

Lawrence Tallon  
Chief Executive  
Medicines and Healthcare products Regulatory Agency  
10 South Colonnade  
Canary Wharf  
London  
E14 4PU

6<sup>th</sup> June 2025

Dear Lawrence,

We are writing as members of the UK MedTech Forum to acknowledge, support and comment on the MHRA's ongoing efforts to protect patients, promote innovation, and improve market access through regulatory reform. The sector shares the MHRA's aim of developing a regulatory framework that improves outcomes for patients by ensuring safety and access to clinically proven technologies. To be effective, regulatory reform must also support the sustainable growth of the UK HealthTech industry, encourage investment in domestic innovation, and help maintain the UK's position as a globally competitive first-launch market.

We strongly believe that:

- Improved patient outcomes through safe and timely access to clinically proven technologies must be central to all regulatory processes.
- Regulation should be sustainable and efficient to attract investment and support UK-based research, development, and manufacturing.
- The UK should retain its global competitiveness by fostering a regulatory environment that is agile and conducive to innovation and early market access.

To support these aims, we urge the MHRA to prioritise the following measures:

***Recognition of EU CE-marked Devices***

We strongly recommend the introduction of an indefinite and near-automatic recognition mechanism for CE-marked devices certified under the EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) for the Great Britain market. This approach would:

- Avoid the duplicative premarket assessments such as those set out in the MHRA's consultation of November 2024 for devices already subject to rigorous evaluation under EU regulations;

- Reduce the regulatory burden and associated costs for manufacturers;
- Safeguard patient access to a wide range of safe, effective, and high-quality medical devices and diagnostics.

According to the 2024 ABHI/CPI Pulse Survey<sup>i</sup>, and MedTech Europe's 2024 Regulatory Survey<sup>ii</sup> there are growing concerns around regulatory costs and delays, which are affecting market viability and innovation pipelines across the UK and the EU. These findings highlight the importance of addressing systemic barriers to ensure continued access to innovation in the UK.

### ***Internationally Aligned Reliance Pathways***

We call for the establishment of a proportionate, streamlined, reliance-based pathway for premarket approvals from trusted international regulators, such as the US FDA, Health Canada and TGA, Australia. Such pathways should reflect international best practices, reduce unnecessary duplication, and ensure proportionate oversight - particularly for SMEs and novel technologies, including software and AI-driven medical devices and IVDs. Regulatory agility is essential to enable rapid, safe access to innovation without compromising standards.

We encourage the MHRA to accelerate implementation of alternative routes to market, including recognition and reliance models, as outlined in its 2022 consultation and reinforced in the 2023 Spring Budget. The UK HealthTech sector stands ready to engage fully in co-developing and piloting these new regulatory mechanisms.

The MHRA's membership of the IMDRF represents a valuable opportunity for the UK to take a leadership role in international harmonisation, and in doing so work to support patient safety, data exchange and market access for both new and proven healthtech products globally.

We appreciate MHRA's leadership in this area and look forward as a sector to continuing to work together to co-create a framework that supports better patient outcomes and a thriving, globally competitive HealthTech ecosystem.

Yours sincerely,



Edmund Proffitt  
Chair, UK MedTech Forum

For and on behalf of:

**ABHI**

**AXREM**

**barema**

**BDIA**

**BIVDA**  
British In Vitro Diagnostics Association

**MEDILINK UK**

**PAGB**  
The Consumer Healthcare Association

Please could any response be addressed, in the first instance, to:

Edmund Proffitt

Chair, UK MedTech Forum and Chief Executive, BDIA

[edmundproffitt@bdia.org.uk](mailto:edmundproffitt@bdia.org.uk)

*The UK MedTech Forum is a group of UK-based membership organisations operating in the field of medtech. The Forum was established in 2015 and comprises medtech trade associations representing manufacturers of medical devices and in vitro diagnostic medical devices (IVDs).*

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<sup>i</sup> <https://www.abhi.org.uk/media/fvhmxbqi/2024-pulse-of-healthtech-survey.pdf>

<sup>ii</sup> <https://www.medtecheurope.org/resource-library/medtech-europe-2024-regulatory-survey-key-findings-and-insights>