

BIA response to NICE consultation on changes to charging for Technology Appraisals and Highly Specialised Technologies

The BIA has responded to the National Institute for Health and Care Excellence (NICE)'s consultation on charging for Technology Appraisals (TA) and Highly Specialised Technologies (HST). For further details about the consultation, please visit the [consultation page on the NICE website](#).

Consultation questions

Proposal 1 - Confirming evaluation timelines and commitment to pay

Please see section 26 to 34 for the background information. For the proposal details, please see section 35 to 38.

1. Does the charging consultation paper clearly explain the justification for proposal 1?

Yes, the justification for this proposal is clearly explained in the consultation paper.

2. Does the consultation paper provide enough detail on the proposed changes?

Yes, the paper provides sufficient detail on this proposal.

3. What consequences of implementing the proposed changes are there for industry?

The BIA understands that NICE wishes to drive forward a more predictable work programme by reducing the impact of scheduling changes. The proposed changes, in combination with the introduction of a change fee, could result in higher costs for industry due to unforeseen and unavoidable delays.

4. Do you have any other feedback to share on proposal 1?

N/A

Proposal 2 - Introduction of a change fee

Please see section 26 to 34 for the background information. For the proposal details, please see section 39 to 44.

5. Does the charging consultation paper clearly explain the justification for proposal 2?

The consultation provides a justification for the introduction of a change fee, but no detail has been provided on how the proposed fee of £18,610 has been calculated. The BIA understands that timeline changes and delays can lead to administrative costs for NICE, but the proposed change fee seems very high. Furthermore, much of the work conducted for a scheduled technology appraisal would likely be repurposed for a future committee date and would not be wasted effort. NICE should provide a clear explanation of the costs that it incurs as a result of topic rescheduling, and how these costs vary depending on the timeline and notice given.

6. Does the consultation paper provide enough detail on the proposed changes?

Further clarity is required on whether this is a one-time delay or whether companies could be charged multiple times. Regulatory timelines can change regularly, and charging companies multiple times for changes to the scheduling of the same topic could lead to very high fees for something that is outside of the company's control. Additional detail is also required on at what point in the appraisal process pushing regulatory timelines results in a charge.

7. What consequences of implementing the proposed changes are there for industry?

The introduction of a change fee in scenarios which are outside of company control is a significant concern. For example, if there are regulatory delays, this is likely to be caused by third party organisations (e.g., MHRA, EMA) and companies should not be penalised for this. Furthermore, where a company requests a change to timelines, this will be to ensure they can provide the most up-to-date data and robust analyses, which could help to speed up the overall process.

This proposal could result in some unintended consequences for NICE, including reducing the incentive for companies to communicate early about any anticipated delays, and potentially less mature and robust evidence bases. Ultimately, this proposal could result in slower patient access to treatments if companies hold off on scheduling their appraisals until later in the process to avoid the risk of fees.

The proposed change fee could also disproportionately impact smaller companies, especially those with limited existing revenue streams.

8. Do you have any other feedback to share on proposal 2?

The financial impact of rescheduling on NICE is likely to be significantly lower if sufficient notice has been provided, as work can be repurposed, and slots can be filled with alternative topics. NICE should charge a change fee only when sufficient notice has not been given to allow this to happen.

As with the other charges and overall increase to the fees, it is important that NICE demonstrates increased value to companies in return for the higher costs (see question 21 for more detail).

Proposal 3 - A charge for technical engagement

Please see section 45 to 49 for the background information. For the proposal details, please see section 50.

9. Does the charging consultation paper clearly explain the justification for proposal 3?

While the paper does provide some justification for the introduction of a charge for technical engagement it does not provide sufficient explanation of the size of the charge at 5% of the STA charge. Moreover, if technical engagement is effective in speeding up the overall appraisal process, then this could help reduce NICE's overall costs, making it difficult to justify an additional charge.

The paper also proposes that NICE will decide if technical engagement is required to support a topic's progression, but this should be a decision made in conjunction with the company. Otherwise, there could be a perceived incentive for NICE to push more things through technical engagement to recuperate costs.

10. Does the consultation paper provide enough detail on the proposed changes?

More detail is required on how the fee has been calculated.

11. What consequences of implementing the proposed changes are there for industry?

The introduction of a fee for technical engagement could particularly impact more complex topics, including innovative treatments with more uncertain evidence bases, including those for rare diseases.

12. Do you have any other feedback to share on proposal 3?

N/A

Proposal 4 - The charge for pilot topics and amendments to processes

Please see section 51 to 52 for the background information. For the proposal details, please see section 53 to 54.

13. Does the charging consultation paper clearly explain the justification for proposal 4?

Although the BIA understands that pilot topics may incur different costs for NICE, the justification for this proposal is not clearly set out in the consultation paper.

14. Does the consultation paper provide enough detail on the proposed changes?

Insufficient detail is provided on the proposed changes. In particular, the paper notes that the ‘pathways’ approach could become a business-as-usual approach, but no detail is provided how this would impact fees.

15. What consequences of implementing the proposed changes are there for industry?

The proposed changes could disincentive companies from participating in pilots. As pilots can help NICE to evolve its methods and processes, companies should instead be incentivised to participate, especially as participating in a pilot presents certain risks for companies.

16. Do you have any other feedback to share on proposal 4?

N/A

Proposal 5 - Updates to refund procedures

Please see section 55 to 56 for the background to the proposal. For the proposal details, please see section 57 to 61.

17. Does the charging consultation paper clearly explain the justification for proposal 5?

Yes, the justification for the proposal is clearly explained.

18. Does the consultation paper provide enough detail on the proposed changes?

Additional clarification is required on some points, including a what point in the NICE process the refund would take place and what the specific payment terms and milestones are. This would support companies’ financial planning.

Further clarification is also required on Appendix 3 point 2, which states that “Where an evaluation has required substantially different resources of a standard assessment, alternative refund models may be explored by NICE”. It is unclear what types of alternative refund models may be explored, and how the model will be determined. More detail is also required on how NICE would define and measure “substantially different resource”.

19. What consequences of implementing the proposed changes are there for industry?

It is positive that NICE is establishing eligibility for a refund once a company has submitted to NICE and the submission review has started. However, it is important that the refund procedures are transparent and fair, ensuring that costs paid are aligned to resources used. A more granular, milestone-driven invoicing process may be preferable as it would ensure costs paid are more closely aligned to resources.

20. Do you have any other feedback to share on proposal 5?

N/A

Other comments

21. Do you have any other comments or feedback to share on the changes to charging for Technology Appraisal (TA) and Highly Specialised Technologies (HST)?

The BIA understands the need for NICE to review its charges in order to recover associated costs, however a greater degree of transparency is required in the justification for the increased fees and additional charges and ensure compliance with [HM Treasury's guidance, Managing Public Money](#).

It also very important that NICE is able to demonstrate how it will deliver increased value to companies for the higher fees. Otherwise, there is a risk that the increased fees will damage the attractiveness of the UK as a launch market, especially for smaller companies with no or limited revenues from existing products. Companies are also experiencing budgetary pressures due to inflation, while at the same time NICE requires them to demonstrate the cost-effectiveness of their product at thresholds which have not changed in over 20 years.

In order to deliver increased value to companies, the BIA proposes that NICE commits to the following actions, which would help to demonstrate to industry that NICE is focused on driving continual improvements to its processes. We recommend:

- The publication by NICE of more data on its own processes, creating more transparency and accountability. This should include the collation of data on variations between committees, to help drive greater consistency.
- The introduction of 'after-action reviews' after each appraisal with all participants represented. This would help to identify continual learnings and improvements within NICE, helping it to deliver timely and relevant advice.
- Changes to committee meetings to make them less adversarial for patients and clinicians. Lessons can be learned from the Scottish Medicines Consortium (SMC)'s Patient and Clinician Engagement (PACE) process, which has helped to make sure that the views patients and clinicians are valued highly in the appraisal process.

NICE should also consider how it prepare patients and clinicians through the process.

- The development of success criteria to review the performance of the External Assessment Groups (EAGs) in appraisals. We also recommend that NICE should control EAG contracts, rather than NIHR, noting that NICE already appoints EAGs for the evaluation of medical technologies.

About the BIA

The BIA is the trade association for innovative life sciences and biotech industry in the UK, counting over 500 companies including start-ups, biotechnology, universities, research centres, investors and lawyers among its members. Our mission is to be the voice of the industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation.

BIA represents the interests of its members to a broad section of stakeholders, from Government and regulators to patient groups and the media. We also work with organisations at an international level to ensure that UK biotech is represented on the global stage including EuropaBio, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the International Council of Biotechnology Associations (ICBA).

BIA is the key thought leader for the sector, operating across a wide range of areas such as policy, finance, science, regulatory, legal, skills and talent as well as genomics, engineering biology and techbio.