



**HEALTHTECH REGULATIONS:
DRIVING ECONOMIC
GROWTH AND ENSURING
PATIENT SAFETY IN THE UK**

A FRAMEWORK FOR SAFETY, GROWTH AND GLOBAL LEADERSHIP

The HealthTech sector in the UK stands at the crossroads of economic opportunity and healthcare transformation. As of 2022, the sector comprised over 4,465 companies, employing approximately 154,000 individuals, and generating an annual turnover of £34.3 billion. HealthTech is a cornerstone of the UK economy, and at the same time, it develops medical technologies, devices and diagnostics that meet the highest standards of patient safety and performance.

The dual mandate of fostering economic growth while protecting patient safety, as outlined in the Medicines and Medical Devices Act, requires a regulatory framework that is not only robust but also dynamic and forward-looking. This framework must address evolving healthcare needs, encourage innovation, and streamline market access to ensure the UK remains a global leader in HealthTech. Innovation is the lifeblood of the HealthTech sector, driving advancements that save lives and improve quality of care. However, new technologies can only make a difference when they are rapidly accessible to patients. The UK regulatory framework must bridge the gap between development and adoption, ensuring that life-saving innovations reach patients without unnecessary delay.

This can include **conditional approvals** that allow early access based on preliminary evidence, with ongoing monitoring to ensure continued safety and effectiveness. MHRA's Innovative Devices Access Pathway (IDAP) goes some way to address this need, though currently only eight products are being assessed within IDAP and there is no new round of applications in sight. To have real impact, IDAP must be more ambitious in how many products are assessed.

Proactive engagement between regulators and innovators is another critical component. Early and transparent dialogue ensures that developers understand compliance requirements, reducing the risk of delays or costly redesigns. Initiatives like regulatory sandboxes - where new technologies are tested in controlled environments - offer a structured, yet flexible approach to fostering innovation. MHRA's AI sandbox is a good example of this where five products have been put forward for the sandbox. In the future this will need to be extended to bring in additional innovative technologies that show promise in the early diagnosis and treatment of clinical conditions.

By prioritising early patient access, the UK regulatory framework can improve health outcomes and enhance the global competitiveness of the HealthTech sector in the UK. Early adoption of innovative technologies establishes the UK as a preferred market for launching new products, attracting investment and bolstering economic growth.

In vitro diagnostics (IVDs) play a pivotal role in modern healthcare by enabling early detection, diagnosis, and monitoring of diseases. The global IVD market is rapidly expanding, driven by advances in precision medicine and increasing demand for personalised healthcare solutions. For the UK to remain competitive in this space, it is essential for MHRA to implement a specific, forward-looking plan for IVD regulation that fosters growth while maintaining rigorous safety and performance standards. Like the MHRA software roadmap, this plan should include support for IVD innovators including expedited pathways, clear guidance for manufacturers, and streamlined post-market surveillance systems. By doing so, MHRA can reduce time-to-market for groundbreaking diagnostics, attract investment from leading IVD manufacturers, and position the UK as a global hub for diagnostic innovation. Furthermore, tailored IVD regulations will enable healthcare providers to adopt new technologies more quickly, improving patient outcomes and driving efficiency in the healthcare system. Without a robust and growth-oriented approach to IVD regulation, the UK risks falling behind in a competitive and innovation-driven global market.

In a post-Brexit landscape, **sovereign regulation coupled with international regulatory alignment** has become a cornerstone of market stability. Even with a forward-thinking UK-specific regulatory framework for innovation, the indefinite recognition of CE marking is a practical solution to ensuring seamless market access for HealthTech manufacturers in UK that avoids wasted duplication of effort.

CE marking, as a globally recognised and trusted regulatory system, signals that a HealthTech product meets rigorous safety and performance requirements. By continuing to accept CE-marked products, the UK provides manufacturers with clarity and continuity. Other manufactured products in the UK rely on this recognition to reduce the administrative burden and costs associated with duplicative conformity assessments. In the HealthTech sector this will free resources for innovation and expansion.

Indefinite CE marking recognition offers several advantages. It simplifies export processes for UK manufacturers targeting European markets, maintaining the UK's position as a key player in the global supply chain and it encourages international companies to continue investing in the UK market, knowing that their CE-marked products can be marketed without additional regulatory hurdles.

Following historical scares associated with the older EU directives, the UK was a key part of the push to ensure the new EU regulatory framework would be able to address these risks. The additional scrutiny under EU MDR and IVDR greatly reduces the risk of poor-quality products reaching patients and will therefore ensure that patient safety is not compromised under this approach. CE marking has now become a rigorous standard, underpinned by robust clinical evaluation and strengthened by new robust UK post-market surveillance requirements. By **recognising CE marking indefinitely**, the UK ensures that safety and performance are maintained while fostering an environment of regulatory efficiency.

HealthTech innovation is inherently global, with new devices often developed in markets such as the US, Australia, and Canada. These jurisdictions have robust regulatory systems, trusted worldwide for their rigorous evaluations and high safety standards. By **streamlining reliance on approvals from these markets**, the UK can create efficiencies, accelerate market access, and align with global best practices. As with the older EU systems, international regulatory frameworks are not without their past controversies. And as with the EU, continued strengthening of regulatory frameworks (particularly in the US) has reduced the risk of poor-quality products reaching patients.

Incorporating recognition and reliance models into the UK regulatory framework allows regulators to leverage assessments conducted by trusted counterparts. This does not mean a wholesale adoption of foreign decisions; rather, it entails recognising the robust methodologies and evaluations already completed, reducing unnecessary duplication. For instance, a device approved by the US Food and Drug Administration (FDA) or Australia's Therapeutic Goods Administration (TGA) could undergo a more focused UK review, concentrating only on market-specific considerations.

This strategy offers significant benefits. For manufacturers, it reduces time-to-market and associated costs, making the UK a more attractive destination for innovation and investment. For regulators, it enables resource optimisation, allowing greater focus on high-risk or novel technologies. For patients, it ensures faster access to safe and effective HealthTech.

Aligning with global best practices also strengthens the UK's reputation as a regulatory leader. By collaborating with trusted international counterparts at forums such as the International Medical Device Regulators Forum (IMDRF) and International Organization for Standardization (ISO), the UK contributes to the development of harmonised standards, facilitating the global flow of HealthTech innovation.

Economic growth and patient safety are complementary. A regulatory framework that prioritises safety also establishes trust, which is essential for the adoption of new technologies. Patients, healthcare providers, and industry stakeholders all benefit from confidence in the safety, quality and performance of HealthTech.

Post-market surveillance is a critical component of this trust. By mandating new, robust and wide-ranging systems for monitoring device performance after commercialisation, the MHRA ensures that potential risks will be identified and mitigated promptly.

This not only protects patients but also enhances the reputation of UK HealthTech, driving global demand for UK products.

Clear reporting requirements for adverse events and safety incidents foster transparency and accountability among manufacturers. This culture of openness reassures both domestic and international markets that the UK takes patient safety seriously, strengthening its position as a leader in HealthTech innovation.

A CALL TO ACTION

The UK HealthTech sector has the potential to drive economic growth while delivering transformative healthcare solutions. Achieving this requires a regulatory framework that supports innovation, ensures market stability, and aligns with global standards while maintaining the highest levels of patient safety.

By fostering innovation and early patient access, recognising CE marking indefinitely, and streamlining reliance on trusted approvals, the UK can strike the perfect balance between economic opportunity and healthcare responsibility. Such a framework will not only secure the UK's position as a global HealthTech leader but also improve health outcomes for patients at home and abroad. As regulatory and industry leaders work together to shape this future, the UK HealthTech sector stands poised to thrive in an increasingly competitive global landscape.

Without an effective UK system supporting innovation and early patient access, without continued and indefinite recognition of CE marking, and with only a checkbox approach to international reliance, MHRA now risks the UK's position as a global HealthTech leader and also risks undermining improved health outcomes for patients. The UK HealthTech sector stands poised to address an increasingly competitive global landscape. MHRA now needs to do the same.



January 2025

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