

## NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

### Consultation on the draft remit, draft scope and provisional matrix of consultees and commentators for a proposed appraisal

#### Procedure Note

This note sets out the procedure for consultation on the draft remit, draft scope and provisional matrix of consultees and commentators for a proposed appraisal, following the STA process.

#### What are we asking you to do?

##### 1. Comment on the draft remit and draft scope for the proposed appraisal

The draft remit is the brief for the proposed appraisal. The attached Appendix B contains the draft remit. It also contains the draft scope which has been developed from the remit. The draft scope outlines the question that the proposed appraisal would answer.

- a. Please let us know if you have any comments to make on the draft remit. Please pay particular attention to any licensing issues with the technology involved and if the wording accurately reflects the issue NICE is being asked to produce the appraisal on.
- b. Please consider whether anything has been omitted from the draft scope, or whether you have any other comments. Please pay particular attention to the 'comparators' and 'other considerations' section, and detail what the appraisal ought to consider in order to be most effective.
- c. Please consider whether within the remit or the scope there are any issues relevant to equalities. Please pay particular attention to whether changes need to be made to the remit or scope in order to promote equality or eliminate unlawful discrimination, or if there is information which could be collected during the assessment process which will enable the Institute to take account of equalities issues when developing guidance.

- Please submit your comments using the reply form attached. If you have no comments to make on the draft remit or draft scope, please indicate this on the form. The completed reply form should be sent to the Institute, by email where possible, by the date indicated in the attached letter. Only one reply form should be submitted by your organisation.
- Please do not submit edited versions of consultation documents, as comments submitted in this way cannot be considered.
- Where email is not possible, please submit the completed reply form on a CD-ROM.

#### Note for Manufacturers and Sponsors

Manufacturers and sponsors are asked to include, along with their comments on the draft scope, information regarding any pending licence applications for their technology. This must include the timeframe within which regulatory approval is anticipated (including CHMP opinion, where appropriate). Please note that, if the appraisal is confirmed, the Institute will not put into the public domain, nor circulate amongst consultees and commentators, any documents for consultation before the technology concerned has received regulatory approval. If you consider that any information on pending license applications should be treated as confidential, the relevant information should be clearly marked (i.e. highlighted

and / or underlined) and the rationale for doing so should be clearly stated. In addition, a date should be given indicating when it is anticipated that the information can be released.

### **2. Comment on the provisional matrix of consultees and commentators for the proposed appraisal**

The provisional matrix of consultees and commentators (Appendix C) is a list of organisations that we have identified as being appropriate to participate in this proposed appraisal (for definitions of *consultee* and *commentator*, please see the glossary at the end of this document). If you have any comments on the content of the provisional matrix, please submit them using the comment form, as detailed in the box above. If you have no comments to make on the provisional matrix, please indicate this on the form.

As NICE is committed to promoting equality and eliminating unlawful discrimination we are keen to know if we have missed any important organisations from the lists contained within the matrix and which organisations we should include who have a particular focus on relevant equality issues.

**Please note that your comments will be published on the NICE website if the proposed appraisal is formally referred.**

### **3. Complete and return the attached 'contact details' form**

To ensure that all future correspondence and documentation relating to this proposed appraisal reaches the appropriate person in your organisation, please complete as fully as possible the **contact details form** and email it back to us by the date in the attached letter. It is important to include an email address where possible. **(IMPORTANT: If your organisation manufactures the technology in question and is currently awaiting regulatory approval, please note that you must provide contact details for BOTH the person whom you would like to receive further information about this proposed appraisal AND the person in your organisation responsible for the regulatory submission if they are not the same.)**

The draft remit, draft scope, and provisional matrix of consultees and commentators will be published on the Institute's website five working days after this letter is sent.

### **What Happens Next?**

All provisional consultees and commentators have been invited to attend the next stage of the process, which is a **scoping workshop**. The aim of the workshop is to further explore the draft remit and scope. You should have already received your invitation to the workshop within the last few weeks. Please note that expressing views at the scoping workshop does not replace making written comments on the draft remit, draft scope and provisional matrix of consultees and commentators.

Following the scoping workshop, the Department of Health will review the draft remit in response to the comments received and the discussion at the workshop. The Institute will similarly review the draft scope and the provisional matrix of consultees and commentators.

**Please be aware that at this stage there is no guarantee that an appraisal will be conducted.** This will be determined in part by the comments on the draft scope and remit, and by the issues raised at the scoping workshop, with the final decision as to which topics will be referred being made by Department of Health Ministers.

If the appraisal is formally referred it will be planned into the existing work programme. There are a number of factors that influence the timing of an appraisal. These include:

- the availability of slots in the work programme - there are already a large number of appraisals scheduled into the work programme and any new topics are scheduled around these.
- a requirement to timetable in Committee discussions as near to receipt of Marketing Authorisation as possible.

If you believe at this stage that it would be inappropriate, or not possible, for your organisation to be involved, please let the Project Manager know in writing by email or letter. If you do not contact the Project Manager you will continue to receive documentation if the appraisal is confirmed.

You can find more information about the Institute and its technology appraisals on the NICE website ([www.nice.org.uk](http://www.nice.org.uk)).

### Glossary

#### **Evidence Review Group (ERG)**

An independent academic group commissioned by the NHS Research and Development Health Technology Assessment Programme (HTA Programme) to assist the Appraisal Committee.

#### **Consultees**

The manufacturer/sponsor of the technology is invited to make an evidence submission, respond to consultations and has the right to appeal against the Final Appraisal Determination (FAD).

Healthcare professional and patient/carer groups are invited to submit a statement<sup>1</sup>, respond to consultations, nominate experts and have the right to appeal against the Final Appraisal Determination (FAD).

Primary Care Trusts are invited to submit a statement, respond to consultations and have the right to appeal against the Final Appraisal Determination (FAD).

The Department of Health and the Welsh Assembly Government can respond to consultations and have the right to appeal against the Final Appraisal Determination (FAD).

#### **Commentators**

Commentators are able to respond to consultations and they receive the FAD for information only, without right of appeal.

#### **Health Technology Appraisal**

NICE carries out appraisals of new and established health technologies at the request of the Department of Health. The directions to NICE are to appraise the clinical effectiveness and cost effectiveness of the technologies. The technologies can be medicines (e.g. drugs for diabetes), medical devices (e.g. asthma inhalers), diagnostic techniques (e.g. screening for ovarian cancer), or procedures (e.g. surgery for obesity).

#### **Single Technology Appraisal**

NICE carries out appraisals of new and established health technologies at the request of the Department of Health. The directions to NICE are to appraise the clinical effectiveness and cost effectiveness of the technology. The technology can be a medicine (e.g. drug for diabetes), medical device (e.g. asthma inhaler), diagnostic technique (e.g. screening for ovarian cancer), or procedure (e.g. surgery for obesity).

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<sup>1</sup> Non manufacturer consultees are invited to submit statements relevant to the group they are representing.