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Aligned MHRA-NICE approval pathway benefits industry over patients

Approval mechanisms must be grounded in patient need and population health

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In April 2026, the UK government announced a new pathway to expedite the availability of new medicines in the NHS.[1] The joint regulatory and health technology assessment (HTA) approval pathway is designed to make products available three to six months sooner by aligning National Institute for Health and Care Excellence (NICE) decisions with those of the Medicines and Healthcare Products Regulatory Agency (MHRA), such that regulatory and HTA decisions are issued simultaneously.[2]

The MHRA evaluates the clinical efficacy and safety of new medicines before market authorisation, while NICE assesses their clinical effectiveness and cost effectiveness against existing alternatives in the NHS. These processes have different evidence requirements. Ideally, both sets of decisions are underpinned by randomised controlled trials that compare new drugs against the standard of care and evaluate patient relevant outcomes such as mortality. In recent years, however, regulators have increasingly relied on small non-randomised studies without control arms, measuring surrogate endpoints that do not reliably predict clinical benefit for patients.[3]

These shifts in the evidence base supporting new drug approvals have complicated HTA, as comparative effectiveness and long term cost effectiveness are difficult to establish without comparators or clinical endpoints. Meaningful alignment of regulatory and HTA evidence requirements would strengthen both processes and reduce the risk of ineffective, harmful, or low value products reaching the market.

However, this is not what the new pathway offers. Rather than aligning evidentiary standards, it runs two independent processes in parallel with the aim of synchronising their conclusions. This will be achieved by NICE bringing its technology appraisal process forward to run concurrently with MHRA's regulatory review. Similar parallel pathways exist in Australia and Canada, where they have enabled earlier funding decisions compared with sequential assessments.[4]

The new pathway brings clear advantages for industry. Products reaching the market sooner begin accruing revenue earlier and benefit from a longer period before sales become eligible for rebates under the voluntary agreement between the UK government and the pharmaceutical industry.[5] The rebate-free window is three years from regulatory approval, and companies will no longer have to wait for subsequent NICE assessment before starting sales. This pathway also fulfils explicit commitments in the NHS 10 year plan and the life sciences sector plan to make the NHS a more commercially attractive market.[6]

Benefits to patients and the NHS are, by contrast, considerably less clear. Earlier access to effective new drugs can matter for patients with substantial unmet needs, and months of delay can carry clinical consequences. But the pathway does not target this population; it will expedite NHS availability of new medicines irrespective of evidence of added therapeutic benefit. In Canada, parallel HTA resulted in no difference in time to availability between drugs with and without added therapeutic benefit.[7] UK patients with unmet needs already have mechanisms for early access. For example, the MHRA's early access to medicines scheme facilitates access to investigational products that do not yet hold a marketing authorisation,[8] and the innovative licensing and access pathway aims to streamline regulatory and HTA processes for medicines with potentially transformative benefits.[9]

Risks

The new pathway will impose timelines to ensure that MHRA and NICE decisions are reached simultaneously. Fixed deadlines on drug evaluation have historically been associated with higher rates of adverse events,[10] and medicines approved through expedited regulatory pathways have a greater frequency of post-marketing safety events (such as boxed warnings and safety related labelling changes) than those approved through standard routes.[11-13] This is particularly concerning given that the MHRA has already compressed its procedures through international recognition pathways, whereby regulatory decisions made in other jurisdictions, including the US, receive near automatic UK approval.[14] As a growing share of new drug approvals in the US benefit from expedited regulatory programmes,[15] the UK is increasingly exposed to greater uncertainty about the safety and efficacy of drugs approved in other settings.

A further implementation challenge compounds these concerns. Companies will in some cases be required to submit evidence to NICE before the MHRA review has begun. NICE committees will therefore be asked to deliberate on a product whose pharmacokinetic, efficacy, and safety profile has not been vetted by the regulatory authority. NICE committees already need to make recommendations under conditions of growing uncertainty in the evidence base.[16] The pathway will ask them to do so on evidence that is both uncertain and unscrutinised.

Opportunity costs

The wider NHS consequences are no less serious. Evidence suggests that the population health effect of new medicines recommended by NICE between 2000 and 2020 was negative, meaning that the

resources spent on those drugs could have generated more health if directed towards more cost effective interventions.[17] The new pathway will bring expensive medicines into NHS commissioning earlier, extending the period over which they divert resources from other services. These health opportunity costs will be felt more acutely because of the 2025 US-UK trade agreement, which commits NICE to raising its cost effectiveness threshold by 25%.[18] This means that the NHS will pay more per unit of health benefit from new drugs than it derives from equivalent spending elsewhere in the system. The health opportunity cost of new medicines (in terms of health generated from more cost effective care forgone) will inevitably increase further.[19]

This pathway is the latest in a series of policies that have progressively prioritised commercial considerations over those of patients and the NHS. A renewed commitment to grounding medicines access policy in patient need and population health is needed. At a minimum, the government should set out the assumptions underpinning this pathway and assess its expected benefits and harms across all affected stakeholders—not only industry, but patients and the wider NHS. NICE has stated it will evaluate how the pathway performs, but its focus on "where same-time publication was not achieved and how we can improve" suggests that synchronisation of decisions will be the predominant metric of success.[20] The more important question is whether the NHS will be adequately protected from the earlier adoption of medicines that prove harmful, ineffective, or poor value.

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