

UK sets out world-leading pathway for space-manufactured drugs

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Patients could benefit from more effective, higher quality and longer lasting medicines as the UK sets out a clearer route to bring drugs manufactured in space safely to market.

The unique environment of microgravity, impossible to replicate on Earth, can improve how biologic drugs form, behave and work within the human body and have the potential to improve outcomes for people with cancer, rare diseases and other conditions by enhancing the quality, stability and performance of complex medicines.

To help turn these advances into real world treatments, UK companies developing medicines in space will now benefit from a coordinated package of measures announced today to support the rapid growth of in-orbit manufacturing. The measures will provide industry with greater regulatory clarity and a clearer pathway from research in orbit to patient access on Earth. As set out in the UK Government's £2 billion Life Sciences Sector Plan, these innovations could expand treatment options and improve outcomes across the health system.

Led by the UK Space Agency, with support from the Medicines and Healthcare products Regulatory Agency (MHRA), the Regulatory Innovation Office (RIO) within the Department for Science, Innovation and Technology (DSIT) and the Civil Aviation Authority (CAA), the package includes regulatory guidance, case studies, a regulatory sandbox and strengthened supply-chain engagement. By providing this clarity now, the UK is helping industry bring space-made medicines closer to patients.

Read the joint statement from the UK Space Agency, MHRA, RIO and CAA.

Space Minister Liz Lloyd said:

The UK is taking medical breakthroughs from orbit to patient - tackling the practical barriers that have held back commercial in-orbit manufacturing, from regulatory uncertainty to supply chain gaps.

Lord David Willetts, Chair of the UK Space Agency and Regulatory Innovation Office, said:

In-orbit manufacturing of pharmaceuticals represents a significant opportunity for the UK, combining the growth potential of our space sector with the promise of better treatments for patients.

The UK Space Agency is committed to supporting the companies pioneering this work, from microgravity platform providers to biotech and pharmaceutical firms. Setting out a clear adoption pathway with well-defined regulatory requirements gives investors and entrepreneurs the confidence they need to bring these innovations to market. The UK is open for business in space-enabled pharmaceuticals, with the ambition and capability to

lead globally.

The government is committed to advancing in-orbit servicing, assembly and manufacturing, having identified it as a priority capability area for UK leadership, growth, and national security.

The UK's regulatory environment is already well suited to innovative models of pharmaceutical production and spaceflight operations. Demonstration missions such as Space Forge's ForgeStar 1 and Astroscale UK's ELSA-D have positioned the UK at the forefront of licensing novel space technologies, proving that in-orbit manufacturing is no longer speculative. The UK Space Agency is also investing in early-stage development projects such as the £250,000 feasibility study for BioOrbit, a pioneering start-up that is exploring a scalable system for crystallising biologic drugs in space to enable at-home cancer treatments.

To support continued growth, the government are developing new guidance products, launching a Re-entry Regulatory Sandbox, and progressing work to streamline licensing for higher-cadence in-orbit operations.

Credit: BioOrbit

Rosemary Whitbread, Head of Space Regulation Policy at the UK Civil Aviation Authority, said:

Space manufacturing unlocks cutting-edge products that simply can't be made here on Earth.

As the UK space regulator, we play a key role in enabling these groundbreaking innovations, which have the potential to deliver real health benefits and drive economic growth.

We are confident that in-space manufacturing can be licensed under the UK's current rules, as long as companies go through the normal approval steps, ensuring that these ideas and innovations take shape, safely, securely and sustainably.

To support innovators directly, the UK Space Agency and Innovation Accelerator team at MHRA are preparing principles-based case studies that will outline clear regulatory routes for space, biotech and pharmaceutical companies.

Dr Paul Bate, CEO of the UK Space Agency, said:

Our investment in innovative projects is matched by focused work through our Unlocking Space Portfolio to connect space companies with the pharmaceutical sector and public health partners. We want to ensure that promising microgravity research doesn't stall at the experimental stage but progresses towards treatments that improve people's lives.

This is about turning the UK's strengths in space and life sciences into a competitive advantage that delivers for patients and for growth.

Building on the MHRA's experience in developing innovative and proportionate regulatory pathways, including the MHRA's world-first framework for decentralised and modular manufacturing launched in 2025, the Agency works closely with developers and partners to ensure that existing and future regulations remain fit for purpose for medicines manufactured using advanced and novel manufacturing approaches. This includes manufacturing that may take place in microgravity or other unique environments, where modular manufacturing and atypical distribution practices may occur.

Lawrence Tallon, CEO at the Medicines and Healthcare products Regulatory Agency said:

The UK is well placed to enable safe, cutting-edge innovation in space-enabled biomanufacturing. Our existing medicines regulations already support advanced and novel manufacturing approaches, including those that take advantage of microgravity.

Through joint case studies and early scientific and regulatory advice, the MHRA is helping to shape a clear pathway from in-orbit manufacture to patient access - supporting innovation while maintaining the highest standards of safety, quality and patient protection.

I encourage developers to engage with us early, through our Scientific and Regulatory Advice services and the MHRA Innovation Accelerator, so we can help them navigate regulatory expectations and bring safe, effective space-enabled medicines closer to patients.

Dr Katie King, CEO of BioOrbit said:

BioOrbit is pioneering the future of medicine in space, unlocking advanced therapies that directly benefit UK patients and support the NHS.

The UK Government's commitment today sends a clear signal: Britain isn't watching from the sidelines, we're leading it. BioOrbit is proud to be driving that mission - from orbit to patient, faster than anyone thought possible. These initiatives will help build a stronger pipeline of innovation, support new jobs and investment, and ensure the UK remains a world-leading destination for life sciences and advanced space technologies. This is a long-term effort to ensure that breakthroughs made in space translate into better, faster and more effective medicines for people on Earth.

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