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# National Institute for Health and Care Excellence Reinvented: Eyes on Innovation and Enhanced Patient Access

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The UK's health technology assessment (HTA) body, National Institute for Health and Care Excellence (NICE), is undergoing what has been described as the largest-scale overhaul in its history. With a series of stakeholder consultations on proposed changes to its product selection, methods, and processes, NICE intends to embrace new technologies and ensure patient access to lifesaving treatments, aspiring to make the UK a "first to launch" country.

The first aspect of this review aims to align topic selection with the needs of healthcare professionals and patients and make it more transparent and efficient. In this review, NICE will consolidate all selection processes into a single manual while broadening the scope of medical technologies that NICE will appraise. In the medicines space, as of April 2020 NICE has appraised all new active substances and significant license extensions except when there is a "clear rationale not to do so." The new manual aims to identify clearer and more predictable criteria about which medicines will be directed to the highly specialized technologies (HST) program, the route that allows a higher cost-effective threshold but that has been criticized for having a too narrow and confusing scope.

For medical devices, selection criteria will also include medical device technologies that "are likely to be highly disruptive or lead to a stepwise change to an established care pathways in the UK." The scope of new technologies to be appraised includes use of artificial intelligence and digital technologies. Interestingly, the new manual will introduce a formal appeal procedure for challenging decisions on topic selection.

The second, and possibly more exciting, aspect of the review is the consultation aiming to revamp NICE's methods and processes for assessing new technologies. NICE's ambition is that the methods will be future-proof and enable the UK to foster innovative treatments. This overhaul has been necessitated by the leaps in scientific and technological advances in healthcare (with innovations including advanced therapy medicinal products (ATMPs), personalized medicine, and digital health technologies) but also by new ways of analyzing the value of a health technology to the healthcare system.

NICE has identified the need to be "faster and more effective" and create simple and pragmatic evaluation methods. It is therefore embracing new criteria in its decision-making, including accommodating unmet medical needs and smaller patient populations and catering for uncertainty and integration of real-world evidence (RWE) in its methods. It wishes to facilitate treatments for rare conditions, ATMPs, and emerging innovations such as histology-independent cancer medicines. It has recognized that predictability is key to attracting company launches especially in areas of uncertain value propositions, where evidence gaps in traditional models have produced uncertainty.

Feedback on NICE's consultations has been positive, including from industry. Bioindustry Association has commented that this review has "sent an important signal to the innovative biotech sector that the UK is

serious about ensuring access to new medicines," while the Association of the British Pharmaceutical Industry has welcomed this review as one that shows the UK's commitment to researching, developing, and making available new medicines and technologies.

The initial feedback will be reviewed and will give rise to a draft program manual that will be put to consultation in June to July 2021 with a targeted publication date of September 2021 for the new program manual and October 2021 for the new processes and methods implementation.

This is not NICE's first attempt to stay current. For instance, in February 2019 NICE launched a scientific advice service on designing patient preference studies. This was aimed at involving patients more formally in the HTA procedure and using these studies as supplementary evidence to evaluate a medical technology. Brexit is providing a further incentive to ensure the UK remains an attractive market.