July 29, 2022

Latest Post-Brexit UK regulatory development on medical devices and in vitro diagnostic medical devices: UK Government Response to the future UK regulatory framework

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On 26 June 2022, the Medicines and Healthcare products Regulatory Agency (the "MHRA") published the Government's response (the "Response") to the consultation on the future regulation of medical devices in the United Kingdom (the "Consultation"), which occurred at the end of 2021, reported in a previous Alert.

The Response highlights the two broad categories of changes proposed by the Consultation:

1. Regulations which are aimed at improving patient safety and safeguarding public health, by ensuring the quality of medical devices through regulatory oversight. These include the reclassification of certain products; the strengthening of post-market surveillance; and the expansion of the scope of the regime to cover non-medical (often cosmetic) products, which have a similar risk profile to medical devices.

2. Regulations which are aimed at increasing innovation in, and access to, medical devices. These include updates to the rules covering software and artificial intelligence as medical devices and the introduction of alternative routes to market, such as a pathway for 'Innovative MedTech', which would grant the MHRA additional powers to authorise initial market approval.

The Response recognises the need for the UK to be seen as a favourable place in which to carry out research relating to medical devices, develop medical devices and manufacture or supply medical devices. Many of the proposed changes broadly realign the UK with the EU regime, which was altered post-Brexit by the implementation of the EU Medical Devices Regulation (2017/745) and the In Vitro Diagnostics Regulation (2017/746). Indeed, the Response itself notes that the proposals align the UK with international best practice in areas where the existing regime was deficient. In general, divergence with the EU regime is where necessary for the protection of UK patients.

The respondents were generally positive about the changes proposed by the Consultation. When asked if the changes were proportionate, 67% said yes as opposed to 17% saying no, while 92% were positive as to the level of ambition on display. As such, the Response suggests only limited alterations to the initial proposals. However, there are some notable changes in approach. For example, in Chapter 11, the government decided against making changes in scope with respect to implantable devices, deeming that the products considered for regulation were either already within scope, or that there was no strong rationale for them to be so covered. There was also very strong support from respondents in certain areas such as a globally harmonised device identification and coding system allowing for unambiguous identification of devices on the UK market.

The Response approves of a staged transition to the new framework, which is planned to be adopted in 2023. Chapter 15 of the Response provides the details on this point. Devices which are either UK Conformity Assessed or CE marked may remain on the market until their certificates expire or for a period of three to five years (dependent on the type of product), whichever is sooner. This is provided in order that the devices are not subject to significant changes in design or intended purpose, and that all post-market requirements applicable for the product under the new regulations are complied with. Further, transitional provisions will apply to clinical investigations commencing prior to the new regulations taking effect, provided they comply with new reporting requirements.

Finally, the Response refers to two areas outside of the scope of the Consultation where we can anticipate future publication.

1. The Equity in Medical Devices Independent Review, established to review the extent and impact of potential ethnic and other unfair biases in the design and use of medical devices, is due to report by mid-2023. The MHRA have promised extensive guidance on how manufacturers can address issues that may be raised by the review.

2. Second, while the Response does discuss limited changes to the regulation of software and AI as a medical device, more detailed guidance, policy and standards are to follow, with the MHRA announcing a work programme on the topic. In addition, the UK Government published on 18 July 2022 a policy paper establishing a pro-innovation approach to regulating AI, which will be the subject of a separate Alert.