

UK and US deepen regulatory cooperation on medical devices, building on wider pharmaceutical partnership

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- The announcement builds on today's wider US-UK pharmaceutical partnership, which removes tariffs on UK medicines exports and encourages companies to launch new treatments in the UK.
- Closer US-UK regulatory collaboration supports the UK's global life sciences leadership, reducing duplication for innovators while maintaining world-class safety standards.

The Medicines and Healthcare products Regulatory Agency (MHRA) is stepping up its collaboration with the US Food and Drug Administration (FDA) to support faster access to safe and innovative medical technologies in the future for patients in both countries.

Today's US-UK pharmaceutical partnership further strengthens this collaboration while also removing tariffs on UK medicines exports and encourages companies to bring cutting edge treatments to the UK earlier.

The MHRA and FDA will work closely on options to improve and align regulations for medical devices. This includes exploring future mutual recognition mechanisms (ways to recognise parts of the individual approval processes), reducing duplication for manufacturers and streamlining approval processes to help patients access new medical technologies sooner.

Both regulators' work will remain independent and ensure strict safety standards are maintained.

Health Innovation and Safety Minister, Dr Zubir Ahmed, said:

"Closer working between the UK and the US means that future innovative medical technologies – better diagnostics, smarter devices, life-changing treatments – can reach NHS patients sooner, without compromising on the safety standards we rightly expect.

"This is the correct next step. We've already acted to secure improved access to life-changing medicines for NHS patients. Now we're working to make sure the devices and technologies that go alongside them follow the same path.

"The UK is serious about being one of the best places in the world to develop and launch health

innovations - and this partnership shows exactly what that commitment looks like in practice.”

UK Science Minister Lord Vallance said:

“The UK’s MedTech sector employs over 195,000 people and leads the way on innovative and important technologies that help us lead healthy, longer lives.

“The MHRA is a global leader in regulation and this partnership with the US will strengthen this further, providing faster access to safe and innovative medical devices in both our countries.”

Lawrence Tallon, MHRA Chief Executive, said:

“This marks an exciting moment for UK innovation. By strengthening our working relationship with the FDA, we are allowing cutting edge medical technologies to reach patients faster and more efficiently than ever before.

“This is exactly the kind of partnership that enables the UK to stay at the forefront of global life sciences.

“Importantly, this is just the beginning, and I am looking forward to building on the growing US-UK collaboration as we continue to strengthen our shared commitment to safe, high-quality innovation for patients.”

Working closely with trusted global regulators is a key part of MHRA’s ambition to ensure the UK remains world leading in life sciences research, development, and launching innovative new products. This will give companies clearer, more predictable processes and help patients access safe, new technologies sooner, complementing the economic and health benefits delivered through the wider US-UK partnership.

Technical work between the MHRA and FDA will continue over the coming months to assess opportunities for closer alignment and explore where future mutual recognition mechanisms may be appropriate.

Any future arrangements will continue to meet the UK’s stringent statutory requirements for safety, quality, and effectiveness.

Peter Ellingworth, ABHI Chief Executive, said:

“Closer cooperation between the MHRA and FDA is a positive step towards reducing regulatory duplication and accelerating patient access to HealthTech that saves and enhances lives. For UK businesses, greater alignment between two of the world’s leading regulators will provide more predictable pathways and support faster routes to market, while maintaining the highest standards of safety and performance.

“It will also strengthen the UK’s position as an attractive launch market for investment, ultimately ensuring patients in both the UK and US benefit earlier from global innovation. ABHI has long advocated for this approach and is committed to supporting its delivery.”

Julian David, techUK Chief Executive, said:

“This commitment by the MHRA and FDA to deepen regulatory cooperation is an important step forward for patients and for the UK’s health sector. Greater alignment between trusted regulators will give innovators clearer, more predictable pathways and help ensure that safe, cutting-edge

technologies reach patients more quickly.

“techUK has long called for smarter, internationally connected regulation, and this announcement shows real momentum toward reducing duplication while maintaining the highest standards of safety and effectiveness. Closer cooperation will be especially valuable for UK innovators and SMEs, helping them navigate regulatory requirements more effectively and bring breakthrough products to market faster.

“We look forward to working with both regulators, industry, and the wider health system to help realise the benefits of this approach and strengthen the UK’s position as a global leader in medical technology.”

Notes to editors:

- The 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.
- The MHRA is an executive agency of the Department of Health and Social Care.
- The US Food and Drug Administration (FDA) is responsible for protecting public health in the United States by ensuring the safety, efficacy and security of human and veterinary medicines, biological products, and medical devices.
- For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

<https://www.gov.uk/government/news/uk-and-us-deepen-regulatory-cooperation-on-medical-devices-building-on-wider-pharmaceutical-partnership>