MedTech Europe
from diagnosis to cure

PRESS RELEASE

MedTech Europe welcomes the amendment of the Medical Devices Regulation and urges similar action for the IVD Regulation

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MedTech Europe welcomes the recent adoption by the European Council and European Parliament of the European Commission's proposal to amend the Medical Device Regulation (MDR), which will:

- Defer the 26 May 2020 date of application by 12 months, to a new date of 26 May 2021, and
- Create the immediate possibility to grant EU-wide derogations to certain medical devices, e.g., those critically needed to help combat the COVID-19 outbreak.

We understand this amendment of the MDR will take legal effect as soon as it is published in the EU Official Journal.

The longer transition time will not change the full commitment the medical device industry is giving to ensure complete and swift implementation of the new Regulation. As we have been doing since Day 1, our sector will continue to comply with all new requirements, so that the objectives of the Regulation are met in full.

The amendment will allow the medical device industry to maintain maximum focus on helping healthcare systems to combat COVID-19, and on addressing the pandemic's impact on the whole healthcare ecosystem. The sector's number one priority right now is to supply safe and well-performing devices to patients, healthcare professionals and healthcare systems on the COVID-19 front line.

Furthermore, MedTech Europe believes that the time must be used to continue rapidly building the new regulatory system and bringing it into full functionality, for example by having a greater number of notified bodies designated and operational under the MDR, by developing the needed MDR guidance documents, and so on. The additional time will also enable the EU to update its Mutual Recognition Agreement with Switzerland and its Customs Agreement with Turkey. MedTech Europe and its members are fully committed to use the additional time wisely and work with all involved stakeholder on the remaining open implementation questions.

Nevertheless, MedTech Europe is continuing to call for the same measure to be implemented for the *in vitro* Diagnostic Medical Devices Regulation (IVDR). Whilst the IVDR foresees a longer transition period than that of the MDR, diagnostic manufacturers note that, even before the COVID-19 pandemic, very little progress had been achieved yet, to get the new IVDR regulatory system ready. For instance, well into the second half of the transition period, there are still only 2-3 Notified Bodies designated under the IVDR, and critically-needed IVDR guidance documents, on topics like performance evaluation and the new risk classification criteria, are yet to be published.

Moreover, since the present COVID-19 outbreak, the IVDR implementation progress has come to a total halt. Already before the pandemic, the European Commission had indicated that focus on the implementation of the IVDR would only start in earnest after the MDR transition period has ended. Consequently, MedTech Europe strongly believes that the transition timeline needs to be adapted by at least 12 months, both to address today's reality and to prevent unintended fall out in the future.

Finally, MedTech Europe regrets that the EU institutions and national authorities have decided not to establish the immediate possibility for EU-wide derogations to be granted to critically needed IVDs, as has now been done for certain medical devices. This would have greatly helped facilitate timely and even access to the new COVID-19 tests needed for the EU population. With this missed opportunity, these critically needed tests can only receive derogations via applications in each individual Member State (i.e., 27+1 times), as elaborated in the national laws transposing the current IVD Directive. We hope that the EU institutions will look into this specific issue again and find adequate solutions.

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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