

News story

# MHRA announces new recognition routes to facilitate safe access to new medicines with seven international partners

The new recognition routes open additional options for the MHRA to bring cutting-edge medicines faster to UK patients by leveraging the expertise and decision-making of trusted regulatory partners

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From: [Medicines and Healthcare products Regulatory Agency](#)

[\(/government/organisations/medicines-and-healthcare-products-regulatory-agency\)](https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency)

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New regulatory recognition routes for medicines will be established using approvals from Australia, Canada, the European Union, Japan, Switzerland, Singapore and the United States, the Medicines and Healthcare products Regulatory Agency has announced today.

This means that patients will have access to safe and effective medicines that have been approved by trusted regulatory partners in other countries. The new international recognition routes will sit alongside the MHRA's own unique innovation pathway for medicines which integrates early regulatory advice with health technology assessment advice.

These recognition routes, which have been facilitated by existing international partnerships such as those developed through the [Access Consortium](https://www.gov.uk/guidance/access-consortium) (<https://www.gov.uk/guidance/access-consortium>) and [Project Orbis](https://www.gov.uk/guidance/guidance-on-project-orbis) (<https://www.gov.uk/guidance/guidance-on-project-orbis>), mark the start of a new international recognition framework for medicines that will be in place by the first quarter of 2024.

The new framework will allow the MHRA to make the most of the expertise and decision-making of trusted regulatory partners to streamline assessments of specific products. As a result, cutting-edge medicines that have been approved in other countries will get to UK patients more quickly, with cost reductions and streamlined regulatory processes for industry.

As a sovereign regulator, the UK regulator will still be responsible for approving all 'recognition route' applications under the new framework, ensuring that all products are safe and of sufficient quality to be licensed in the UK. The MHRA will maintain rigorous scrutiny and retain the authority to reject applications if the evidence provided is considered insufficiently robust.

At the time of the UK's exit from the European Union, the MHRA introduced temporary routes to market for European approved products in Great Britain, known as EU 'reliance' routes, to ensure that patients could continue to have timely access to new treatments. These temporary routes are due to expire at the end of 2023.

While the international recognition routes announced today focus on medicines, work is underway to establish similar routes for medical devices. As part of this ongoing work, the MHRA will launch a new targeted consultation on medical devices that will gather views on a wide range of topics, including recognising conformity assessments or approvals from international regulatory partners.

**Dr June Raine, MHRA Chief Executive, said:**

“ We are focused on providing UK patients faster access to the absolute best, most cutting-edge, and safest medical treatments. By fast-tracking access to approved products from other countries, we’re ensuring that innovative healthcare solutions reach those in need without delay.

“ The introduction of the new routes will complement the work being done through the MHRA’s [Innovative Licensing and Access Pathway \(ILAP\)](https://www.gov.uk/guidance/innovative-licensing-and-access-pathway) (<https://www.gov.uk/guidance/innovative-licensing-and-access-pathway>), establishing an additional avenue for accelerated access to life-saving new medicines. Combining MHRA’s globally recognised high standards with improved flexibility and a sustained collaborative approach across the healthcare system, the ILAP is helping reduce the time to market for innovative treatments by developing medicines that are both regulatory and access ready.

“ Through this new dual approach, we will contribute to the UK’s ambition to be a global science superpower, by making the UK one of the best places in the world to bring life-changing healthcare products to patients safely.”

A £10m funding from HM Treasury was [announced earlier this year](https://www.gov.uk/government/news/mhra-to-receive-10m-from-hm-treasury-to-fast-track-patient-access-to-cutting-edge-medical-products) (<https://www.gov.uk/government/news/mhra-to-receive-10m-from-hm-treasury-to-fast-track-patient-access-to-cutting-edge-medical-products>) to support the development of this new recognition framework.

**Find out more**

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(<https://www.linkedin.com/company/164969>)

## Notes to editors

1. 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.
2. The MHRA is an executive agency of the Department of Health and Social Care.
3. For media enquiries, please contact the [newscentre@mhra.gov.uk](mailto:newscentre@mhra.gov.uk).

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