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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

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

On behalf of our member organisations, Gene People supports strengthening the mechanism for setting the NICE standard cost-effectiveness threshold through a clear and accountable ministerial direction, where this is intended to improve access to medicines and support investment in innovative treatments in the UK. However, for the rare disease community, this change will have a limited impact if it is not accompanied by an increase in capacity and strengthening of the Highly Specialised Technologies (HST) Programme.

The process and mechanism by which ministers set or amend the threshold must be transparent and clearly articulated. Decisions of this significance should be informed by evidence and include meaningful consultation with patients, families, carers and representative organisations, including rare disease voices.

We support ministerial direction being limited to the standard cost-effectiveness threshold and do not support ministers having further involvement in NICE's methods or processes. Preserving NICE's independence is critical to maintaining trust in its guidance and ensuring confidence among patients, clinicians and the life sciences sector.

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

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

Gene People agrees that direct ministerial direction on the standard cost-effectiveness threshold should apply to all NICE guidance that makes recommendations on health spending, including technology appraisals and highly specialised technology (HST) evaluations. Excluding HSTs from this change would risk further disadvantaging people

living with rare and genetic conditions, many of whom already face limited or delayed access to effective treatments.

Further detail is needed on the process by which ministers will make these decisions, the evidence that will be considered, and how potential impacts on different patient populations will be assessed. Meaningful consultation with patients, families, carers and representative organisations, including rare disease voices, must be an integral part of this process.

Applying a single, ministerially directed threshold across NICE guidance must not result in a narrowing of access for those with the highest unmet need. Safeguards are therefore needed to ensure that people living with rare diseases are not left behind and that the HST Programme is appropriately resourced and able to fulfil its intended role.

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?

- Disagree

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

Gene People disagrees that NICE should not be required to consult on proposed changes to its procedures that result from a ministerial direction on cost-effectiveness thresholds. While we recognise that ministerial direction on thresholds could clarify and strengthen the mechanism for improving access to medicines, including for people living with rare and genetic conditions, this does not remove the need for consultation.

Any consideration of changes to NICE cost-effectiveness thresholds must include consultation with the patient community. Decisions of this nature have significant implications for access to treatment and should not be implemented without transparency or engagement. Once a ministerial decision has been made, NICE should still have the opportunity to consult on the procedural changes required to implement that decision. This would provide patients with a clear and open opportunity to express their views and highlight potential unintended consequences.

Maintaining a consultation requirement also acts as an important check and balance, helping to preserve NICE's independence and public trust. Removing this safeguard risks weakening confidence in the system and undermining the legitimacy of decisions that directly affect people's health and lives.

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)

Gene People supports the ambition to remove ambiguity and introduce greater clarity into how NICE cost-effectiveness thresholds are set. A more direct mechanism for setting thresholds is welcomed, particularly given the pace of scientific advancement and the increasing number of innovative medicines entering development. However, rare disease communities must not be left behind as these changes are implemented. Any changes to how thresholds are set or applied must take into account the Highly Specialised Technologies (HST) Programme.

It is essential that any process for changing NICE cost-effectiveness thresholds is transparent and includes meaningful consultation with patients, families, carers and representative organisations. Decisions of this significance will shape access to treatment for years to come and must reflect lived experience as well as economic considerations.

While we believe ministers have a legitimate role in setting thresholds, NICE should remain independent to develop its processes and methods in close collaboration with relevant stakeholders, including patients. This is key to maintaining independence, fairness and credibility. Consultation and openness are critical to maintaining public trust and confidence in NICE's guidance and recommendations.

Gene People is grateful for the opportunity to respond to these proposals and would welcome continued engagement as the regulatory changes are developed and implemented.