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NEW MEDICAL DEVICE REGULATIONS ADD BURDENS AND PRESSURES

The medical device landscape continues to evolve rapidly across the EU as we have seen in 2021 and 2022. There has been new EU legislation for medical devices and in vitro diagnostics (IVDs) to ensure that the myriad of innovative products placed on the EU market are effectively regulated. In addition, guidance documents are constantly being introduced and updated so that industry can better understand how to comply with the new rules.

Recent EU legislative changes have inevitably increased the regulatory burden on medical device companies, even though they are necessary to ensure the safety of end-users. With Notified Bodies being unable to keep up with demand, there have been delays in the supply chain. Concern is mounting across EU member states as to the availability of devices and the potential impact on patient health. Measures are now being taken to try to alleviate some of these pressures, but it is likely that challenges will remain in the EU throughout 2023 and beyond.

Although no longer in the EU, the UK has taken careful note of the challenges that are being faced by its European neighbours. The Medicines & Healthcare products Regulatory Agency (MHRA), the UK regulator for medical devices, has indicated that the introduction of new medical device legislation will be pushed back to July 2024. In addition, it will allow CE-marked devices to be placed on the UK market until 2024 in order to ease regulatory burdens and ensure adequate supply of medical devices in the UK.

EU compliance and Notified Bodies under pressure

The introduction of the new EU Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Devices Regulation (IVDR) in May 2021 and May 2022 respectively, significantly increased the demand for conformity assessments by EU Notified Bodies. With both new and existing devices needing to go through the conformity assessment procedure and only a limited number of EU Notified Bodies designated, demand for services has continued to significantly outweigh supply. Thousands of devices are awaiting conformity assessment and the industry has become increasingly frustrated that its products cannot reach the end-users that they were designed to assist. While these legislative measures were put in place to ensure the safety of patients, they are now effectively preventing some devices from being made available. This delay could have a negative impact on the health of EU citizens.

The phased roll-out of the IVDR will ease some of the pressure on Notified Bodies. However, EU regulators recognise that additional measures are needed to ensure that the new requirements do not hinder the medical device industry and patients are not adversely impacted. National regulators are being advised to be flexible in their approach, by allowing hybrid audits, engaging with manufacturers so that the conformity assessment process is more efficient and being proactive in providing support for small and mid-sized enterprises (SMEs) and those new to the application process.

In August 2022, the EU's Medical Device Coordination Group (MDCG) published a position paper on the significant challenges posed by the shortage of Notified Bodies and the increased requirement for conformity assessments. The paper recommends increasing Notified Body capacity, improving access to Notified Bodies and encouraging regulators to be flexible and pragmatic. If these steps are taken, it should help alleviate some of the regulatory burden, although it is likely that more action and guidance will still be needed to address the ongoing challenges.

UK proactively addressing new regulatory pressures

Post-Brexit, the regulation of medical devices in Great Britain fell out-of-step with the EU, since the new EU MDR and IVDR only apply in the EU and Northern Ireland. With the recognition that UK regulation needs to be brought into line with both EU and international requirements, the UK Government launched a Consultation in 2021 on the future regulation of medical devices.

The UK Government's response to the Consultation was published in June 2022. The medical device industry planned for the UK's new regulations to take effect in July 2023. However, given the significant issues that have been encountered in the EU, the new draft Medical Device Regulations will now be published in early 2023, with an expected implementation date of July 2024. Breathing space has also been provided for companies that currently market devices in the UK and the EU, as products that are validly CE-marked can now remain on the UK market until July 2024.

This delay until 2024 also provides an opportunity to designate more Approved Bodies, (the UK equivalent of EU Notified Bodies) to respond to increasing demand. Hopefully, this will allow the UK to avoid the conformity assessment bottleneck the EU has been experiencing. The good news is that the pool of Approved Bodies is growing in the UK. The MHRA recently confirmed that a fourth entity has joined the three current UK Approved Bodies and six more entities are currently seeking designation. These additional Approved Bodies will increase the UK's capacity to process conformity assessments for medical devices, although further designation will be needed to keep up with demand from industry.

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New guidance for borderlines products

Significant focus in the EU remains on the practical difficulties faced by industry in complying with the new MDR and IVDR. However, the EU continues to produce guidance to support the medical device industry in addressing regulatory compliance grey areas.

Borderline products continue to present difficult questions for industry and regulators and guidance documents can be extremely useful in providing reasoned direction for all parties. Borderline products in the present context are often those where it is unclear if they are medical devices or medicinal products. Borderline issues often arise with herbal products, substance-based devices and medical device and medicinal product combinations.

The Medical Device Coordination Group (MDCG) offered some clarity in this area in April 2022 with the MDCG 2022-5 Guidance on borderline between medical devices and medicinal products. In September 2022, a related manual and background note were published which are intended to complement the April 2022 Guidance. The manual offers classifications of more than 100 borderline products in more than nine product categories. The MDCG notes that the views expressed in the manual are not legally binding. It also cautions that it should only serve as a "tool" for the case-by-case application of community-legislation by the member-states.

Of course, these documents will evolve as the landscape of new and innovative devices continues to change and industry should keep abreast of new guidance as it becomes available.

Conclusion

As medical devices become more complex, legislators are striving to ensure the continued safety of patients by increased regulation. Increasing regulation has led to significant challenges for industry and Notified Bodies over the past year. However, with continued guidance and some flexibility by regulators, the industry should be able to continue to innovate and patients receive the devices that they need.