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Medical Devices and In Vitro Diagnostics – Targeted Revision of EU Rules

The European Commission recently launched a call for evidence on a targeted revision of the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR). The initiative aims to improve the availability of safe and innovative devices, enhance EU competitiveness, and streamline regulatory requirements.

The deadline for feedback to the European Commission was Monday, 6 October 2025, and below is the ABHI response.

Public summary (max 4000 characters)

ABHI welcomes the European Commission's targeted evaluation of the Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR). Representing UK HealthTech manufacturers, developers and service providers across the UK, EU and global markets, ABHI's submission reflects collective member experience and highlights areas for targeted revision to support patient access, innovation and regulatory efficiency.

ABHI's comments cover general medical devices, IVDs, software and AI, addressing both sector-wide and sector-specific issues. The submission recognises the interconnectedness of regulatory frameworks for all HealthTech products.

ABHI supports the Commission's objectives to improve device availability and streamline regulatory requirements. The UK HealthTech sector is a key contributor to the European medical technology ecosystem, with UK companies manufacturing and supplying CE-marked devices and IVDs used across the EU. The MDR and IVDR frameworks directly affect patient access, clinical research and health system resilience in both the EU and UK.

Continued UK recognition of CE marking under MDR and IVDR maintains supply continuity and supports EU health system interoperability. ABHI encourages the Commission to facilitate international regulatory cooperation including recognition and reliance mechanisms and to ensure clinical and performance evidence can be used efficiently across jurisdictions. The UK's proposed indefinite recognition of CE marking is part of a broader international reliance strategy including routes for products approved in the US, Canada and Australia. Regulatory divergence risks duplicative compliance burdens and could undermine the global standing of CE certification.

ABHI members depend on frictionless cross-border movement of goods and services including testing, diagnostics and clinical support between the UK and EU. Changes to MDR and IVDR should consider operational realities, ensuring regulatory requirements do not disrupt supply chains, delay service delivery or create barriers to collaboration. Predictable and harmonised rules for device classification, documentation and post-market obligations are essential for access and competitiveness.

ABHI calls for risk-based and proportionate regulation, streamlined requirements for low-risk and legacy devices and platform-based certification for combination products. ABHI supports improved coordination and reduced duplication in clinical evidence generation including harmonised study approvals, ethics review and data collection. Recognising the role of medical devices, IVDs, software and AI within broader clinical research frameworks is important, as is integrated evidence generation and alignment with clinical trial regulations.

International recognition and reliance should reduce duplication, facilitate trade and improve patient access globally. The credibility and robustness of the CE marking system will influence UK recognition policies. Continued engagement with MHRA and EU stakeholders is essential to support regulatory coherence and ensure recognition and reliance mechanisms are robust and interoperable.

ABHI highlights the need for improvements in post-market activities including data sharing, coordinated market surveillance and streamlined vigilance reporting. Alignment with international data standards and digitalisation of data sharing and conformity assessment will help the EU and UK remain competitive and relevant.

ABHI looks forward to continued engagement with the European Commission and other stakeholders to ensure the regulatory framework supports innovation, patient safety and access to high-quality medical technologies across Europe.

Full ABHI Response to EU Call for Evidence

Introduction

ABHI welcomes the opportunity to contribute to the European Commission's targeted revision. As the representative body for the UK HealthTech industry, ABHI's membership includes manufacturers, developers, and service providers operating across the UK, EU, and global markets.

ABHI supports efforts to improve the functioning of MDR and IVDR, particularly where they enhance device availability, reduce regulatory burden, and support innovation. We encourage the Commission to consider how revisions can facilitate international regulatory cooperation, including recognition and reliance mechanisms, and ensure that clinical and performance evidence can be used efficiently across jurisdictions.

Strategic and Economic Relevance of UK HealthTech to the EU

The UK HealthTech sector is a significant contributor to the European medical technology ecosystem. ABHI members manufacture, supply, and support CE-marked medical devices and IVDs that are used by clinicians and patients across the EU. The EU's regulatory framework under MDR and IVDR therefore has direct implications for EU patient access, clinical research, and health system resilience.

According to the UK Office for Life Sciences, the UK exported £10.1 billion in medical technology products in 2023, with a substantial proportion destined for the EU. The UK ranks 11th globally for MedTech exports, and CE-marked devices originating from the UK are routinely used in EU hospitals and diagnostic services. These include essential technologies such as blood glucose monitors, HIV test kits, and self-test diagnostics, which support frontline care across Member States.

UK-based diagnostic services and clinical laboratories support EU patients through cross-border testing, interpretation, and data exchange. Disruption to CE recognition or regulatory misalignment could affect the availability of these services and delay access to critical diagnostics. The UK's continued recognition of CE marking under MDR and IVDR helps maintain supply continuity and supports EU health system interoperability.

The UK is a key partner in EU **clinical research**. UK institutions contribute to multistate clinical trials, particularly in oncology, rare diseases, and diagnostics. The UK government invests £1.6

billion annually in clinical research through the National Institute for Health and Care Research (NIHR), and the NHS receives an average of £26,311 per patient from commercial clinical studies. These collaborations generate shared evidence that supports CE marking and benefits EU patients.

The UK's proposed indefinite recognition of CE marking is part of a broader **international reliance strategy**, which includes routes for products approved in the US, Canada, and Australia. For EU stakeholders, this reinforces the importance of maintaining a credible and efficient CE framework. Regulatory divergence risks duplicative compliance burdens and could undermine the global standing of CE certification.

ABHI urges the European Commission to consider the strategic value of UK-EU regulatory cooperation. Revisions to MDR and IVDR should support mutual reliance, facilitate trade, and ensure that patients across Europe continue to benefit from safe, effective, and innovative technologies originating from the UK.

Cross-Border Movement of Goods and Services

Many ABHI members actively sell into the EU and rely on CE marking to access other jurisdictions that recognize CE certification, notably **Northern Ireland**. The CE mark remains a critical route to global markets for UK-based companies, and its continued credibility and efficiency are essential for maintaining access and competitiveness.

Beyond product sales, ABHI members also provide a range of services that depend on the cross-border movement of CE-marked medical devices and IVDs. These include **testing, diagnostics, and clinical support services** delivered between the UK and EU. The ability to move devices and associated components freely and predictably across borders is essential to maintaining service continuity and patient access.

Any changes to MDR and IVDR should take into account the operational realities of these cross-border activities. This includes ensuring that regulatory requirements do not inadvertently disrupt **supply chains**, delay **service delivery**, or create barriers to collaboration between UK- and EU-based institutions.

ABHI also notes the importance of regulatory predictability for **logistics and customs processes**. Clear and harmonized rules governing device classification, documentation, and post-market obligations can reduce administrative burden and support **smoother movement of goods and services**.

In the context of the UK's planned recognition of CE marking under MDR and IVDR, the EU's regulatory framework will continue to have direct implications for UK-based manufacturers and service providers. ABHI encourages the Commission to consider how revisions to MDR and IVDR can support interoperability, minimize friction at borders, and facilitate continued collaboration across jurisdictions.

Clinical Investigation and Performance Study

ABHI members generate clinical evidence in both the UK and EU to support CE marking and UKCA marking. This evidence underpins regulatory approvals and is essential for demonstrating safety, performance, and clinical benefit. It is increasingly important that regulatory frameworks support streamlined approaches to clinical investigations and performance studies across jurisdictions.

This includes multistate clinical investigations for medical devices, performance studies for IVDs, and the use of MD/IVD products in clinical trials involving investigational medicinal products (CTIMPs). Fragmentation in regulatory requirements can lead to duplication, delays, and increased costs, which ultimately impact patient access and innovation.

ABHI supports efforts to improve coordination and reduce duplication in clinical evidence generation. The EU's targeted revision of MDR and IVDR should consider how to facilitate joint or harmonized approaches to study approvals, ethics review, and data collection.

In addition, ABHI notes the importance of recognizing the role of MDs and IVDs within broader clinical research frameworks. Devices are increasingly used in combination with medicinal products or as part of complex diagnostic pathways. Regulatory systems should support integrated approaches to evidence generation, including alignment with clinical trial regulations and recognition of shared data standards. This is particularly relevant in the context of 'Project COMBINE', which aims to streamline clinical investigation and performance study processes across Member States. ABHI welcomes initiatives that promote regulatory efficiency and interoperability, and encourages the Commission to build on COMBINE's outputs to support practical implementation.

Efforts to harmonize requirements and enable mutual recognition of clinical data would support international reliance strategies and reduce barriers to market access. ABHI encourages the Commission to consider how revisions to MDR and IVDR can facilitate these outcomes and ensure that clinical evidence can be used efficiently across jurisdictions.

ABHI supports harmonized and efficient approaches to evidence generation, including exemptions for low-risk studies (such as standard venipuncture or capillary sampling) and reduction of duplication in documentation and reporting.

Proportionate oversight for low-risk IVD studies should be considered, including exemptions for studies involving only **standard venipuncture or capillary blood sampling**, when approved by an ethics committee and conducted within normal diagnostic parameters.

ABHI recognizes the essential role of specialized laboratory services in supporting patient care and safety through clinical studies. To ensure that patients benefit from timely access to high-quality diagnostics and digital health solutions, it is important that the regulatory framework enables proportionate, risk-based pathways for in vitro diagnostics (IVDs) and software used in clinical study settings. ABHI supports further dialogue on how best to facilitate the development and use of non-commercialized, study-specific IVDs and software by qualified laboratories, while maintaining robust standards of quality and patient care.

UK Recognition of CE Marking

The UK's Medicines and Healthcare products Regulatory Agency (MHRA) has confirmed its intention to consult on indefinite recognition of CE marking under MDR and IVDR, as part of a broader international reliance strategy. This strategy also includes additional routes to market for products approved in the US, Australia, and Canada, alongside UK-specific pathways.

ABHI supports international recognition and reliance as mechanisms to reduce duplication, facilitate trade, and improve patient access globally. The EU's revision of MDR and IVDR is therefore directly relevant to UK stakeholders, as the credibility, efficiency, and robustness of the CE marking system will influence the scope and implementation of UK recognition policies.

For UK-based manufacturers, continued recognition of CE marking offers a pragmatic route to market and supports trade with **Northern Ireland**, the EU, and other jurisdictions that accept CE certification. At the same time, the UK must ensure that its regulatory system remains attractive for innovation and investment. This requires careful balancing of domestic priorities with international cooperation.

ABHI encourages the European Commission to consider how revisions to MDR and IVDR can reinforce the reliability and global standing of CE marking, thereby supporting recognition strategies in third countries. This includes ensuring that post-market systems, clinical evidence requirements, and conformity assessment processes remain proportionate and predictable.

ABHI will continue to engage with MHRA and EU stakeholders to support regulatory coherence and ensure that recognition and reliance mechanisms are underpinned by robust and interoperable frameworks.

ABHI supports global harmonization and reliance mechanisms, including acceptance of international audits, evidence, and real-world data.

Post-Market Activities

ABHI members are actively engaged in post-market activities across the UK and EU, including vigilance reporting, market surveillance, and data-driven performance monitoring. These activities are essential for ensuring patient safety, maintaining regulatory compliance, and supporting continuous improvement of medical devices and IVDs.

The targeted revision of MDR and IVDR presents an opportunity to strengthen coordination in post-market oversight. ABHI encourages the Commission to consider the following areas:

- **Data sharing and interoperability**: Improved mechanisms for sharing post-market data between national competent authorities, notified bodies, and manufacturers could enhance responsiveness and reduce duplication.
- **Coordinated market surveillance**: A more structured approach to joint surveillance activities across Member States could improve efficiency and reduce burden on manufacturers operating in multiple jurisdictions.
- **Vigilance and user-reporting**: Streamlining vigilance reporting requirements and enabling more effective user-reporting mechanisms would support early signal detection and improve post-market safety outcomes. Harmonization with global reporting formats (e.g., IMDRF codes) should be considered.

ABHI supports efforts to make post-market systems more proportionate, predictable, and interoperable. These improvements would benefit manufacturers, regulators, and patients, and could also support the UK's recognition of CE marking by reinforcing the robustness of EU post-market oversight.

System Interoperability

Alignment with international data standards will support global regulatory cooperation. Digitalization of data sharing and conformity assessment processes will help the EU and UK to stay competitive and relevant.

Enabling the use of multiple device classification and nomenclature systems that meet minimum interoperability criteria would support regulatory alignment and facilitate more effective surveillance and reporting.

Conformity Assessment

Predictable, consistent, and transparent Notified Body processes are essential. ABHI supports binding timelines, annual performance reporting, and standardized documentation requirements for Notified Bodies. Guidance on addressing deficiencies and harmonization of administrative forms would further reduce burden and improve consistency. Standardization of forms and processes for technical documentation submission is recommended to reduce unnecessary administrative burden.

ABHI supports differentiated compliance pathways based on device risk, with **streamlined requirements for low-risk and legacy devices**. **Platform-based certification** for combination products should be enabled, reducing unnecessary reassessment where underlying technologies remain unchanged.

Some Sector-Specific Issues – IVDs and AI/software

The principles and recommendations outlined above—including those on regulatory cooperation, risk-based approaches, evidence generation, post-market activities, and conformity assessment—apply across all sectors, including IVDs and software. The following comments are specific to these sectors and should be read in conjunction with the broader recommendations already set out.

For IVDs, in addition to the general points on risk-based and proportionate regulation, evidence generation, and post-market activities, there are particular challenges around documentation requirements—especially for Class C and D devices. These requirements should be streamlined, with exemptions available for certain studies and reduced SSP requirements where appropriate, to avoid unnecessary duplication and cost. It is also important to establish distinct documentation standards for analytical and clinical performance studies, recognising their different endpoints and methodologies.

For software and AI, the general principles of harmonisation, reliance, and proportionate oversight are especially relevant given the rapid pace of technological change. ABHI supports the development of harmonised frameworks for software as a medical device (SaMD) and artificial intelligence, including adaptive oversight models for AI/ML (such as predetermined change control plans). Alignment with IMDRF and FDA approaches is encouraged, alongside cybersecurity requirements mapped to international standards (for example, IEC 81001-5-1 and FDA Cyber 2023). A dedicated framework for SaMD and AI should be considered to support consistent regulation of rapidly evolving software and digital health technologies.

These sector-specific comments are intended to supplement, not replace, the general recommendations above, and highlight areas where additional clarity or flexibility may be needed to ensure effective and proportionate regulation for IVDs and software.