Implementing the New MD and IVD Regulations: Industry Calls for Solutions to Ensure Continuity of Care to Patients

The medical technology industry has significant concerns about the state of implementation of the new Medical Devices Regulation (MDR) and the new *In Vitro* Diagnostic Medical Devices Regulation (IVDR), which apply from May 2020 and May 2022 respectively.

The industry is calling urgently on the European Commission, the European Parliament and all EU Member States to provide solutions that will rapidly install the functionality of the new regulatory systems and thereby safeguard the continued availability of life-saving and life-transforming medical technology products.

Medical technology manufacturers are investing heavily to comply with the new regulations and will be ready to submit files to maintain the supply of over 500,000 medical technologies to patients and healthcare systems across Europe.

However, the industry's ability to keep products on the market beyond the 26 May 2020 and 26 May 2022 deadlines, could be seriously jeopardized by the slow progress in putting into place the critical infrastructure that will enable the new regulatory systems to work.

In the event of insufficient time between the establishment of the system and the (re-) certification of products before the dates of application, products will not be allowed on the market anymore. Consequently, they will be no longer available for patients and healthcare systems.

Essential Regulatory System Elements Must Be in Place Early On

The new regulations adopted in May 2017 include a three and five-year transition period for medical devices and IVDs respectively, allowing for the new regulatory systems to be set up early during the transition period.

Yet, there is slow progress achieved to date in putting in place the essential elements of these systems, including:

- **Notified Bodies**: these bodies need to be (re-)designated before they can assess and (re-)certify the compliance of medical devices (MDs) and *in vitro* diagnostics (IVDs) with the new regulations;
- **Implementing Acts**: after 14 months into the transition period, only 2 out of the 18 system-critical implementing acts (named as mandatory by the European Commission) have been published so far;

- **Expert Panels, Reference Laboratories, and Common Specifications**: these are essential for certain new products and high-risk devices to be CE marked to the regulations;
- **Standards and Guidelines**: these are needed for industry and other players to provide a common interpretation of how to correctly apply the new regulations;
- **Eudamed**: this new database for medical devices should be ready on time to strengthen market surveillance and transparency and to contribute to a uniform application of the regulations.

Industry depends on these elements being in place well before the compliance deadlines in order to be able to (re-) certify products under the new regulations on time. This is crucial to ensure the industry's ongoing ability to supply medical technology solutions to patients and healthcare systems.

Notified Body Capacity and Expertise: Aspects That Need Urgent Attention

Notified Bodies are responsible for assessing and (re-)certifying most MDs and IVDs for them to be placed on the European market. Both new regulations ask for even greater Notified Body obligation (e.g. new analysis of clinical benefit assessment) and for more products than ever before based on the new rules (e.g. up classifying of medical devices and new oversight of more than 35.000 IVDs).

A fully-functioning Notified Body system is needed early on, with sufficient capacity to manage the workload under the current and future regulatory framework in a timely manner.

As of today, our assessment is that Notified Body availability with needed expertise and sufficient capacity cannot be ensured early enough and hence an urgent solution is needed.

In this regard, the industry has four main areas of concern:

- **Can (re-)designation happen in time?** There has been no 'big bang' in applications by current Notified Bodies to be (re-)designated under the new regulations. At the same time, the (re-)designation process will take 18 months on average per Notified Body.

- **Can Notified Bodies get enough resources and expertise?** Already today there are limited resources and expertise available for Notified Bodies to recruit and train personnel in order to sufficiently address the new requirements of the regulations.

- **Can Notified Bodies handle the workload in the time left between the moment they are (re-)designated and the end of the transition periods,** knowing that (re-)certification is required for:

- Products already on the market today;
- Products on the market that will need Notified Body oversight for the first time, e.g. *85% of all IVDs, numerous reusable devices for routine surgery or software like mobile apps etc.;*
- Products that are new and innovative.

All these products will need (re-)certification to the new rules to be allowed on the market.

- **How will Brexit impact the current transition process?** Currently, between 30 - 40% of medical technologies in the EU are (re-)certified via UK Notified Bodies. With the event of Brexit, it is uncertain if these Notified Bodies will continue to operate in the EU or if their capacity will need to be transferred to an EU Notified Body. At the same time, it also remains uncertain if the certificates of these 30-40% of products will continue to be valid in the EU.

The 'Grace Period' Is Not a Solution for Avoiding (Re-)Certification Bottlenecks

Both regulations provide certain existing products with a 'grace period' ending on 26 May 2024. The grace period allows for certain devices to be placed on the market with a valid certificate issued under the medical devices directives beyond the end of the transition periods. However, this mechanism is not seen as providing a system-wide solution for three reasons:

1. Certificates based on the current directives must still be renewed **before** 26 May 2020 (for MDs) and **before** 26 May 2022 (for IVDs). This creates an enormous increase in demand for renewals of certificates under the directives. Notified Bodies must manage these renewals at the same time as they are handling other key obligations like:
   - their (re-)designation to the new regulations
   - (re-)certification of products to the new regulations

2. There is no 'grace period' option for product categories which have no Notified Body certificate under the current directives and which due to the upgraded mechanism will now require a Notified Body for the first time.

3. For the 'grace period' to work Notified Bodies must have sufficient capacity and resources to handle such an increase in demand.

Call for Action

MedTech Europe is calling on the European Commission, European Parliament and all EU Member States, to have an urgent discussion of solutions that will ensure that there is appropriate time for the systems to be ready to function. The industry calls for:

- **Actions to address challenges on the transition timing**
  Industry envisages at least three options to be explored either alone or in combination:
  a) A 'stop the clock' mechanism, that freezes the remaining transition time for both regulations until full readiness of the system has been achieved;
  b) An extension of the critical dates of 26 May 2020 and 26 May 2022, for all products;
  c) An extension of the critical dates of 26 May 2020 and 26 May 2022, for legacy products only.

  Options b) and c) would require a specific timeline to be agreed upon.

- **Actions to make the 'grace period' an effective instrument and overcome the bottlenecks**
  These could include, for example:
  a) Extending its scope to include all products and particularly the legacy products;
  b) Having a more feasible and flexible timing.

MedTech Europe is ready to cooperate with the EU institutions and all affected stakeholders to identify and deliver an optimal way forward. We urge all concerned parties in the strongest possible terms to act now, in the interest of patients and industry alike.

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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 675,000 people. There are more than 27,000 medical technology companies in Europe, of which 95% are SMEs.

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