MHRA targeted consultation on the indefinite recognition of CE-marked medical devices

Consultation response submitted by The Health Tech Alliance

Proposal 1: ***Do you agree with proposal 1, which would extend the current transitional arrangements for devices that comply with the EU Medical Device Directive to align with the transitional timelines published by the EU?***

Answer: **Yes**

The HTA supports the proposal to extend the current GB transitional arrangements for devices that comply with the EU Medical Devices Directive (MDD) so that they align with the EU timelines, allowing eligible MDD-compliant devices to be placed on the GB market until 31st December 2028, and to update these timelines in future if the EU makes further adjustments. We consider this alignment important to prevent avoidable disruption to the supply of established devices and to provide greater predictability for manufacturers and the NHS.

From our members' perspective, aligning GB and EU timelines will help avoid a situation where devices can still be lawfully placed on the EU and Northern Ireland markets under valid MDD certificates, but can no longer be placed on the GB market. This misalignment creates a risk of supply disruption for UK patients and services, and could lead to the withdrawal of certain legacy products from the UK, even if they are clinically important. In previous feedback to MHRA, the HTA noted that evolving and frequently changing UK-specific requirements can already contribute to delays in registrations and product launches; a consistent end date with the EU would reduce this risk rather than contribute to it.

From a practical perspective, many of our members plan regulatory strategies on a pan-European basis, centred on MDR and IVDR milestones. As a result, introducing earlier, GB-only cut-off dates for devices that are still acceptable in the EU adds complexity without a clear safety benefit, particularly given that these products have already been subject to conformity assessment under the MDD framework. For SMEs and suppliers of specialised devices, an earlier GB end date can be difficult to absorb and may influence decisions about whether to continue to serve the UK market.

An aligned transitional period would also provide the MHRA and UK Approved Bodies more time to implement the new UK framework in a more orderly way, while allowing industry to adapt systems, labelling and documentation without repeated changes. In our response to the MHRA Stakeholder Survey on Medicines and Medical Devices Legislation, HTA members called for streamlined, clearer regulation and a reduction in unnecessary administrative burden. A single, coherent transitional timetable across GB and the EU aligns with that objective, and should help maintain continuity of patient access across a period of wider regulatory reform.

Proposal 2: ***Do you agree with proposal 2, which would indefinitely recognise devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation?***

Answer: **Yes, for devices which would be classified the same or lower in GB**

The HTA supports the proposal to indefinitely recognise CE-marked devices that comply with the EU Medical Devices Regulation (MDR) and the EU In Vitro Diagnostic Medical Devices Regulation (IVDR), and we believe this recognition should apply to all device classes. We consider this as a key building block of the UK's emerging international reliance strategy and an important way to maintain continuity of supply, support innovation and avoid unnecessary duplication.

Our members view MDR and IVDR as robust regulatory frameworks that already provide a high level of assurance on safety, performance and post-market surveillance. Allowing CE-marked MDR/IVDR devices to be placed on the GB market indefinitely, subject to registration and UK post-market obligations, would help address several concerns from industry about the operation of the current regulatory system. HTA members have reported that evolving UKCA requirements, repeated changes to labelling and documentation, and a lack of recognition of international conformity assessments have all contributed to regulatory duplication, higher costs and, in some cases, the deprioritisation of the UK as a launch market. A stable, long-term commitment to CE-recognition under MDR/IVDR would provide greater predictability, allowing companies to plan using a single evidence package for both GB and EU markets.

From the perspective of the NHS, indefinite recognition would also protect patient access to a wide range of devices and IVDs and the resilience of UK health services; MHRA's own analysis had indicated that approximately 90% of devices currently on the GB market remain CE-marked. This approach to recognition would also reduce the gaps in device availability arising from regulatory divergence.

We recognise that MHRA has highlighted cases where a device's risk classification under MDR/IVDR differs from the GB classification rules. From our perspective, these differences can be managed within an indefinite recognition model by strengthening UK post-market surveillance and information-sharing, rather than by restricting recognition to only those devices with identical classifications. In addition, introducing a system that differentiates between devices on the basis of current differences in EU and GB classification risks creating further uncertainty over time as classification systems evolve, particularly given that the GB classification system and pre-market legislative framework are not yet finalised. The MHRA is already strengthening PMS expectations through the 2024 amendments, and these can be applied consistently to all devices on the GB market, whether UKCA- or CE-marked.

Overall, we favour indefinite recognition for all MDR/IVDR devices, supported by clear UK PMS and reporting requirements. However, if MHRA ultimately believes that additional UK pre-market scrutiny is required where GB classification is higher than in the EU, the HTA agrees that an international reliance route is an appropriate and proportionate way to manage this.

Proposal 3: ***Do you agree with proposal 3, which would introduce an international reliance route for devices that comply with the EU Medical Device Regulation and EU In Vitro Diagnostic Medical Device Regulation where the risk classification is higher under MDR 2002?***

Answer: **N/A**