Medicines and Healthcare products Regulatory Authority
10 South Colonnade
London
E14 4PU
United Kingdom

18 December 2024

By email only: futuredevicesregulations@mhra.gov.uk

Dear Sirs

Consultation on Medical Devices Regulations: Routes to market and in vitro diagnostic devices

We welcome the opportunity to provide comments on the Medicines and Healthcare products Regulatory Authority further consultation on medical devices regulation. We have commented only on those questions that are within our remit, which for the purposes of this letter focuses on patient safety and victims of defective medical devices. We also provide some general comments, which we hope you will find useful.

Alternative routes to market

While we do not have specific comments on the proposals relating to alternative routes to market and international reliance, we have noted previously that requiring manufacturers to comply with a separate set of regulations to bring products to the UK market will increase costs for those manufacturers which are likely to be passed on to consumers. Manufacturers may alternatively decide not to make a new product available in Great Britain at all (Northern Ireland will remain within the existing European regime), and instead only comply with the European regime, in order to keep costs down. Therefore, a separate regulatory regime for medical devices in Great Britain is likely to increase costs and reduce patients' access to new treatments and devices, reducing patient choice and potentially their access to safer products.

Alongside consideration of alternative routes to market, there should also be the introduction of a requirement for regulators to share information with other regulators. It is vital that regulators share information so that if a regulator in another country suspects that a device is defective, the UK regulator can be made aware of this and act accordingly.

Traceability

We are not in a position to comment on whether UDIs should replace UKCA marking on medical devices. However, on traceability, we would raise again, as we did in 2021, the importance of a central database for all medical devices, which can feed into specifically created registries for different devices which hold more detailed information on device safety and patient outcomes. Currently, registries are ad-hoc, niche and have often been created as the result of a catastrophe. Registries are effective methods of detecting defects, and in empowering patients to make choices, as they allow the public to see failure rates, for example, of a particular product. This is particularly important given the previous

Government's decision not to take forward the requirement that economic operators identify and record any lay person/user/patient/directly supplied with the medical device, given concerns about the workability of this requirement in practice. If lay persons/users/patients provided with the device are not identified, it is even more important that there is a central database relating to device safety and patient outcomes, to provide an opportunity for those lay persons/users/patients to identify if there are any issues with the device.

Assimilated EU Law

We would agree that the regulatory status quo should be maintained, and that the regulations should continue to apply in Great Britain until such time as they are replaced with updated UK law. We agree that allowing the regulations to expire would cause significant disruption and leave gaps in the current regulatory framework, and would have negative impacts on patient safety.

General comments

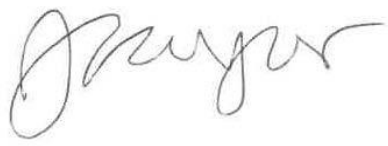
We would reiterate that a key focus of the MHRA should be patient safety. The framework agreement[1] between the Department of Health and Social Care and MHRA was last updated in April 2024. The four key strategic aims of the MHRA as listed in section 5 of the framework agreement do not explicitly include patient safety. Instead, the Agency is focused towards ensuring rapid access to products, and efficiency in its "business model". We propose that the MHRA's strategic aims are revised so that patient safety is the paramount consideration.

We also propose the Agency's strategies should adopt more of a precautionary approach to the avoidance of harms, not sacrificing patient safety for the goal of innovation.

There should be also consideration of how the MHRA operates, as highlighted in the *First Do No Harm* report, to enable it to become more public facing. There should be reform to ensure that the MHRA's work focuses on listening to patients' experiences and to the creation of registries and holding manufacturers to a higher standard.

We hope that our comments prove useful. If you would like to discuss anything in this response further, please contact Alice Taylor, alice.taylor@apil.org.uk, in the first instance.

Yours faithfully



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APIL

[1] https://www.gov.uk/government/publications/dh-and-mhra-framework-agreement/framework-agreement-between-dhsc-and-the-medicines-and-healthcare-products-regulatory-agency