EPF Statement on the Postponement of the Application of the Medical Devices Regulation

27 April 2020

The COVID-19 outbreak and the associated public health crisis presents an unprecedented challenge to national authorities, health institutions, economic operators, and patients.[1]

The public health crisis has created extraordinary circumstances that demand substantial additional resources, as well as an increased availability of vitally important medical devices. Those extraordinary circumstances have a significant impact on various areas covered by the Medical Devices Regulation (EU) 2017/745, such as the designation and work of notified bodies and the placing on the market and making available on the market of medical devices in the Union.

On 22 April, the Council approved the European Commission's proposal to postpone the application of the Medical Devices Regulation to prioritise the fight against coronavirus. [2]

Considering this situation, the European Patients' Forum (EPF) welcomes the postponement by the European Commission[3] of the date of application of the Medical Devices Regulation (MDR) by one year to 26 May 2021, in order to alleviate pressure on key actors and ensure effective implementation of the regulation and the changes that patients need.

The new Regulation promises to bring important changes for patients who rely on medical devices to improve their health and quality of life, and have a fundamental right to expect that the devices they use are safe, after being authorised for use in the EU. These changes include enhanced safety requirements particularly for high-risk devices[4], strengthened transparency[5] and strengthened post-market surveillance.

[1] EPF Statement on the COVID-19 Pandemic: https://www.eu-patient.eu/COVID-19/epf-covid-statements/epf-statement-on-the-covid-19-pandemic/

[2] https://data.consilium.europa.eu/doc/document/PE-10-2020-INIT/en/pdf?utm_source=POLITICO.EU&utm_campaign=3b51a955bc-EMAIL_CAMPAIGN_2020_04_22_03_07&utm_medium=email&utm_term=0_10959edeb5-3b51a955bc-190571555

[3] https://ec.europa.eu/commission/presscorner/detail/en/IP_20_589

[4] EPF briefing on patient safety in the new regulation: https://www.eu-patient.eu/globalassets/policy/medicaldevices/briefing-for-patients-on-patient-safety-in-the-new-medical-devices-regulation.pdf

[5] EPF briefing on transparency in the new regulation: https://www.eu-patient.eu/globalassets/policy/medicaldevices/briefing-on-information-to-patients-and-transparency-in-the-new-medical-devices-regulation.pdf

We believe that the postponed date of application should be seen, not only as an opportunity to ensure an effective implementation of the medical devices regulation, in the designation of notified bodies to ensure access to medical technologies and patients' safety, but should also be used to accelerate the successful implementation of many other important elements of the system such as quality guidance, public access to information and a fully transparent regulatory framework within the deadline.

Transparency throughout the new system is a priority for patients as well as for healthcare professionals.[6] A fully functioning EUDAMED database is imperative to the operationalisation of the new regulatory system. The new regulatory system and commitments of strengthened transparency and public access to clinical information (e.g. Summaries of Safety and Clinical Performance to be shared through EUDAMED) will simply not work without a fully functioning EUDAMED. In light of the postponed date of application of the MDR, it is essential that EUDAMED be fully operational by May 2021, and that its implementation is not postponed until the date of application of the IVDR in 2022, as was previously announced.

In order to ensure that patients will continue to benefit from timely access to safe and high-quality medical devices, a seamless transition to the new regulatory framework is vital. EPF encourages policy makers, authorities, and stakeholders to continue efforts and preparations as much as possible to assure the implementation of the MDR and IVDR within the deadlines. EPF pledges to lend its support in this task.

ABOUT EPF:

The European Patients' Forum (EPF) is an umbrella membership-based organisation that works with patients' groups in public health and health advocacy across Europe. Our 74 members represent specific chronic disease groups at EU level or are national coalitions of patients. https://www.eu-patient.eu/

[6] BioMedical Alliance Statement on the postponement of the application of the Medical Devices Regulation: https://www.biomedeurope.org/images/news/2020/Statement_MDR_Delay_09.04.pdf