NICE COST EFFECTIVENESS THRESHOLD REGULATIONS CONSULTATION

Submission from The Brain Tumour Charity

The Brain Tumour Charity is the world's leading brain tumour charity and the largest dedicated funder of research into brain tumours globally.

As a charity we provide support to the brain tumour community through the funding of new, innovative research, as well as through events, a dedicated support team, and advocating for necessary change to improve the lives of those affected by this disease.

We welcome the opportunity to submit to this consultation inquiry and share some our answers on the cost effectiveness threshold regulations consultation.

Proposed amendments to the NICE regulations

Proposal 1

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

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 200 words)

The Brain Tumour Charity oppose the first proposal in totality to *give ministers a limited power of direction to set the core cost-effectiveness threshold that NICE uses in the development of guidance.*

The basis of this opposition is that it may create a culture of uncertainty for innovation, with the thresholds potentially shifting quickly and without appropriate reflection or consultation. This is at a time when industry are already anxious the VPAG rebate is creating a level of uncertainty which is discouraging UK medicine launches.

The proposed change also has the potential to turn NICE into a political tool where thresholds could be lowered when budget pressures are restrictive. Given the current economic climate, with strict public spending requirements, this is a live and ongoing concern.

Both points could risk innovators deciding the UK is not a viable place to invest due to its potential for fluctuation and uncertainty. This means that areas of high unmet need, like brain tumours, will be disproportionately disadvantaged as new, innovative treatments are necessary to see improved outcomes for these patients. This risk has already been highlighted by a 2025 survey from the ABPI and the Bioindustry Association (BIA) of pharmaceutical companies developing medicines to treat rare diseases which found that the majority of companies did not expect their full future pipeline of rare disease medicines to reach UK patients.

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? This includes technology appraisal and highly specialised technology evaluation recommendations.

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 200 words)

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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 agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Optional, maximum 200 words)

The Brain Tumour Charity oppose the second proposal to r*emove the requirement for NICE to consult on methods changes where these result from a ministerial direction.*

The basis of this opposition is that it has the potential to weaken the perception of NICE's independence and strong global reputation.

At present NICE is able to state that it provides "rigorous, independent assessment of complex evidence". NICE's reputation around the world is, in part, built on guidance being developed by engaging with UK clinicians, patients and patient organisations, researchers and many other sector partners.

By removing a core requirement of this wider engagement, it undermines a core principle of NICE and its reputation may be harmed. As a result of this change the UK could no longer be a key global reference market for the life sciences industry, risking further global investment in research, clinical trials and innovative treatments.

Patient and patient organisations are already marginalised in decisions around decisions on methods changes, and rather than remove this form of engagement, we should be working towards better co-production with partners.

Additional comments

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

If these proposals are approved and implemented, The Brain Tumour Charity would recommend that there are strict protections in place to ensure that changes are made in a transparent and robust manner, with clear rationale published each time a change is made.

The rationale should include a degree of robust scrutiny applied to any and all changes from experts, to ensure a degree of sector alignment and no unintended consequences.

Additionally, there should be a limit on the number of changes that are allowed to be made within a specified timeframe.

Without these safeguards, the potential harm to NICE and the wider UK life sciences sector is significant and jeopardises our world leading reputation.

Regarding the consultation, given that the potential significant impact on the UK life sciences sector, this process has been inadequate. The consultation period should be longer, with more considered engagement with sector partners. A full impact assessment should also be conducted and form a part of that engagement. The Brain Tumour Charity encourages NICE to review this process and conduct a more considered consultation in the coming months.

Appendix One

Current legislative framework

NICE was formed in 1999 and was re-established as an executive non-departmental public body under the Health and Social Care Act 2012. It provides evidence-based guidance for the NHS and social care, including technology appraisal and highly specialised technology evaluation recommendations.

Under the Health and Social Care Act 2012 and associated regulations, NICE is responsible for setting its own methods and processes. The cost-effectiveness threshold that is used in the development of NICE's guidance and recommendations is a matter of public policy that is a reflection of the amount of the healthcare budget that should be apportioned to innovative new treatments, taking into account a range of factors. The government therefore considers that it should be treated as discrete from NICE's methods and processes and should be set by the democratically-elected government.

Ministers currently have no power to direct NICE on the procedures that it uses in the development of its guidance, including technology appraisal and highly specialised technology evaluation recommendations. Any changes to the approach that NICE takes must be aligned with its statutory duties and consulted upon. Financial controls apply under Managing public money, requiring HM Treasury approval for decisions that are novel, contentious or repercussive.

The current legislative framework means that there is no clear mechanism for initiating an amendment to the NICE cost-effectiveness threshold to support government priorities.

The government is proposing to amend the National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (the NICE regulations), as follows.

Appendix Two

Proposal One

Give ministers a limited power of direction to set the core cost-effectiveness threshold that NICE uses in the development of guidance, including technology appraisal and highly specialised technology evaluation recommendations.

Regulations 5(4), 7(9) and 8(8) of the NICE regulations provide that NICE must establish a procedure for the appraisal of technologies that it has been directed to appraise. Ministers do not have a power to direct NICE as to the threshold that it uses and there is therefore no clear mechanism for amending the threshold.

The proposed change would enable ministers to direct NICE to use a specific cost-effectiveness threshold in the development of its guidance and recommendations. The government considers that the change is necessary to enable the threshold that NICE uses to take into account a broader range of factors, such as industrial policy objectives, economic growth and investment, which are properly matters for the elected government. The change would also ensure that there is a clear route for amending the threshold. NICE would continue to be responsible for the wider methods and processes that it uses in the development of its guidance.

It will remain vitally important that NICE is able to develop its guidance and recommendations free from political interference, in accordance with the framework that it operates within. The existing provisions to safeguard NICE's independence by prohibiting ministers to direct NICE as to the substance of its guidance and recommendations, will remain unchanged.

Appendix Three

Proposal Two

Remove the requirement for NICE to consult on methods changes where these result from a ministerial direction.

Regulations 5(5), 7(9) and 8(8) of the NICE regulations provide that NICE must consult "such persons as it considers appropriate" in the development of the procedures that it uses in the development of its advice, guidance, information and recommendations.

We are proposing to amend the regulations to provide that there is no requirement for NICE to consult on consequential changes to its procedures where necessary to reflect a direction from the Secretary of State. Therefore, where NICE has been directed to use a set standard cost-effectiveness threshold in the development of its guidance, it would be unnecessary for NICE to consult separately on the changes that it makes to its procedures to implement the direction.

