BIA response to changes to NICE regulations: cost-effectiveness threshold consultation

Summary

The BIA has responded to DHSC's consultation on changes to NICE regulations: cost-effectiveness threshold. Summary of BIA response:

- The BIA welcomes the clarity this consultation provides in establishing a clear distinction between ministerial responsibility for setting NICE's cost-effectiveness thresholds while maintaining NICE's operational independence in the development of its guidance and recommendations.
- However, we believe that further reform is needed to extend ministerial powers beyond amending NICE thresholds to include future methods changes that require additional investment to implement.
- We are concerned that no commitment has been made to increase HST thresholds in line with the STA threshold and urge that a proportional increase is needed to ensure patients with ultra-rare conditions can benefit from the increased thresholds and the UK commercial environment is improved for all drug developers.
- The BIA opposes the proposal to remove NICE's duty to consult on procedural changes resulting from ministerial decisions. A transparent review process is important to ensure decisions do not translate into implementation changes that unfairly disadvantage certain populations or products.
- We are concerned that increasing the threshold alone will not address the UK's declining attractiveness as a launch market for innovative medicines, barriers within existing appraisal frameworks, or the limitations of NICE's cost-neutral remit.

Consultation questions

Proposal 1

Do you agree or disagree that a ministerial power of direction, as outlined under proposal 1 in the consultation document, should be limited to the NICE standard cost-effectiveness threshold?

Agree

Neither disagree nor agree

Disagree

Don't know

Please explain your answer. (Max 200 words)

The BIA welcomes the clarity this proposal provides in distinguishing between ministerial responsibility for setting NICE's cost-effectiveness threshold, and NICE's operational independence in applying its methods in the development of its guidance and recommendations.

The BIA recommends establishing a transparent, robust review process to ensure thresholds remain responsive to inflation, NHS budgets and government priorities for growth and life sciences investment. It is essential that decisions on medicine spending remain stable and evidence-based amid shifts in political priorities, ensuring thresholds reflect long-term socioeconomic value whilst preserving the UK's credibility and competitiveness in life sciences and patient access to new treatments.

While a more defined mechanism for updating the threshold is welcome, increasing the threshold alone will not address the UK's declining attractiveness as a launch market for innovative medicines. This is especially pertinent for rare disease medicines, which face challenges meeting standard appraisal frameworks that have not evolved to accommodate for smaller populations, limited evidence bases and higher uncertainty.

Further reform is needed to move beyond NICE's cost-neutral remit, a significant barrier to evolving appraisal methods. We believe that ministerial responsibilities should extend beyond directing NICE's thresholds to include future methods changes that require an increased budget to implement.

Do you agree or disagree that the power to direct NICE about the standard cost-effectiveness threshold should apply to all NICE guidance that makes recommendations on health spending?

Agree

Neither disagree nor agree

Disagree

Don't know

Please explain your answer. (Max 200 words)

The BIA agrees the power to direct NICE about the standard cost-effectiveness threshold should apply to all NICE guidance that makes recommendations on health spending.

NICE's HST programme is an important route for enabling access to treatments for ultra-rare diseases. However, the BIA is concerned that no commitment has been made to increase HST thresholds in parallel with the STA threshold. This is paramount to ensure patients with ultra-rare conditions can benefit from the increased thresholds and the UK commercial environment is improved for all drug developers.

Crucially, raising thresholds alone will not deliver improvements needed to enhance access to rare disease medicines. The BIA has long highlighted the restrictive HST entry criteria, which limits the number of products being routed through this pathway. As reinforced by findings from the 2025 BIA-ABPI rare disease survey, many companies report challenges in satisfying the eligibility criteria which subsequently influence decisions on submitting products to NICE. Many rare disease products are therefore assessed under STA which is poorly suited to small populations.

We recommend a more pro-innovative approach should be applied to the HST criteria to ensure alignment with ambitions to grow UK life sciences and support access to transformative treatments.

Proposal 2

Do you agree or disagree that NICE should not be required to consult on any proposed changes to its procedures that are necessary as a result of a ministerial direction on cost-effectiveness thresholds?

Agree

Neither disagree nor agree

Disagree

Don't know

Please explain your answer. (Max 200 words)

The BIA recognises that certain high-level changes to NICE's procedures, including those relating to cost-effectiveness thresholds, may arise from ministerial decisions. However, we oppose the proposal to remove NICE's duty to consult on procedural changes resulting from such decisions. In these circumstances, the Government or NICE should be required to consult on how changes will be implemented to uphold transparency, predictability and meaningful engagement with stakeholders.

We strongly believe that close stakeholder involvement, including from industry, clinicians and patients, is essential to ensure that the practical implications of procedural changes are fully reviewed and understood. Consultations of this nature should clearly outline how implementation will delivered, monitored and evaluated in practice.

For smaller patient populations with uncertain evidence bases, small procedural changes can have significant impacts and influence on appraisal outcomes. Maintaining a consultation requirement is therefore critical to ensuring that ministerial decisions do not translate into implementation changes that inadvertently disadvantage certain populations

or products. Stakeholder insight is vital to avoid potential unintended consequences and to ensure that changes to the appraisal system are aligned with the needs of patients with rare diseases.

If there are any further points you would like to make in relation to the proposed regulatory changes set out within this consultation, please include them here. *(Max 300 words)*

Recent developments in the commercial environment mark an inflection point in shaping the UK's approach to valuing and pricing innovative medicines. We welcome the clarity this consultation provides regarding the regulation of NICE's cost-effectiveness threshold. However, we remain concerned that the recently announced STA threshold increase does not keep pace with inflation and is not accompanied by a commitment to maintain alignment in future. This uplift will do little to address fundamental challenges with outdated appraisal frameworks or the limitations of NICE's cost-neutral remit which undermine wider government objectives to strengthen the UK's life science sector and expand medicine spending.

We would welcome further transparency on the rationale for the 25% uplift, the evidence underpinning it and how NICE's remit will evolve beyond raising the baseline threshold.

The BIA urges government to ensure rare diseases remain a priority within the evolving commercial medicines landscape. As highlighted in a recent BIA policy report, appraisal and reimbursement frameworks must be modernised to unlock access to rare disease medicines, including by evolving NICE methods to capture long-term and societal value and considering alternative assessment routes for rare disease treatments that are not suited to traditional HTA approaches.

Clarifying ministerial responsibility to include the evolution of NICE's methods would be an important step forward. This would help to create a clear route for government to drive the reforms needed to support its ambitions for NHS innovation and life sciences, alongside other changes to improve the UK's commercial environment for innovative medicines and ensure rare disease patients can benefit from translating cutting-edge science into new treatments on the NHS.

These issues reinforce the importance of setting a renewed, long-term vision for the next UK Rare Disease Framework, with a strong focus on addressing persistent barriers in the access to medicines landscape.

About the BIA

The BIA is the trade association for innovative life sciences and biotech industry in the UK, counting over 600 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. Please contact Senior Policy and Public Affairs Manager Rosie Lindup at rlindup@bioindustry.org for any further information regarding this consultation response.