## Comments

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<table>
<thead>
<tr>
<th>Section Number Primarily Related to your Comment (please enter only one)</th>
<th>Other Section Numbers Related to your Comment</th>
<th>Comments</th>
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<tr>
<td>4.3</td>
<td>4.4 to 4.9</td>
<td>Example: Can the wording please reflect who is responsible for these actions.</td>
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<tr>
<td>General</td>
<td></td>
<td>NICE technology appraisal processes are recognised to be complex, and it is important that NICE does all it can to support the understanding of those who have an interest in the process – particularly patients, patient representatives, clinicians and professional organisations who can offer valuable evidence to NICE committees. The changes introduced in the updated guide should be evaluated in order to ensure that these are genuinely supporting stakeholders to engage effectively in NICE processes.</td>
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<td>General</td>
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<td>It should be noted that Cancer Research UK does not provide evidence to individual technology appraisals but monitors the development of the overall process and engages with the media when approached to provide a clinical view on specific decisions. We consulted some of the members of the NCRI Consumer Liaison Group, which comprises over 80 patients involved in research of whom many have contributed to NICE appraisals, to inform the views expressed below, though specific comments are attributable to Cancer Research UK only.</td>
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<tr>
<td>General</td>
<td>3.6.2</td>
<td>We welcome the consolidation of STA and MTA processes into one process guide, and the intention behind this to clarify the overall appraisal process by highlighting the similarities between both processes. However, the guide is still a complex document which would require a considerable amount of time for non-experts to</td>
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fully understand. The work of the Public Involvement Programme (PIP) is invaluable to facilitating lay
engagement in NICE processes, but more could potentially be done to ensure that the supporting
documentation is accessible. NICE could consider producing a lay guide to the process, which would
supplement other engagement from the PIP team and be easy to refer to at any given time.

2.1-2.4  2.3.1  The new text explaining the approach to selection of technologies (2.1-2.4) will be helpful going forward as
this element is not always clear. This section could benefit from a case study of a completed appraisal to
demonstrate how the topic selection process has worked in practice. Furthermore, the text does not address
the issue of small patient numbers within certain disease areas and how this issue is handled by NICE.
Population size is considered in 2.3.1 but the text could benefit from further explanation of how technologies
for rare diseases specifically are handled within this process.

Section 2  
Section 2 should also explain the impact of the new Pharmaceutical Pricing Regulation Scheme (PPRS),
which states that companies will be able to request a NICE appraisal under the value-based assessment
approach which is currently in development.

1.15  
Section 1.15 refers to the service level agreements in place to ‘disseminate the NICE technology appraisal
guidance within the devolved administrations’. We would like to see a fuller explanation of these agreements
and of how NICE works with the devolved nations, as it is not always well understood – particularly by the
wider public and media – how NICE guidance applies outside of England and how its processes may differ
from other frameworks across the UK which support access to medicines.

3.4.9  
We welcome the new process guide’s efforts to explain the appraisal process through the extension of
invitations to Stakeholder Information Meetings to commentator organisations (Section 3.4.9), aimed at
exploring technical aspects and identifying important evidence to be included in stakeholder submissions. The
quality of stakeholder evidence is crucial to a fair appraisal and it is helpful that NICE is increasing the level of
information it provides about the evidence it expects to see.

3.6  
Section 3.6, which discusses external participation in technology appraisals, provides a helpful summary of
how NICE ensures that a balanced sample of clinicians and patients are represented on committees.
However, scenarios in which no committee member has extensive clinical experience with a new technology –
for example, where a drug has been trialled outside the UK and licensed by the EMA prior to NICE
appraisal – are not discussed. There is a risk that the evidence being provided in this case will represent third-
party opinion and committee members’ views may differ extensively. The new process guide should explain
how such situations are handled and, where appropriate, how NICE seeks to proactively consult with a wider
group of clinicians and patients to obtain a balanced view.

3.6  General  
The process guide should also seek to explain how NICE ensures that a range of clinicians are engaged in
technology appraisals to avoid a situation where the same experts are consistently taking part and
representing a narrow view of clinical practice in a given area.

Section 1 (Table 1) 2.6.2 We note that NHS England and CCG representatives are now listed as stakeholders, which reflects the health system reforms that took effect in 2013 (Table 1: Participants in the Technology Appraisal processes, also Section 2.6.2). NICE may wish to clarify in the guidance how this change may have an impact. Selecting CCG representatives at random, for example, may not be the best approach to selecting individuals with the right level of specific expertise to contribute to a technology appraisal as different CCGs will cover different demographics with varying priorities.

3.1.11-12 We welcome moves to increase transparency around, and accountability for, the evidence examined by NICE during technology appraisals (3.1.11-12). Recent public discussions about openness in reporting of clinical trials results highlight the important role of high-quality evidence in informing new research as well as treatment decisions, and this also applies to understanding the cost-effectiveness of new medicines.

3.1.24-25 The new text (3.1.24-25) which discourages the marking of information as confidential is helpful. It is important that consultees are able to access as much information as possible to make informed comments on appraisals, subject to confidentiality agreements. Furthermore, the processes should be as streamlined and efficient as possible, so that new drugs can be approved for the NHS to treat patients in need quickly. The handling of confidential information is a resource- and time-consuming activity for the Appraisal Team, and reductions in amount of information marked confidential should streamline the appraisal process.

Please email this form to: 2013TAProcess@nice.org.uk

Closing date: Friday 28 March 2014 5pm

PLEASE NOTE: NICE reserves the right to summarise and edit comments received during consultations, or not to publish them at all, where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would be otherwise inappropriate.