

**National Institute for Health and Care Excellence  
(NICE)**

**Proposals for increasing capacity within NICE's  
technology appraisal programme**

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## Introduction

1. In recent years, the capacity of the technology appraisal (TA) programme has been increased to meet a growing demand. Before 2014-15, we produced, on average, 30 appraisals each year. The 2017-18 target is 55 appraisals.
2. We have so far managed to accommodate this increase without changing the basic appraisal process. However, as demand for technology appraisal guidance is anticipated to rise to a steady state of 75 topics each year, we will need to both increase the programme's resources and make changes to the appraisal process. This paper sets out the process changes we intend to make.
3. The increase in demand is being driven by a number of trends in the life sciences sector. In particular:
  - Regulators are granting marketing authorisations at earlier stages in development for more products; in the case of medicinal products through accelerated assessment, conditional marketing authorisation the priority medicines initiative (PRIME), and
  - Developments in 'personalised medicine' are resulting in multiple indications for new drugs. Companies are applying for marketing authorisations for more than 10, and sometimes up to 20, therapeutic indications, where in the past it would have been exceptional to receive more than 5. This applies to cancer drugs, in particular.
  - The requirement for our appraisals processes to expedite timely access to clinically and cost effective technologies
4. As the number of individual topics increases, our ability to be flexible in the scheduling of an increasing number of topics is becoming more limited. There are a number of reasons for this, including:
  - We are expected to prioritise medicinal products that receive a positive opinion as part of the MHRA early access to medicines scheme (EAMS) when scheduling topics into the appraisals work programme.
  - We now publish guidance within 90 days of marketing authorisation for all cancer products.
  - An increasing number of topics require more than two committee discussions. Companies frequently ask to submit additional evidence during consultation on provisional recommendations, often including new patient access schemes. Appraisal committees often ask for further input from companies, for example when considering whether to recommend a drug for new Cancer Drugs Fund.

5. Technology appraisals are becoming more complex and require an average of 2.5 committee discussions (slots), and multiple consultations to work through the full extent of the case and progress to publication of final guidance. Scheduling an extra 20 appraisal topics into the work programme requires creating the equivalent of an additional 50 committee slots per year. The committee work currently operates on the basis of the appraisal committees considering the full extent of the case for clinical and cost effectiveness at their committee meetings. The existing committee structure does not have the capacity to accommodate this level of activity and, unless changes are made to how the committees are used, it will not be possible to add more topics into the work of the current four appraisal committees.
6. Approximately 80% of final NICE guidance is positive whilst 60% of draft recommendations are negative. In our current process, a positive draft recommendation significantly reduces the time and resources involved in publishing the final guidance. The proposed amendments to the process aim to enable us to maximise the ability to reach a final decision at the first committee meeting, increasing process efficiency and increasing our ability to ensure timely access to cost effective new health technologies for the benefit of patients.
7. In making changes to the appraisal process, we will need to maintain the valuable external challenge provided by the external academic review groups (ERGs). Colleagues at the National Institute for Health Research (NIHR) and the Department of Health have confirmed that the Health Technology Assessment programme, which commissions these groups, has the capacity to support the development of up to 75 appraisals, but to do this, we will need to ensure that the ERG contribution is tightly focussed.
8. The main emphasis of the process adjustments laid out in this paper is on undertaking more work before the topic reaches the committee. This will allow us to deliver the projected increase in output, without increasing capacity at the committee stage and enable us to draw more on the talent and expertise of our internal staff, and make their contribution even more rewarding.
9. No adjustments are being made to the Guide to the Methods of Technology Appraisal.

## Summary

10. The process adjustments set out below, retain the familiar elements of the current single technology appraisals (STA), while aligning them more efficiently. The components of the recently implemented Fast Track Appraisal (FTA) process will be adjusted accordingly.

11. In particular, the proposed changes will:

- Provide clear, recognisable milestones for companies and other stakeholders, linking them to key stages in regulatory pathways, providing more time for NICE to engage with companies early in the appraisal process;
- Release capacity for the appraisal committees as more of the scientific and technical elements are pulled forward into the workup of topics. Together with an increase in funding, this should allow us to publish, up to 75 appraisals, using the same committee resource that is now available;
- Enhance our ability to deliver the ambitions set out in the Accelerated Access Review and the emerging Life Sciences Strategy, when required to do so.

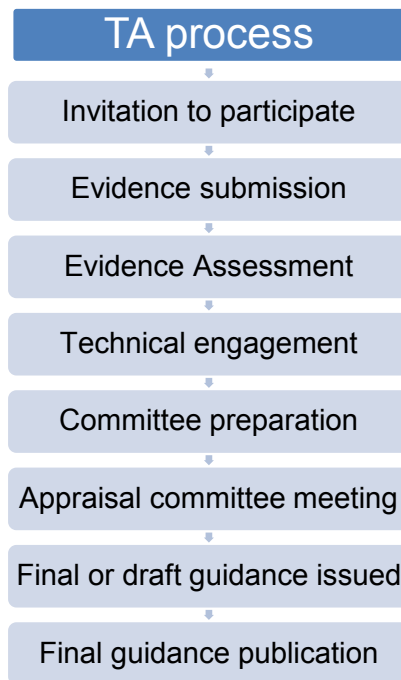
## Process Adjustments

12. We intend to utilise all phases of the existing technology appraisal processes, but re-arrange the sequence of steps to increase internal and external efficiency. The proposed adjustments comply with the statutory duties of NICE laid out in the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013.

13. The adjustments are primarily designed to allow the technology appraisal team to prepare more effectively in advance of the appraisal committee discussions. The key adjustments are:

- Defining more points within the process for formal discussions with companies on the technical and fiscal elements of their submission.
- Allowing more opportunities for scientific and technical issues to be addressed before a topic reaches the appraisal committee decision stage.
- Providing for more efficient consultation mechanisms.
- Alignment of the timeliness targets for all technology appraisal output, with guidance within 90 days of marketing authorisation for all new drugs.

14. The adjusted Technology Appraisal process will be arranged into the following sequence. Each stage is described in more detail:



## Invitation to participate

15. Currently, the date at which companies are invited to participate in a technology appraisal is linked to the expected date of marketing authorisation, which is in turn linked to when the appraisal committee meets to allow timely guidance production. Working backwards from when the committee is expected to meet, we currently allow 21 weeks between the invitation to participate and the committee meeting.
16. We propose to invite the company to participate in a technology appraisal earlier in the regulatory timeline, using date of the submission of the dossier to the regulatory agency to invite companies to start developing an evidence submission for NICE. Inviting companies to prepare their submission at this stage in their regulatory process allows greater opportunities for us to engage with them during this phase and to explore the likely methodological and technical issues. It also allows us the flexibility to adapt company engagement to the regulatory progress and allows time for companies to respond to questions.
17. As is currently the case, consultee and commentator organisations will be invited to participate in the appraisal at the same time as the company.

## Evidence submission and participation

18. The current ordering of STA process steps assumes that companies understand their best value proposition at initiation of appraisal. In practice, most companies may not be aware of what is required at this point in the appraisal to formulate their fully formed proposal.

19. We propose to enhance the ability of the NICE team to manage the evidence submission phases of the process. This can be achieved by NICE staff, the independent evidence review group and key committee members, where relevant, contributing to technical discussions with companies as early as possible.
20. As now, the principal evidence will be provided by the company, using a detailed specification developed by NICE. For new medicinal products that are subject to regulatory approval we are contemplating aligning the deadline for submission to NICE with day 120 of the regulatory process.
21. Other stakeholders will be asked to submit statements at the same time as we receive the company submission. As is currently the case, stakeholders will be asked to nominate clinical and patient experts, who will be asked to submit personal statements. If the statements from non-company stakeholders are sufficiently clear, and/or individual clarification resolves enough of the uncertainty, this earlier timing of their engagement may reduce the need for experts to attend the committee meeting, increasing the ratio of topics to committee meetings. This approach is currently being implemented in Fast Track Appraisal.
22. Once a submission has been received from the company, there will be a series of fixed opportunities for NICE to engage with the company at specified points in the appraisal process to discuss the methodological and technical elements of the submission.

## Evidence Assessment

23. We propose to adjust the evidence assessment process to allow greater opportunity for a group consisting of NICE technical staff, the ERG and members of the committee to seek clarification from the company on the existing evidence submission, requesting further analyses, and performing their own exploratory analyses. This team will function as the 'technical team' to the appraisal committee and will consist of NICE technical staff, and ERG and appraisal committee members.
24. The technical team will develop a report for the appraisal committee, setting out the scientific consideration of the case for clinical and cost effectiveness put forward by the company.

## Technical engagement

25. We propose to introduce a technical engagement step. Consultees and commentators will be provided with the opportunity to comment on the content of the report developed by the technical team for the appraisal

committee before it is considered by committee. This report will include references to:

- Company submission (and model where appropriate)
- ERG critique of the company submission
- Statements by stakeholder organisations and clinical and patients experts
- Overview of the interactions with the company regarding the technical aspects of the case
- Scientific judgements reached by the technical team to the appraisal committee.

26. This engagement step with consultees and commentators will be open for 20 working days. Engaging in the way with consultees and commentators before the committee meeting should significantly reduce the amount of time the committee spends debating technical elements of the appraisal at the committee meeting itself.

## Committee preparation

27. The period between technical consultation and the committee meeting will be used by the technical team to finalise their technical report, taking into account the comments received. There will be some time at this stage to further resolve substantive issues and for the company to engage in further discussions.

## Appraisal committee meeting

28. With much of work done before the meeting, we expect committee to meet only once for the majority of topics. Committee discussions will continue to meet in public (subject to the regulatory status of the product).

29. Company representatives and the ERG are expected to attend all first committee meetings for topics. It may not always be necessary for clinical, patient, and commissioning experts to attend the committee meeting if their submission statements are sufficiently clear, and/or individual clarification resolves enough of the uncertainty. A need assessment will be made by the technical team to the appraisal committee, in conjunction with the chair, at an appropriate time in the lead up to the meeting, and on that basis experts will be invited. This is the process currently being used for Fast Track Appraisals.

30. The committee can come to one of the following recommendations:

- Recommended for routine commissioning;
- Not recommended for routine commissioning;

- Not recommended for routine commissioning, but recommended for inclusion in the Cancer Drugs Fund or in some other form of available managed access arrangement.
31. In exceptional circumstances, the committee may find it is unable to develop recommendations for the technology at this point without further scrutiny, or further submission of evidence. If this is the case, there is the possibility for a pause. This will take no longer than the period between meetings of the same appraisal committee; usually 30 calendar days. After this final pause, the committee will be required to come to one of the three recommendations set out above.
32. The outcome of the appraisal committee meeting will be shared with consultees and commentators within 5 working days of the committee meeting. This will be a brief statement of the committee decision.

### Final or draft guidance issued

33. Because of the increased interaction at earlier stages of the process, we envisage that a majority of recommendations can be released as positive guidance, in the form of a Final Appraisal Determination (FAD). If a FAD is issued, consultees will be invited to appeal or raise any issues of factual accuracy. Commentators will be asked to raise any issues of factual accuracy. This is the same as the current process. Whilst we anticipate being able to release more FADs after the first committee meeting, we do not envisage a change in the overall proportion of positive or negative appraisals.
34. Formal public consultation will take place if the preliminary recommendations from the Appraisal Committee do not recommend use of the technology. This is the same as the current process.
35. Where the committee makes recommendations that limit the use of the technology further than the marketing authorisation (or instructions for use) for the indication being appraised other than the value proposition submitted by the company (an 'optimised' recommendation), we propose to undertake a 10 working day targeted consultation with consultees and commentators only. Responses from this consultation will be reviewed by the appraisal committee chair and committee members of the technical team to the appraisal committee who will consider whether, and to what extent, changes to the consultation recommendations are required. Proposed amendments to the consultation recommendations will be presented electronically to appraisal committee members for review and endorsement. Adjusting the consultation process for optimised recommendations in this way will significantly increase the efficiency of consultation, the processing of



consultation comments and the demands on the appraisal committee time at their face to face meetings.

## Final guidance publication

36. Subject to appeal, or significant matters of factual accuracy, NICE will normally publish the final guidance within 21 calendar days of the deadline for appeal.

## Other considerations

37. Where a company is not willing or able to submit, we will publish a document stating that no submission was received and as a result NICE is unable to formulate guidance recommendations. This is the same as currently the case with terminated appraisals.
38. Appendix 2 presents the timeline for the appraisal of a new medicinal product that is subject to regulatory consideration by the European Medicines Agency. Each process step is shown in relation to the regulatory timeline.
39. As the current TA process can also apply to medical technologies not subject to the EMA procedures, steps of the kind described above will also be developed for these technologies.

## Risks

40. The following issues log has been developed and ways in which we might address them are set out in the following table.

**Table 1. Risks associated with TA process adjustments**

Issue	Response and Actions
NICE staff perceive the changes to have a large impact on their roles and responsibilities leading to concerns about remuneration and motivation.	We have mechanisms to ensure meaningful staff involvement in the development of the new procedures. Although it is not anticipated at this point, we will review job descriptions where necessary to ensure the new tasks required of the appraisal team are captured in their role.
The impact of the changes on NICE's capacity to deliver 75 outputs has been underestimated, with consequences for staff availability and funding and/or cost recovery.	We will perform detailed workforce planning analyses when developing the new processes, repeat these analyses regularly after implementation, and liaise with NICE finance and HR on implications for funding and/or cost recovery.
Concerns raised by stakeholders about the changes to consultation arrangements for optimised appraisals	We will seek advice on whether our Regulations allow NICE to set the arrangements for consultation as proposed
NICE's international reputation for thoroughness and inclusivity is perceived to be compromised.	During and after consultation, we need to ensure it is clear that the same vigilance and robustness is being applied in our technology assessment steps It will be important to develop a communication plan to ensure that it is understood that all the building blocks of NICE technology appraisal processes are still in place but rearranged in a different way.
Work undertaken before licensing is unnecessary because the product does not gain regulatory approval.	Most products do not fail to be granted a license. We will continue to develop robust systems to monitor regulatory progress as early awareness of changes to product development timelines will be crucial to efficient appraisal programme planning.
Current appraisal committee members are uncomfortable with the new arrangements	Appraisal committee members may perceive the new arrangements as a loss in their autonomy. We will need to engage with committee members and explain that their input into technical discussions is not being diminished as committee members will be part of the new technical review arrangements. We will also seek their input into the development of these arrangements. We will

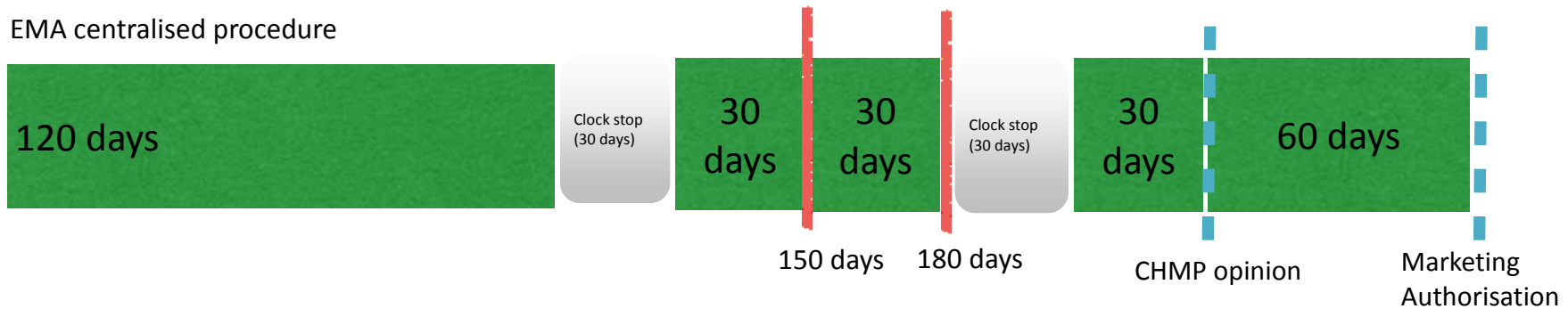
Issue	Response and Actions
	also develop a contingency plan for recruitment of new committee members, if they decide that the new arrangements are not suitable for them
The perceived independence of appraisal committee decision making is reduced by the introduction of the technical review and engagement processes	<p>The aim of the technical review and engagement step is to develop the technical information in a way that committee members have the information they need to make decisions on the technical elements of the appraisal as quickly as possible.</p> <p>We will work closely with the advisory body chairs and other members to develop the processes for their involvement in the technical review and the template for the content of the technical report to the committee</p>
The changes proposed for involving clinical specialists, and patient and commissioning experts could lead to a challenge from stakeholders; in principle, and for individual topics	We will clearly document the decision whether or not to invite experts to attend a meeting, and we will ensure that these decisions and any subsequent invitations will be made timely to give notice for these individuals to attend.

# Appendix 1 – Overview of current TA processes

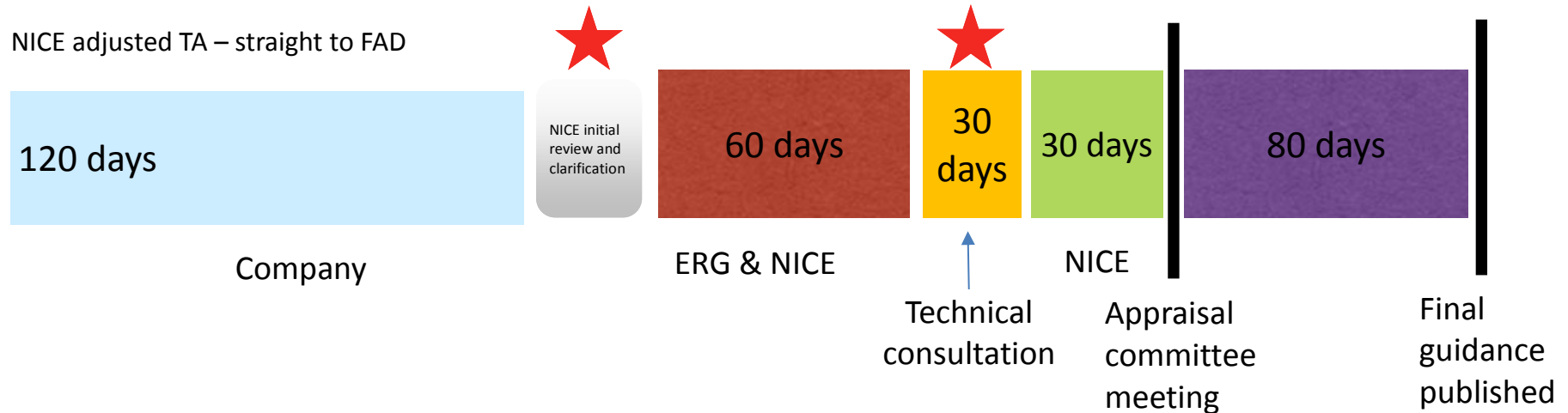


## Appendix 2 - Adjusted TA process overview (presented for pharmaceuticals)

EMA centralised procedure



NICE adjusted TA – straight to FAD



 Opportunity for commercial dialogue

**Where a consultation is required a maximum of 60 days will be added to the process**