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The Medical Device Regulation, COVID-19 and Brexit

EU/UK – February 2020

Regulation 2020/561 (Regulation) was passed by the EU in April last year to take account of issues raised by the COVID-19 pandemic and to defer the date of application of certain provisions of Regulation 2017/745 (MDR) by one year.

The Regulation was published on 24 April 2020 through an EU accelerated procedure, and although the COVID-19 pandemic is still a major issue, the expiry of the one-year deferral is fast approaching.

The Regulation recognised that the COVID-19 outbreak and the associated public health crisis presented an unprecedented challenge to EU member states and constituted an immense burden for national authorities, health institutions, Union citizens and economic operators. Further, it recognised that the public health crisis created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices, that could not reasonably have been anticipated at the time of adoption of the MDR.

The Regulation effectively provided considerable regulatory easement for the medical device industry, notified bodies and EU regulators, and with a view to allow more directed action against the pandemic.

Importantly, the Regulation reduced the chances of shortages or delays in the supply of vitally important medical devices to the market due to the COVID-19 pandemic, and postponed the application of certain important provisions of the MDR from 26 May 2020 to 26 May 2021.

The Regulation amended the MDR by deferring the repeal of the current Medical Device Directives (Directive 90/385 and Directive 93/42), thus, ensuring the continuity of current conformity assessment procedures.

The Regulation also amended the MDR to defer requirements relating to the functionality of EUDAMED, which has impacts for manufacturers, importers and others in the medical device supply chain.

What Will Change Under MDR?

With the approaching expiry of the one-year deferral under the Regulation, focus is again shifting to what is required under MDR.

MDR impacts many aspects of medical device regulation, from development and the need for clinical evaluation, registration and oversight of Notified Bodies, to greater controls over actors in the supply chain and vigilance and market surveillance arrangements.

Much effort has already gone into plans for implementation of MDR, given the wide-ranging changes that will apply to manufacturers and Notified Bodies, and the need for development of new systems to carry out new processes.

Many provisions of the Regulation relate to product requirements, assessment procedures and certifications that will apply.

The 26 May 2021 date is important because certain products (e.g. certain aesthetic devices) that were not previously covered by EU medical device controls will need to comply with the new medical device regulations on this date.

Additionally, actors in the supply chain have enhanced obligations and these will apply to different types of operators, e.g. to importers, authorised representatives and distributors.

Brexit

Alongside the nearing of the deadline for application of major provisions of MDR, the UK ended the transition period for leaving the EU at 11 p.m. on 31 December 2020.

As widely reported, Northern Ireland will be operating within the EU regulatory regime under the Northern Ireland Protocol.

However, the UK Medicines and Healthcare products Regulatory Agency (MHRA) has indicated that for Great Britain (GB – the UK, without NI), MDR will fully apply in EU Member States from 26 May 2021. As these regulations did not take effect during the transition period in GB, they were not EU law automatically retained by the EU Withdrawal Agreement Act and will, therefore, not automatically apply in GB. This means that the provisions contained within the MDR will not be transposed into law in GB and will not be implemented in GB.

Having noted the above, the MHRA has indicated that for transition periods it will recognise EU certification.

The Practical Impact

Given the complexity of the MDR alongside the implementation rules, it is important that manufacturers and suppliers be aware of when new obligations will apply and carry out an analysis of how they sit with current product portfolios and products that are being developed or coming to market soon.

Capacity issues in the system are also a concern and planning around relevant support will be critical.

Other areas to consider are the possibility that further easements arise from in the EU and whether there is, in fact, any divergence in the application of regulatory rules across the UK going forward. The latter seems doubtful given that the UK has committed to align with the EU, at least in the short term, and the natural sense that applying aligned systems seems to make.

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