Winding down to the EU IVD and Medical Devices Regulations Deadlines: The Finish Lines in Sight?

26 November 2019 – Today marks the half-way point of the EU IVD Regulation's (IVDR) five-year transition period and the start of the final six months to the EU Medical Devices Regulation's (MDR) date of application.

The medical technology industry shares the Regulations' goals of patient safety and transparency and remains committed to doing all it can to comply with the new rules in due time.

However, despite the industry's efforts to get ready, we remain seriously held back by the slow and piecemeal implementation of the new regulatory framework.

As we have maintained throughout the Regulations' transition periods to-date, this incomplete implementation by the EU Member States and European Commission threatens the continuity of patient access and care, both in Europe and in the more than 100 countries around the world that rely on the EU CE marking of medical technologies.

MedTech Europe recognises and welcomes the increased political attention to the MDR in recent months, and the efforts of the European Commission and Member States to find solutions to that Regulation's transition challenges, especially the low availability and capacity of Notified Bodies.

While it is critical to maintain this political commitment to find pragmatic solutions to the MDR implementation, we also firmly believe that the EU is long overdue in devoting the same level of attention and energy to the IVD Regulation. The IVDR presents a considerable challenge since 85% of over 50,000 IVDs will need certification by Notified Bodies in the next 30 months (equal to more than 330 IVDs per week).

Although 2.5 years still remain until the IVDR's date of application, MedTech Europe is alarmed that only about ten organisations have applied so far to be Notified Bodies under that Regulation. Of these ten organisations, only two have received their license to operate (i.e., their 'notification') as Notified Bodies under the Regulation.

Given that the IVD Regulation brings an estimated eight-fold workload increase to IVD Notified Bodies, it is clear that the EU needs to start urgently and proactively addressing this situation if patients and healthcare systems are to retain access to diagnostic tests.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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