MHRA and NICE invite early adopters to trial accelerated aligned pathway – six months ahead of schedule

Friday 10 October, 2025

Pharmaceutical companies who make qualifying medicines can now take advantage of a streamlined approvals pathway for medicines much earlier than anticipated.

Aligned pathway will streamline decisions on licensing and value for medicines, helping patients to benefit from them sooner.

The Medicines and Healthcare products Regulatory Agency (MHRA) and National Institute for Health and Care Excellence (NICE) are now offering some pharmaceutical companies early access to the aligned pathway six months earlier than projected, as user research begins to shape the next phase of the programme. The pathway is now accepting applications from manufacturers who make medicines which have been designated by the NICE and the MHRA for early access.

The aligned pathway delivers on government ambitions in the Regulatory Action Plan, 10-Year Health Plan for England and the Life Sciences Sector Plan by streamlining regulation, accelerating access to medicines for patients and the NHS, and improving the UK's global competitiveness in life sciences.

The pathway brings together the MHRA's licensing process and NICE's value assessment process, meaning decisions will be published at the same time, instead of consecutively. This will reduce the 90-day gap between marketing authorisation and NICE guidance decisions, meaning faster patient access, support for the NHS and a more efficient route for industry.

A new fully integrated joint scientific advice service, launching by April 2026, will provide a single-entry point for coordinated advice from the MHRA and NICE to help avoid delays and support alignment. The service is designed to help companies successfully adhere to aligned pathway timelines, providing enhanced clarity and confidence in investment decisions by providing evidence requirements early and avoiding unnecessary delays.

Pharmaceutical companies are encouraged to register products on UK PharmaScan at least three years before marketing authorisation and to engage early with both organisations.

NICE and the MHRA will continue to work more closely to improve efficiency, transparency and timely access to innovative treatments.

Any companies with a technology appraisal already scheduled who believe their product may be suitable for the aligned pathway should contact the NICE scheduling team – scheduling@nice.org.uk.

Notes to Editors

1. Our joint blog post with further guidance on the aligned pathway is available here.
2. The aligned pathway was announced by the Medicines and Healthcare products Regulatory Agency (MHRA) and the National Institute for Health and Care Excellence (NICE) in July following the publication of the Regulatory Action Plan from HMT in March 2025.
3. Pharmaceutical companies will also need to commit (at global level) to the Aligned Pathway timelines. To support this approach, NICE will offer priority scheduling for medicinal topics following the Aligned Pathway, ensuring these medicines can progress through its evaluation process in time to achieve simultaneous publication with regulatory decisions.
4. The National Institute for Health and Care Excellence (NICE) provides useful and usable guidance for health and care practitioners, including rigorous, independent assessment of complex evidence for new health technologies.
5. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
6. The MHRA is an executive agency of the Department of Health and Social Care.
7. NICE is an executive non-departmental public body of the Department of Health and Social Care.
8. For media enquiries, please contact newscentre@mhra.gov.uk or call 020 3080 7651.

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