

News Release

UK and Singapore team up to launch new fast track pathway to speed up access to breakthrough health technologies

Patients in the UK and Singapore could gain faster access to cutting-edge treatments under a new partnership, which brings two of the world's WHO Maturity Level 4 regulators together with one of the world's leading biotech creators.

Patients in the UK and Singapore could benefit sooner from major medical advances as the UK and Singapore launch a new regulatory innovation corridor to fast track the most promising health technologies today (12 December).

As part of this first-of-its-kind partnership between the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and Singapore's Health Sciences Authority (HSA), companies will have a coordinated fast track pathway to engage both regulators at the same time. Under the new corridor, developers will be able to seek joint advice from both regulators early, helping them plan ahead and design better clinical trials, avoid duplication and reduce delays.

The aim is to speed up patient access to breakthrough therapies in high-impact areas such as cancer, dementia, obesity, rare diseases and advanced diagnostics – without compromising on safety – while strengthening both countries' position as global hubs for life science investment.

Flagship Pioneering, a scientific innovation engine for transformative platforms and products, will be the first company to access the new Regulatory Innovation Corridor. Its early-stage programmes across an ecosystem of more than 40 companies, including Flagship-founded Moderna, span a broad range of new therapeutic modalities that could inform regulatory paradigm shifts on the horizon. This includes next-generation gene therapies, precision immunology and digital health, providing both countries visibility into a strong pipeline of potential breakthroughs to prepare to assess safely and innovatively. This participation by Flagship Pioneering is intended to help test and refine the framework, which will be open to other companies in subsequent phases.

The partnership builds on a long track record of UK-Singapore cooperation in science and technology. Together, the MHRA and HSA will work more closely on early diagnosis,

prevention, healthy ageing and digital health, and supporting national strategies in both countries – including England's 10-Year Health Plan and Singapore's Healthier SG initiative.

The collaboration will be supported by joint work on AI in healthcare, with both regulators acting as the first two pioneer countries in the <u>HealthAI Global Regulatory Network</u>, and also draw on the UK's <u>National Commission into the Regulation of AI in Healthcare</u>. HSA Chief Executive Adjunct Professor (Dr) Raymond Chua has recently joined the National Commission as a member, bringing Singapore's regulatory expertise to help develop the new framework for AI in healthcare.

This new route forms part of wider efforts to unlock growth in UK life sciences and make it simpler for global innovators to bring safe, effective medicines and medical technologies to patients. Recent MHRA initiatives include its <u>Al Airlock</u> – a regulatory sandbox for Al medical devices – which lets companies test new tools with the regulator before wider NHS roll-out; the <u>Innovative Licensing and Access Pathway (ILAP)</u> which streamlines development in areas of urgent unmet need; and its <u>Centres of Excellence for Regulatory Science and Innovation</u> (CERSIs) working directly with researchers to navigate complex science. Together, these changes are designed to streamline development, support investment and provide clearer routes for companies working at the cutting edge of science.

It also builds on HSA's ongoing efforts to strengthen Singapore's position as a leading biotech hub, accelerate access to innovative health technologies, and set the pace in global regulatory innovation. HSA's recent initiatives also include ASCENT¹ – the Centre for Advancing Regulatory Science Research in Next-Generation Therapeutics – a partnership between HSA and A*STAR (Agency for Science, Technology and Research) that will strengthen Singapore's position as a global thought leader in evaluating and approving novel biotherapeutics and digital technologies; and the review of the AI in Healthcare Guidelines (AIHGle), published by the Ministry of Health, HSA and national healthtech agency Synapxe, which provides practical guidance for the safe and effective use of AI across Singapore's healthcare ecosystem. These guidelines are periodically updated to keep pace with emerging AI technologies.

Lawrence Tallon, Chief Executive of the MHRA, said:

"This new fast track route marks a significant shift in how trusted regulators can work together. By bringing together the UK's research strength with Singapore's agile approach to emerging technologies – and working early with companies like Flagship Pioneering – we can help companies build better evidence from the start and avoid delays in development.

"For patients in the UK, this means earlier access to promising treatments in areas where progress is urgently needed. Safety remains at the heart of our mission, and this partnership strengthens our ability to assess fast-moving science while maintaining the high standards the public expects.

"This approach also supports the wider UK life sciences economy. A clearer, more predictable path to market helps attract global investment, gives innovators confidence to develop their products here, and strengthens the UK's position as a leading hub for the next generation of medicines and medical technologies."

Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer of the Health Sciences Authority, said:

"The Regulatory Innovation Corridor marks a significant milestone in how two regulators, Singapore's HSA and UK's MHRA, can come together to advance global regulatory innovation and benefit patients.

Building on our strong collaborative work through the Access Consortium, both HSA and MHRA will co-create transparent, science-based approaches to assess breakthrough technologies. And we are indeed glad to have Flagship Pioneering as the first company accessing this new corridor, which will foster shared learning between all parties and future partners, to enable more forward-looking pathways to move breakthrough ideas in key priority areas from lab to market.

This partnership advances our shared commitment to regulatory science and excellence, and to support Singapore's latest research priorities, enabling faster, smarter pathways for innovation while maintaining public trust and patient safety."

Noubar Afeyan, Ph. D., Founder and CEO of Flagship Pioneering, said:

"Global challenges in human health demand global regulatory innovation. By establishing this corridor, the UK and Singapore are signalling a shared commitment to accelerating breakthrough science responsibly and at scale. Through this partnership, Flagship Pioneering and our companies can engage earlier and more efficiently with two highly respected regulators, helping us advance transformative technologies that have the potential to redefine patient care. We view this as a model for how forward-looking nations can work with innovators to unlock faster, safer paths to patient impact."

Refer to **Annex** for photos.

MEDICINES & HEALTHCARE PRODUCTS REGULATORY AGENCY HEALTH SCIENCES AUTHORITY 12 DECEMBER 2025

ENDS

Notes to editors

- 1. ASCENT is supported by the Singapore Ministry of Health through the National Medical Research Council Office, MOH Holdings Pte Ltd.
- 2. 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.

- 3. The MHRA is an executive agency of the Department of Health and Social Care.
- 4. For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice.

For more updates on public health and safety matters, follow us on social media: $\underline{\text{LinkedIn}}$, $\underline{\text{Instagram}}$, $\underline{\text{X}}$ and $\underline{\text{YouTube}}$.

About Flagship Pioneering

Flagship Pioneering invents and builds platform companies, each with the potential for multiple products that transform human health, sustainability and beyond. Since its launch in 2000, Flagship has originated and fostered more than 100 scientific ventures, operating with \$14 billion of assets under its direction as of its latest capital raise, announced in July 2024. The current Flagship ecosystem comprises more than 40 companies, including Foghorn Therapeutics, Generate Biomedicines, <a href="mailto:Ination Ination Inatio

ANNEX

PHOTOS AND ADDITIONAL INFORMATION FOR REPORTING

Photo 1: Left to right – Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, Health Sciences Authority and Lawrence Tallon, Chief Executive Officer, Medicines and Healthcare products Regulatory Agency



Photo 2: Left to right – Adjunct Professor (Dr) Raymond Chua, Chief Executive Officer, Health Sciences Authority and André Andonian, Chair of Asia Pacific and Strategic Advisor, Flagship Pioneering



Photo credit: Health Sciences Authority