U.S. Chamber of Commerce

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Response to the Consultation on Future Regulation of Medical Devices

The U.S. Chamber of Commerce ("Chamber") is the world's largest business organization. Our members range from small businesses and chambers of commerce across the United States that support their communities, to the leading industry associations and global corporations that innovate and solve for the world's challenges, to the emerging and fast-growing industries that are shaping the future.

The Chamber is a longtime advocate for strong commercial ties between the United States and the United Kingdom. We established the U.S.-UK Business Council in 2016 to help U.S. firms navigate regulatory and other challenges and opportunities arising post-Brexit as well as to represent the views of business as the UK charts a new path on global trade and economic issues. Today, more than 50 leading U.S. and UK firms are active members of the Council. Our Life Sciences Working Group is among the most active, bringing together the pharmaceutical and medical device industries to promote expanded trade and investment between our two markets.

According to a recent U.S. Chamber study, U.S. and UK companies have invested $1.35 trillion in each other's economies, directly creating nearly 2.8 million British and American jobs.[1] We are each other's single largest foreign investors, and the U.S. is the UK's largest trading partner.

The Chamber's U.S.-UK Business Council welcomes the opportunity to provide Her Majesty's Government with comments in response to the consultation on the UK's future approach to regulating medical devices. We welcome opportunities to discuss these and other matters with officials from the MHRA, BEIS, NHS, the British Embassy in Washington, and other UK Government agencies as these proposals are considered.

Following are a series of high-level principles that should guide policymakers as they consider reforms to the UK's medical device regulatory regime.

Introduction

The Chamber welcomes the UK Government's commitment to improved transparency, increased flexibility, and greater cooperation with the private sector and international counterparts as the regulatory framework for medical devices evolves.

[1] U.S. Chamber of Commerce, *The Transatlantic Economy 2021,* https://www.uschamber.com/report/the-transatlantic-economy-2021.

As we have seen throughout the COVID pandemic, medical devices are essential to preserving and protecting patient health, which in turn preserves the health of our economies.

The Chamber encourages the UK Government to: take a pragmatic approach that ensures patients continued access to best-in-class, leading edge devices; provide sufficient transition periods for manufacturers to meet new requirements; establish multiple pathways to regulatory approval; and avoid the imposition of unnecessary new or divergent regulations wherever possible. In so doing, the UK will maintain—and indeed strengthen—its global position as a hub for innovation and life sciences R&D.

Provide for Reasonable Transition Periods

Since a new regulatory system has not yet been outlined, the Chamber is concerned that a June 2023 implementation date is overly ambitious and could, however unintentionally, result in safe products that patients depend on being taken off the market. There is also considerable uncertainty about whether there will be a sufficient number of competent authorities ("Approved Bodies" or ABs) to reinspect and reauthorize the thousands of products already on the market and in use across the United Kingdom.

So far, only two UK ABs (BSI and SGS) are approved to assess medical devices' conformity with existing regulations, presaging a potentially enormous capacity constraint as the rules evolve. The UK has the same huge number of medical devices on the market as the EU, even as the latter's market is larger. The EU has over 20 approved notified bodies for medical devices. It is clear that the UK will need at least a similar number of ABs to support the rollout of its new regulatory system. A sufficient number of ABs must first be designated before manufacturers can realistically be asked to use the UKCA (UK Conformity Assessment) route to market.

We suggest that the UK adopt a transition period of five years after the publication of the new regulatory regime before requirements are imposed on manufacturers of medical devices. This is necessary both to adapt to any changes, as well as for the UK system to designate a sufficient number of ABs to inspect and verify the vast number of devices on the market.

A transition period of this length will help ensure patients continue to have access to life-saving devices they depend on. Lack of a sufficient transition period would also make it tougher for the NHS to make progress in tackling the large backlog of patients needing medical treatments. As our economies continue to fight the COVID pandemic, this is not the time to impose unreasonably fast deadlines on essential medical technologies.

Establish Multiple Pathways to Market

We support the MHRA's plans to base its future framework on existing international best practices from other markets such as the EU Medical Device Regulation (EU MDR), which the MHRA heavily influenced as it was being developed. We also welcome MHRA's intention to consider recognizing regulatory approvals from other leading regulators, including the U.S. Food and Drug Administration. Ideally, the new UK Conformity Assessment (UKCA) mark will bring an additional competitive advantage to the existing regulatory frameworks, providing for a streamlined route to market for products already approved by the FDA and/ or those already CE-marked.

Rather than creating an entirely new regulatory system for the sake of doing so, the MHRA has the opportunity to create a best in class system that recognizes approvals from other leading, trusted regulators for existing devices (subject to verification by UK authorities)—while also working with Approved Bodies and industry to streamline the regulatory process for new devices.

If the UK can strike that right balance, it will solidify the UK's position as a hub for innovation, investment, and research and development in leading edge medical technology. It will also help ensure that new products continue to be delivered to the UK market quickly.

This approach would disproportionately benefit small and medium-sized enterprises who may not have either the capital or the time necessary to seek new regulatory approvals in each market where they would like to operate from or export to.

Finally, against the backdrop of significant resource restrictions—both in terms of financial capital and talent—the MHRA should leverage its connections to and the expertise of its international partner regulators.

Take a Pragmatic Approach to Re-Labeling Products

One very tangible action the UK should consider taking is **imposing a moratorium on physical labeling requirements for existing products—and instead adopt an electronic labeling system for the UKCA.**

Physical labeling requirements would make it incredibly onerous for manufacturers to provide devices to the UK market in the case of an emergency or a spike in COVID-19 hospitalizations, for example. One can imagine a scenario where the UK suddenly has a need for a large number of new ventilators, or if the vaccine booster campaign necessitates a surge in imports of vials or needles. In either scenario, a requirement that each medical device be physically stamped with a new UKCA mark would delay or deter the shipment of new materials to the UK market in a timely manner. That outcome must be avoided. Of course, beyond COVID, people who suffer from myriad

noncommunicable diseases can't wait for their much-needed medical treatments either.

The UK showed a huge amount of regulatory flexibility over the course of the pandemic to ensure British patients received the best possible care. The Chamber feels strongly that new physical labeling requirements should not now be imposed to undermine that flexibility.

Finally, by adopting a new, streamlined, electronic labeling system, the UK could establish an international best practice for conformity assessment—delivering significant improvements on the EU's approach under the Medical Device Regulation. This would also be an added incentive for companies to seek initial regulatory approval for new devices in the UK market, via the electronic UKCA system.

Conclusion

Thank you for the consideration of our views. We look forward to further opportunities to provide input as these vital policies evolve and are implemented in the coming months.

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