How to guide – online consultation on NICE processes of health technology evaluation

**February 2021**

# Introduction

This guide outlines the structure and format of the online consultation form on NICE processes of health technology evaluation. It has been provided for information purposes only, please submit your response using the online consultation: <https://nice.researchfeedback.net/s/processes>

# About the consultation

NICE would like your views on the principles of change consultation for the Centre for Health Technology Evaluation (CHTE) process for evaluating technologies outlined in the consultation document ‘Proposals for change’.

The information collected will be used to inform the next steps for the development of the NICE process for health technology evaluation. Comments will be published in full on the NICE website after the consultation closes (excluding responses from NICE staff and committees). Please do not include any personal information in your response. NICE will not respond to individual comments or suggestions.

This consultation closes on: 15 April 2021 11:59pm

# Saving and return

You can save your response to the consultation at any point and return to complete by selecting 'save' at the bottom of the page. You will be directed to a webpage specifying the link to resume completion of the form. You can bookmark this page or add your email address so a resume link is emailed to you. The email will be sent from 'NICE consultations'. Please note, if you choose the latter, your email address will not be stored.

On submission of your form an automated email will be sent from “NICE consultations” to confirm safe receipt of your submitted comments.

# Structure of the online consultation

The online consultation is structured around the 4 themes of proposed changes:

1. Alignment of the current guidance development processes
2. Opportunities for new process improvements and ways of working
3. Commercial and Managed Access processes
4. Highly Specialised Technologies - vision and principles

For each of the 4 themes, the consultation follows the same overall structure and asks the following questions:

## General comments on theme

* **Would you like to provide general comments in relation to the proposals in this theme?**

(Options: Yes, I would like to provide general comments on this; No, I do not have general comments on this)

* **If yes: Please share your general comments here:**

(Open text box, 9,999 character limit)

## Comments on specific proposals

* **Would you like to add comments relating to specific proposals? If so, please select all that apply from the list below:** (see appendix 1 for full list of proposals, including paragraph references)
* **If specific proposals selected: How strongly do you agree or disagree that you support the proposals related to:** (all selected proposals will be listed individually here. Options: Strongly agree, agree, neither agree nor disagree, disagree, strongly disagree, don’t know/ NA.)

Note: we are trialling the inclusion of this question to help inform our interpretation and analysis of feedback and identify any issues more effectively, we do not propose to publish your responses.

* **If specific proposals selected: Please use this space to share any comments on the proposals:** (all selected proposals will be listed here. Open text box, 9,999 character limit)

## Final comments on theme

* **Please share any final comments on the proposals in this theme below, including any areas that have not been covered or other proposals which you think should be considered.**

(open text box, 9,999 character limit, you can also upload supporting documents relating to this here.)

## Additional questions

There are two supplementary questions included in the consultation

* **Theme 2: Opportunities for new process improvements and ways of working: What changes can we make to our processes to help reduce health inequalities in the way we develop our guidance, stakeholders participate and how health inequalities are identified and considered in making recommendations?**

(open text box, 9,999 character limit, you can also upload supporting documents relating to this here.)

* **Theme 4, Highly Specialised Technologies: Are there any areas where the vision does not address the needs of ultra-rare diseases?**

(open text box, 9,999 character limit, you can also upload supporting documents relating to this here.)

## Final comments on consultation

After all four themes have been considered there is an opportunity to share final comments.

* **Please share any final comments on the consultation here:**

(open text box, 9,999 character limit, you can also upload supporting documents relating to this here.)

## Profile

* **To enable us to confirm safe receipt of your comments, and follow up for clarification if necessary please confirm your:**

Name:

Email:

Organisation:

## Submit and close

Once you reach the end of the consultation it is important that you click ‘submit’ to share your response with the team.

# Appendix 1: Full list of proposals

## Alignment of the current guidance development processes

* Develop a simplified singular process for all Centre for Health Technology Evaluation (CHTE) programmes (para 45)
* Align terminology used across all CHTE programmes (para 46)
* Scoping consultation length will be flexible from 5-20 days dependant on the needs of the topic (para 49)
* Scoping workshops will take place virtually (para 50)
* Scopes for simple topics will not be consulted on (para 51)
* Companies will provide a 'Summary of Information for Patients' with their evidence submission (para 59)
* Patient and carer organisations can provide written submissions to all guidance programmes (para 60)
* NICE will provide dedicated stakeholder relationship managers for patient and carer organisations (para 63)
* Committees will make recommendations on different types of guidance (TA, MTG, HST, DG) (para 67-68)
* Committee meetings will be held virtually (para 69)
* Medical technologies and diagnostics guidance can be developed without consultation (para 71)
* A shorter (less than 20 working days) consultation length can be used for some topics (para 72)
* Terminating, discontinuing and suspending guidance (para 74-76)
* The option of a multiple technology assessment for highly specialised technologies (para 78)
* The option of a multiple technology assessment for medical technologies guidance (para 79)
* Routing topics to clinical guidelines (para 81)
* Retain separate types of technology guidance for Diagnostics, Highly Specialised technologies, Medical Technologies and Technology Appraisals

## Opportunities for new process improvements and ways of working

* Developing guidance on Digital Health technologies (para 24)
* Use Experts from scoping in guidance development (para 85)
* Professional, patient & carer organisations to nominate for all guidance topics (para 86)
* Use Experts nominated for related topics and guidelines (para 87)
* Working in parallel with the regulatory process (para 94-95)
* Technical engagement shall become an option in Technology Appraisals and other guidance programmes (para 102)
* The low ICER fast-track appraisal option will be removed (para 109)
* Develop a cost-comparison fast-track appraisal (para 110)
* Not using a committee to make recommendations in a fast-track appraisal (para 110)
* A simpler approach to evaluations of technologies with multiple indications (para 114)
* Managing company submissions (para 116)
* Developing guidance on combination treatments (para 118)
* Develop a process to evaluate Biosimilars (para 123)
* NHS Treatment eligibility criteria (para 126)
* Recording when NICE Scientific Advice has been sought (para 131)

## Commercial and Managed Access processes

* Commercial proposals and managed access proposals (para 140-145)
* The Budget Impact test (para 147)
* The status of a recommendation for managed access (para 150)
* Managed access entry (para 157-159)
* Data collection agreement development and oversight (para 164-166)
* Managed access exit (para 169)

## Highly Specialised Technologies - vision and principles

* The vision of the highly specialised technologies programme (para 173-176)
* The key principles for the highly specialised technologies programme (para 186-190)
* The criteria for excluding technologies from HST topic selection (para 186-190)