

Medical technology industry ready to support the building of a stronger crisis preparedness

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MedTech Europe welcomes the objective of the European Commission to improve Europe's preparedness and response to future health threats. The presented 'EU Health Union' attempts to address the expectations of European citizens for better coordination and pooling of efforts across the Union to tackle health crises that Europe might face in the future. The interaction between some of the suggested measures and existing EU legislative regulatory frameworks should be further assessed to avoid duplication or legal uncertainty for all stakeholders affected.

The COVID-19 pandemic has become the worst public health threat of our generation. As the first wave swept over Europe in the spring of 2020, it became clear that cooperation between Member States and civil society is critical to ensure that essential medical supplies remain available and are not blocked by unilateral restrictions, such as restrictions on the movement of materials, accessories, products or people. This cooperation contributed to enabling healthcare professionals to carry out their tasks, equipped with the needed medical supplies from our industry.

Stronger cooperation on the following elements would pave the way to strengthening Europe's crisis preparedness and management capabilities. It would allow for rapid and sufficient access to medical technologies needed in future health crises by:

- Preventing unilateral national restrictions on the movement of medical technologies into and within the EU;
- Providing emergency pathways for regulatory approval of new technologies developed to combat the crisis in question; for the COVID-19 pandemic, such technologies included ventilators and diagnostic tests. The current lack of these pathways continue to considerably hamper Europe's crisis response capabilities as compared to other parts of the world;
- Keeping healthcare systems running by procuring and distributing equipment to where it is most needed. In particular, the coordination of multiple procurement mechanisms at EU, national and local level needs to be a priority;
- Providing reliable forecasts and demand models to allow manufacturers for effective planning and production, as well as health authorities for appropriate procurement and response measures.

The proposed legislative measures for an 'EU Health Union' address some of these needs by increasing the EU's capability for early alertness, stronger coordination, and harmonisation of response measures.

MedTech Europe assesses the legislative proposals in view of two criteria: One, do they preserve and improve patient access to needed technologies at times of crisis, and two, do they optimise legal certainty and consistency of regulatory requirements for medical technologies and not add further complexity to the newly established regulatory frameworks.

In this respect some of the proposed measures require further clarification and consideration. For instance:

- The role, composition and practical operation of the proposed new Executive Steering Group for Medical Devices in the European Medicines Agency would need to be harmonious with the activities of the existing Medical Devices Coordination Group, established as the main governing body for implementation of the IVD Regulation (IVDR) and Medical Device Regulation (MDR).
- The proposed transfer of responsibility for administering the IVDR and MDR expert panel to the European Medicines Agency should under no circumstances jeopardise the urgently needed timely deployment and smooth functioning of these panels, which need to start operating as soon as possible, and ideally before the end of 2020.
- The proposal to not duplicate the purchasing efforts under EU 'Joint Procurement Agreements' (JPAs) with initiatives at national level is positive. Further considerations should be made towards higher transparency and the implementation of the purchasing orders under the JPAs. Coordination is also needed for crisis purchasing initiatives that are happening outside of JPAs to allow for a clear view on demands of Member States.

In order to address future health crises, a structured dialogue between the European Commission, Member States, industry and other stakeholders is essential. This dialogue needs to cover preparedness before a crisis and management during a crisis. This has proven to be a valuable pillar during the current COVID-19 pandemic and MedTech Europe would encourage the Council and the European Parliament to institutionalise such dialogue platforms.

In addition to what is already proposed in the EU Health Union package, MedTech Europe also urges EU decision makers to stay focused and take action in establishing the necessary infrastructure to make the new regulatory frameworks for medical devices and *in vitro* diagnostics a success. Having a functioning legislative framework is a prerequisite to ensure the continued patient access to existing and new medical technologies, especially during a health crisis.

Key elements of the new infrastructure are still awaited and are urgently needed to allow for the required re-certification of products ahead of the implementation deadlines. The situation with the IVD Regulation, in particular, remains extremely alarming. For instance, there are still only four Notified Bodies designated to the IVDR to assess – for the very first time – some ~45.000 IVDs needing certification in the 18 months remaining until the 26 May 2022 deadline.

MedTech Europe will further contribute to the discussions on COVID-19 recovery and resilience, for example on essential topics including effective stockpiling¹, purchasing mechanisms, incentivising strategic production or the digital readiness to prepare and manage future health threats.

¹ MedTech Europe, Reflection paper on Sustainable and Effective Stockpiling for Emergency Preparedness , <https://www.medtecheurope.org/resource-library/reflection-paper-on-sustainable-and-effective-stockpiling-for-emergency-preparedness/>

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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