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# NICE Reform Plans Aim To Help Make Post-Brexit UK A 'First-Launch' Country

*HTA Body's Methodology Review Includes Accepting More Uncertainty*

by Ian Schofield

Following a Brexit-induced delay over the summer, England's HTA body NICE has come up with a concrete set of proposals that it says will help it "robustly and efficiently" evaluate innovative technologies such as advanced therapies, histology-independent cancer treatments, and technologies for rare diseases. Industry bodies have welcomed the plans, which have just been put out for consultation.

NICE, the health technology assessment body for England, has launched its long-awaited consultation on changes to the methods it uses to assess new technologies such as medicines, medical products and diagnostics in a bid to ensure the methods "remain cutting edge and future proof."

Life science industry associations have welcomed the proposals, with one group saying the focus on removing significant barriers to access would put the UK on a new footing.

NICE said the proposals were "part of the largest review ever" carried out into the methods and processes it uses to produce its guidance on health technologies. It views the changes as a way to continue to support patient access to medicines and make the UK attractive as a "first-launch country for important and promising new health technologies."

Developments in science and technology have led to rapid changes in healthcare and health technology evaluation, so "a wide-reaching assessment of NICE's health technology evaluation methods is both appropriate and timely," the HTA body said.

The changes are due to be implemented in October 2021.

Among the specific ideas put forward in the consultation document are the introduction of new factors to be taken into account in decision-making, such as the severity of a condition, accepting more uncertainty in individual situations, and a wider evidence base including real world evidence.

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"Taken together, the proposals in this methods review and the high degree of flexibility in NICE's existing methods and decision-making approach aim to provide a broad package that ensures that NICE can robustly and efficiently evaluate innovative technologies," said NICE. Such technologies include ATMPs, histology-independent cancer treatments, technologies for rare diseases, and emerging innovations.

No doubt with the end of the Brexit transition period in mind, Meindert Boysen, NICE deputy chief executive, said: "As we develop a new regulatory and access environment for medicines, medical devices, diagnostics and digital health technologies, our methods should be aimed at supporting early patient access at a reasonable cost to the NHS, for example by encouraging companies to launch their products in the UK first."

"Ensuring that our methods are clear, transparent and predictable should allow us to speed up evaluation processes for new and emerging technologies," Boysen declared. "This is particularly important in our response to COVID-19, but also allows us to further consider how to best evaluate the value of specific new technologies such as cell and gene therapies."

> *The proposed changes "send an important signal to the innovative biotech sector that the UK is serious about ensuring access to new medicines" – Steve Bates, CEO, Bioindustry Association*

The biopharmaceutical industry generally welcomed the proposals. Steve Bates, CEO of the BioIndustry Association, said the planned changes sent “an important signal to the innovative biotech sector that the UK is serious about ensuring access to new medicines.”

Bates said his association was “very encouraged by the focus on removing significant barriers to access, which puts the UK on a new footing, setting the benchmark for health technology appraisals – particularly around modifiers, uncertainty and discounting.” This would "help ensure both that industry can continue to deliver innovative medicines and that patients can access them".

Richard Torbett, chief executive of the Association of the British Pharmaceutical Industry, described the proposals as “a positive first step towards more NHS patients benefitting from the very latest medicines.” They could also act as “a catalyst for global investment, with the UK demonstrating its commitment to researching, developing and using new medicines and technologies,” Torbett said.

According to Bates, implementation of the changes was “fully affordable” because of the 2019 Voluntary Scheme agreed by the ABPI and the Department of Health and Social Care, which aims to improve patient access to the best value medicines and to keep the branded drugs bill affordable for the NHS.

NICE said that “although the 2019 Voluntary Scheme includes measures to mitigate the costs of branded medicines, the effects on healthcare budgets are still important because of healthcare displacement effects within financial years, long-term dynamic effects (such as comparator prices), and effects on other health technologies.”

It added that it was too early to identify and quantify the precise effect of the proposals on individual technologies, wider health care budgets, and how different uses of health care resources were prioritized. “This is because much depends on the views of stakeholders expressed in consultation, and on how the proposals might be implemented in practice.”

## Brexit Delay

Work on the review began back in 2019, but progress – including the present consultation – was held up this year, partly because of changes to the UK regulatory and commercial landscape as a result of Brexit. (Also see "*Brexit Issues Lead NICE To Delay Methods Review*" - Pink Sheet, 29 Sep, 2020.)

Once the six-week consultation ends on 18 December, a further one will be held in February to March 2021 on any changes that need to be made to NICE’s processes. From April to May next year, the responses to the public consultations will be reviewed.

Then from June to July, yet another consultation will be conducted, this time on the new draft program manual. The manual explains NICE's methods and processes for developing, maintaining and updating its guidelines.

NICE will review the responses to that consultation next August. In September, it plans to publish the new programme manual. Implementation of the new processes and methods is slated to begin in October.

## The Proposals

The review covers drug technology appraisals, medical technologies evaluations, highly specialized technologies and diagnostics. It is being conducted in two stages. The first, which involves an assessment of the current methods and the need for change, has already been completed.

In the second stage, NICE will look at the responses to the consultation and "consider the wider implications of any amendments (including any financial effects)." Once this is done, the new methods will be integrated into health technology evaluations.

NICE also says it will move away from the current practice of updating its methods every four to six years and towards a more iterative and modular approach, and that three topics to be considered in future review phases will include genomics, digital technologies and antimicrobial resistance technologies.

In its consultation document, NICE identifies a number of key areas where changes are needed.

## Valuing The Benefits Of Health Technologies

A key aim of the review is to improve the way that factors (modifiers) affecting NICE's decisions are taken into account. One proposal is to do away with the current modifier for life-extending treatments at end of life and bring in a new modifier on severity of disease that would be "more broadly and fairly applicable" than the current end of life criteria, which are mostly applicable to cancer drugs.

NICE also wants to see a greater degree of uncertainty and risk being accepted in certain cases, such as rare diseases and innovative technologies, and proposes another possible modifier: "whether a technology will reduce health inequalities."

It says there is also a case to change how NICE values costs and health effects for health technologies in the future through "discounting", but notes that "the wider policy and affordability implications of such a change go beyond the reach of this review and will need to be considered separately before any change could be implemented."

## Improving The Evidence Base

In terms of the evidence on which health technology evaluations are based, the plan is to refresh and clarify the methods NICE uses to source, review and present the evidence base. NICE says the methods should be clearer about when real world evidence (RWE) might be most valuable and should provide guidance on how to gather and analyze it.

Other ideas include updating the evidence requirements for surrogate outcomes, using a "hierarchy of preferred sources of prices for medicines" when programs like patient access schemes are put in place, and improving the methods for selecting outcomes measures.

## Structured Decision Making

Work so far on the review has shown there is a need to refine the way that clinical and cost-effectiveness analyses as well as NICE's recommendations on health technologies are presented. In addition, NICE says the methods for considering subgroups should be updated to include the presentation of absolute and relative treatment effects.

## Challenges Of New Technologies

Proposed improvements have been identified to help tackle "key challenges" posed by technologies such as ATMPs and histology-independent cancer treatments, as well as rare diseases.

For example, technology evaluations should take account of unpublished evidence and post-marketing surveillance data where relevant, and where there is uncertainty about the long-term health benefits, evaluations should include "scenario analyses that explore the effects of different assumptions about long-term benefits."

When basket trials are used, they should be appropriately designed and analyzed and "include assessment of heterogeneity and allow borrowing between baskets." If a clinical trial does not include a comparator group, "several methods to derive comparative evidence should be explored."

NICE said it will be holding an online consultation *event* on 25 November where stakeholders can put their questions to NICE staff.