

Mitigating the Impact of COVID-19 on Healthcare Systems Urgent Need to Pause the new Medical Technology Regulations Implementation

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Healthcare systems across the globe are fighting one of the worst pandemics in the past 100 years. The medical technology industry is fully engaged in supporting these efforts by providing personal protective equipment (PPEs) and medical devices to healthcare workers, hospitals and patients. At the same time, the medtech industry needs to maintain seamless availability of all medical technologies needed, day upon day, to diagnose, treat and monitor patients suffering from other critical or chronic health conditions.

Currently and for the next few months, helping healthcare systems in fighting this outbreak is and will be everyone's top priority and focus. Health actors are striving to keep PPEs and other critical medical technologies available in the fight against COVID-19 while managing the effects of the pandemic on their organizations. This is severely disrupting healthcare stakeholders' efforts to implement the new In Vitro Diagnostic (IVD) and Medical Devices Regulations ¹ within the fixed transition timelines.

We therefore call on the European Institutions to postpone the implementation of the In Vitro Diagnostics and Medical Devices Regulations until the situation has stabilized and all healthcare stakeholders can again dedicate the resources needed to properly implement the Regulations in a manageable way.

Europe needs not only to manage COVID-19 patients and protect healthcare workers; it is also essential to *safeguard* the overall functioning of healthcare systems. The EU must take urgent action to secure ongoing availability of *all* medical technologies that healthcare systems and patients need, not just those currently experiencing shortages. The effect of the COVID-19 on the medtech industry at the time of implementation of a major overhaul of its regulatory system will have a detrimental impact on availability of life-saving medical technologies. A situation that do not need to add to current challenges. This can be remedied by revising the new Regulations implementation timelines.

Annex I to this document provides various examples of how, due to COVID-19, implementation of the new Regulations has ground to a halt. **Annex II** to this document lists various actions that we urge the EU to immediately take to resolve this situation, in its critical efforts to safeguard healthcare systems battling the COVID-19 crisis.

¹ Regulation 2017/745 on medical devices ('MDR') and Regulation 2017/746 on *in vitro* diagnostics ('IVDR')

Annex I: Impacts of COVID-19 on Implementation of the IVDR/MDR

- **Healthcare authorities:** Are focused on managing a public health emergency. They have fewer resources available for their IVDR / MDR implementation duties, such as Notified Body designation, work on guidance documents, approval of clinical studies and market surveillance activities.
- **Healthcare professionals:** Are also focused on managing the outbreak. They are no longer available to conduct most clinical studies, nor to advise healthcare authorities, industry or Notified Bodies on IVDR / MDR implementation.
- **Notified Bodies:** Travel restrictions prevent many physical audits from happening as foreseen around the globe. Some audits are continuing *remotely*, but others are being cancelled or postponed because they are believed necessary to conduct in person. Notified Body are unavailable, due to lockdowns or self-quarantine. This results in less auditing and certification capacity to meet demand, leading to unexpected delays in conformity assessment for an unknown period.
- **European Commission:** Assessments on whether to maintain the mutual recognition agreement with Switzerland, negotiate the future trade relationship with the UK, and so on, have ground to a halt. The internal market with these countries – who play a critical role in the overall availability of medical technologies – will be disrupted if this cannot be unblocked before the Regulations' dates of application. Additionally, the Commission is similarly affected by the present lockdown, likely affecting its ability to run the needed committees and working groups in an effective manner.
- **Manufacturers:** In numerous product areas, stocks of devices compliant with the Directives are being purchased much faster than originally forecast. Those stocks were manufactured and placed on the market (warehoused) to facilitate the transition to the new Regulations, taking into account the delays in the availability of specific and needed IVDR/MDR guidance.
- **External suppliers/providers:** There are widespread reductions in the availability of core providers upon whom the industry relies. These range from biocompatibility testing laboratories, to printing suppliers for labelling and transport containers, as well as regulatory consultants used for file remediation.
- **Clinical studies:** Both prospective clinical studies and retrospective data collection is delayed and halted in all areas that are not urgent and critical to the fight against COVID-19.

Annex II: Recommended Regulatory Contingencies to Address the Situation

Critical measures needing immediate enactment to safeguard patient care:

- 1) **Postpone the IVDR/MDR transition**, and resume it 6 months after the present crisis has passed*
and
- 2) **Keep the key parts of the current Directives² going after 26 May 2020/2022**. Specifically, delay the denotification of (AI)MDD/IVDD-designated Notified Bodies referred to in IVDR Article 110(1) / MDR Article 120(1), and allow (AI)MDD/IVDD certificates, for which a renewal request has been submitted and no significant non conformities have been identified, to continue being issued after 26 May, as an exception from what is currently stated in IVDR Article 110(1) / MDR Article 120(2)

* The crisis could be considered passed when, for instance the World Health Organisation or other relevant authority (where critical preparedness activities are ongoing) declares the pandemic to be over.

Additional measures that will further support availability of needed medical technologies:

- 3) **Clarify that EU-wide derogations for critically-needed devices – e.g., IVDs for diagnosing COVID-19 or lung ventilators – may already be granted as per IVDR Article 54 / MDR Article 59.** Also, clarify that these derogations may be given to device *types/categories*, not just individual devices
- 4) **Adopt the implementing acts referred to in IVDR Article 92(3) / MDR Article 97(3)**, to enable market surveillance authorities to rapidly ensure the continued availability of needed device categories, via an administratively simple procedure with unified conditions
- 5) **Enlarge the scope of the ‘Grace Period’ in IVDR Article 110(2) / MDR Article 120(2)**, to include all devices that are self-certified under the Directives and not just those with Notified Body certificates
- 6) **Clarify that Notified Bodies may extend the validity of existing (AI)MDD/IVDD certificates filed for renewal before 26 May 2020/2022**, in cases where there are no obvious concerns about the device’s safety or performance, and instead of conducting a ‘renewal audit.’ Defer work on open questions to the surveillance stage

² Directives 90/385/EEC on active implantable medical devices (‘**AIMDD**’), 93/42/EEC on medical devices (‘**MDD**’) and Directive 98/79/EC on *in vitro* diagnostic medical devices (‘**IVDD**’)