Implementing the new IVD and Medical Devices Regulations - Early availability & capacity of notified bodies -

MedTech Europe urgently calls on the European Commission and the Member States to ensure the availability of notified bodies designated under the *In Vitro* Diagnostic (IVD) Medical Devices Regulation and the Medical Devices (MD) Regulation early in the transition periods. A fully-functioning notified body system, with sufficient capacity to manage the workload under the current and future regulatory framework in a timely manner, is vital in ensuring that patients, hospitals, laboratories and healthcare systems have continued access to safe and innovative medical technologies.

The medical technologies industry concerns are threefold:

(1) The additional expertise and capacity that notified bodies need to invest in order to sufficiently address the new requirements of the two Regulations,

(2) The time and capacity needed at authority level to designate new and existing notified bodies under the Regulations, and

(3) The time and capacity needed for notified bodies to complete all necessary certifications of:
   a. products having notified body oversight for the first time, e.g. most IVDs;
   b. products already on the market today needing recertification to the new rules;
   c. new and innovative products in the pipeline to be certified for the first time.

In sum, the industry is concerned that based on the current investment of resources, notified bodies will not be available and be able to certify the vast number of products early enough in the allotted transition period.

One critical element to unlock the bottlenecks is to ensure that there is a sufficient number of available auditors at the authority level for the joint assessment of notified bodies. It is also important to guarantee that there is a necessary number of experts within the notified bodies staff that can complete the certification procedures on time.

For both the IVD sector and MD sector, ensuring the timely readiness of a fully functioning notified body system is essential.

For IVDs, the regulatory framework is fundamentally changing. Not only will more IVDs be in the scope of the new Regulation; there are also many new and strengthened requirements to be met. Moreover, ~85% of all IVDs will require notified body oversight for the first time. IVDs therefore need to be worked on as equal priority to MDs. The designation of notified bodies under the IVD Regulation must happen simultaneously to the designation of notified bodies under the MD Regulation and should not be postponed due to the IVD Regulation's later date of application.

For medical devices, there are already notified body capacity issues today. Due to more stringent requirements under the new MD Regulation, these capacity issues are set to increase. Given the tight transition deadline, and to avoid any disruption in the supply of MDs to the market, sufficient notified body capacity must be ensured early on. This becomes even more critical when existing notified bodies are judged 'unfit' for designation under the new rules, because their workload would need to be absorbed by remaining notified bodies. If this cannot happen quickly, the certification process will be delayed and the supply of products will be at risk of being disrupted.

For the above reasons, it is essential that a robust notified body system be in place. At this point in time, the industry needs, above all, a much greater ambition and clarity from authorities on the notified body designation process. An action plan with prioritisation, clear deadlines, and training plans for auditors is required. It is only through this that product certification can start in time and finish by the end of the transition periods. The ultimate goal is to prevent any disruption to the availability of needed medical technologies to patients and healthcare systems in times of regulatory transition.

Please also see the Annex, enclosed.

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.

For more information, please contact:

- Oliver Bisazza, Director - Regulations and Industrial Policy (o.bisazza@medtecheurope.org)
- Valentina Ancona, Senior Manager - External Affairs (v.ancona@medtecheurope.org)

Annex: Overview of the Data

MedTech Europe believes the below figures demonstrate the **urgent need for the timely availability of notified bodies that are designated under the new Regulations and that have sufficient capacity to manage the significant workload within the transition periods** for IVDs and MDs:

IVDs	MDs
• **Over 95% of the IVD and MD sector is made up of SMEs[1]. These enterprises will rely on effective notified body support and capacity during a critical time of change.**	
• Around 90% of devices are self-certified under the IVD Directive[2]. Under the IVD Regulation, ~**85% of all IVD devices will need notified body oversight for the first time**. • Only 8-10% of IVDs can therefore benefit from the additional transition time given to IVD Directive-certified devices. **For 85-90% of IVDs, the May 2022 date of application is a 'hard stop'.**	• The last three years, as a result of the implementation of the PIP Action Plan[3] have seen the **closure and reduction in scope of over 25% of notified bodies** designated under the MD Directives. Today, under the current system, manufacturers already report capacity issues with the remaining notified bodies – these challenges will certainly increase with the new Regulation.
• There are at least 40,000 IVDs on the market, of which **approximately 35,200 will need oversight by notified bodies**. Assuming that 22 notified bodies will apply for designation under the IVD Regulation, **each notified body would on average need to assess at least 1,600 IVDs**. This is an increase in notified body workload of 780%, or almost by a factor of 8.	• Of the more than **500,000 different medical devices** currently marketed in Europe, around 314,000 are expected to need notified bodies in order to be recertified to the new Regulation. It is vital that notified bodies be designated early enough to be able to cope with this workload, on top of the waves of new products that manufacturers will inevitably seek to certify at the same time.
• Notified body designation can only start after 26 November 2017. According to current NBOG practice, the average **designation time per Notified Body may take 18 months[4]**. This significantly reduces the time during which IVD certification can happen during the transition period.	• Notified body designation can only start after 26 November 2017. According to current NBOG practice, (re)**designation may take 18 months[5]**. With some 56 notified bodies available today and presumably seeking re-designation, **designating authorities** would have to **notify a minimum of 22 bodies a year** (or one every 2 weeks) just to meet the May 2020 date of application.

[1] See The European Medical Technology industry in figures 2016, MedTech Europe 2016
[2] Numbers based on 2012 Commission impact assessment for the IVD Regulation, which gives an estimated breakdown of devices: 50% class B; 35% class C and 5-10% class D.
[3] https://ec.europa.eu/growth/sectors/medical-devices/pip-action-plan_en
[4] See NBOG Guidance on redesignation of notified bodies
[5] See NBOG Guidance on (re)designation of notified bodies