Medicines & Healthcare products Regulatory Agency

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gov.uk/mhra

21 October 2022

Dear Sir/Madam,

Future regulation of medical devices – extension of standstill period

The future Medical Device regime is a substantial reform of the current framework. We are committed to ensuring that the future regime is robust and reflects the detail required to avoid disruption to supplies, support innovation and enable safe access to Medical Devices for UK patients. We are therefore putting in place a twelve-month extension to the current standstill period, aiming to bring the new regulations into force in July 2024. This will provide additional time to develop the legislation and support system readiness.

Under the World Trade Organisation (WTO) Technical Barriers to Trade (TBT) agreement, the MHRA is required to notify the WTO and the draft regulations will be published by the WTO for a period of at least 60 days for comment prior to the regulations being laid within Parliament. This will provide an opportunity to all our key stakeholders to review and comment on the draft legislation before it comes into force.

We continue to work on the development of the future regulations and are now taking the next steps to implement the transitional arrangements and post market surveillance requirements, as outlined in the Government response. For clarity, the timelines for the transitional arrangements will commence from when the new regulations come into force (i.e., July 2024). The MHRA aims to lay legislation within Spring 2023 to bring into force not only the transitional arrangements but also some post-market surveillance requirements. Bringing into force the new post-market surveillance requirements ahead of the wider future regulatory regime reflects the high priority assigned to patient safety in the future framework.

We also acknowledge concerns raised relating to capacity across the Approved Body system. There are currently four designated UKABs, with more in the pipeline. We are working proactively with six organisations who have applied to become UKABs, and several more who have expressed an interest in being designated, to enable them to achieve designation as swiftly as possible. We are taking a pragmatic, flexible approach where it is safe and proportionate to do so, whilst ensuring UK requirements are met. The extension of the standstill period will give more time for this work to progress. The UK remaining an

attractive place to develop and market medical devices is vital for UK patients and we are committed to delivering this through the future regime.

In all areas of our work, we are committed to prioritising and protecting patient safety. The future Medical Device regulations will enhance our ability to do that. We have also been delivering on a series of reforms to improve the overall framework such as the Software and Artificial Intelligence as Medical Device Change Programme Roadmap, launched in the last few days. We will continue to develop these reforms, working with partners across the system and industry stakeholders, including the development of guidance to support the interpretation of the future regulations.

We will be updating our guidance page shortly to reflect the changes.

I would like to thank you for your continued engagement and support on the development of the future Medical Device legislation.

For enquiries relating to the future regulations please contact innovativedevices@mhra.gov.uk

Yours sincerely,

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