the analysis. However, provision of a completely new indirect comparison at the Company Comments stage may constitute a large amount of information which may not be practicable for the SMC to assess (see also section 4 below).

2. Providing clarification

The Company Comments document may also be used to provide further clarification regarding analyses or data reported in the NDC DAD. For example, further clarification and context may be provided as to why a particular Incremental Cost-Effectiveness Ratio (ICER) is less relevant to the appraisal process or represents a less plausible scenario. This is an opportunity to carefully review the NDC DAD and provide notification of any factual inaccuracies as well as suggest amendments. The document should also clarify what data presented in the NDC DAD are academic-in-confidence (AIC) and commercial-in-confidence (CIC) and cannot be presented in the final published SMC DAD. If the Company Comments quotes or presents information which are considered confidential please ensure that appropriate AIC and CIC markings are also applied to these data in the Company Comments document. If necessary, an Updated Checklist of Confidential Information – Company Comments should be submitted with the Company Comments. This is available in the *Making*

a submission section of the SMC website. Note that SMC would not anticipate notification of any further changes after the Company Comments deadline.

3. Presentation style

When compiling the Company Comments document, it may be useful to consider the presentation of the information from the perspective of an SMC committee member, as the Company Comments are included in full in members' paperwork. A bulleted summary of the key points and main issues covered in the response included at the start of the document can be useful where several issues are addressed. In addition, please include a short bulleted summary outlining why SMC should accept the medicine for use in NHS Scotland. Please ensure that the key points regarding a company response are made succinctly in the main body of the Company Comments document. We prefer that appendices are not used routinely but may be included if necessary.

In terms of ensuring that the Company Comments document is succinct and well presented please avoid comments which do not address inaccuracies or deficiencies in the evidence such as re-stating points already presented in the submission, or reiterating positive statements made in the NDC DAD. It is also helpful to indicate how SMC modifiers may apply to the medicine under review, and if applicable highlight how the wider perspectives of the ultra-orphan framework are relevant.

Finally the Company Comments should be submitted as a stand-alone document for consideration by the SMC. It is not appropriate to submit an edited version of the NDC DAD as the Company Comments document; however an edited NDC DAD may be submitted as supplementary information alongside the Company Comments.

4. Provision of additional analyses or data

A submitting company may have been asked to provide specific additional analyses to address weaknesses specified in the DAD. The response to these questions and the related analyses may have been submitted to SMC as a separate document; however it can be helpful to summarise such responses and their impact on any key uncertainties within the Company Comments. On occasion more recent data regarding the efficacy of a medicine may become available between the time of submission to the SMC and the Company Comments stage of the process. These data should be provided alongside references, and copies of references, when submitting Company Comments.

Due to the tight timelines in SMC process, large amounts of new data cannot be accepted at the Company Comments stage since significant amounts of additional data may only be considered through the re-submission process.

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