Implementing the new IVD and Medical Devices Regulations - Resourcing and Governance -

MedTech Europe urges the European Commission and Member States to invest additional resources needed to successfully implement the new *In Vitro* Diagnostic (IVD) Medical Devices and Medical Devices (MD) Regulations. The association also urges to clarify the new governance system under which guidance and secondary legislation will be developed and to ensure the early and meaningful involvement of stakeholders.

The new Regulations pose significant resource challenges for national competent authorities, designating authorities, and agencies, as well as for at least two Directorates-General of the European Commission**.** This investment will be vital in ensuring the timely availability of fit-for-purpose secondary legislation and guidelines, and to make an overall success of the tight transition timelines.

At the same time, early and genuine involvement of stakeholders will be essential when implementing the new system. Stakeholder involvement should not only be when approving the final draft guidance and secondary legislation, but also when conceiving and drafting these documents. By installing a consistent and transparent process, regulators can help ensure an implementation of the new Regulations that is feasible for all actors and that embraces the specificities of both the IVD and medical device sectors.

Resourcing

The proper implementation of any new regulatory regime requires sufficient investment of resources by all players, both in terms of capacity and expertise. It is not only the industry and notified bodies that require this investment in resources but all parties with obligations under the two Regulations. In light of the substantial workload on the near horizon, the industry is seeking reassurance that the European Commission and the authorities will allocate the necessary resources to implement the Regulations smoothly and on-time.

Authorities will need to invest in both the mechanical aspect, e.g. IT systems etc., and in having sufficient number of in-house staff with the necessary expertise to understand and apply both Regulations. This in-house expertise is essential to drafting appropriate secondary legislation and technical guidance, in collaboration with stakeholders.

With respect to the IVD Regulation in particular, MedTech Europe encourages Member States to invest in experts who are sufficiently familiar with IVD products and processes and who are empowered to appropriately implement the specific IVD regulatory framework. This would prevent the risk that principles or content is developed first for the MD Regulation and then inappropriately mirrored to the IVD Regulation.

Governance

In addition to sufficiently resourcing themselves for the new regulatory system, authorities are urged to clearly and transparently communicate the governance system currently being set up. The industry finds it critical to know who will draft the interpretative guidance and secondary legislation, on which topics it will cover, its expected timelines, and when stakeholders will be involved in this process. To this end, the European Commission should play a key role in not

only writing the secondary legislation but also the EU-level guidance. Finally, numerous experiences show the important benefit of consistently and substantially consulting stakeholders early-on.

As with all EU Regulations, we need to ensure a consistent interpretation and enforcement of the new rules across Europe. This requires full alignment on all crucial matters of interpretation ahead of the dates of application. While many points in the Regulations can be sufficiently addressed by a technical staff, complementary support from senior leadership in Ministries and/or Heads of Medicines Agencies is needed on the larger and more structural issues. This is the case for notified body designation, or contingency planning for a scenario where transition arrangements might prove unattainable.

About MedTech Europe

MedTech Europe is the European trade association representing the medical technology industries, from diagnosis to cure. Our members are multinational companies and national medical technology associations operating in Europe and worldwide.

There are more than 500,000 products, services and solutions currently made available by the medical technology industry. These range from bandages, blood tests and hearing aids to cancer screening tests, pacemakers and glucose monitors. Our sector employs more than 650,000 people. There are more than 26,000 medical technology companies in Europe, of which 95% are SMEs.

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