EPF calls for action

to ensure patients' continued access to safe, high-quality medical devices across the EU

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The European Patients' Forum is concerned about emerging reports of disruptions in the availability of many medical devices in the EU. The EU Medical Devices Regulation (2017/745) will become applicable on 26 May 2024, when devices on the market must comply with the MDR.

The withdrawal of some devices from the market, due to various reasons including lack of capacity of Notified Bodies to certify and re-certify devices and the reported high cost of certification, threatens the safety and continuity of care. If a needed medical device is not available when the patient needs it, this can have life-threatening consequences.

EPF calls for the Commission and Member States to take the necessary actions to put patient safety first and urgently find solutions to actual and potential shortages of medical devices. Inevitably this will involve careful balancing of the need for marketed devices to have demonstrated their safety and efficacy, on the one hand, and avoiding disruptions in their availability, on the other hand.

EPF calls for a pragmatic, risk-adjusted approach that takes into account the nature of the devices in question and their potential safety risks, as well as the impact of disruptions on patients. Devices that are critical and at high risk of disappearing from the market should be prioritised, such as those used to treat children and patients with rare or complex conditions. Re-certification deadlines could be extended, provided that patient safety is ensured. Devices with a long-established track-record on safety through data in existing registries for example, could be treated in a more flexible manner to avoid disruptions in supply.

To avoid further problems and delays in implementing the MDR, **EPF calls for urgent action to improve availability of medical devices and tackle the bottlenecks to access**, including: urgently improving the capacity of Notified Bodies and the number of accredited Notified Bodies; timely applications of sufficient quality by device manufacturers; and using data from clinical registries for safety and efficacy monitoring.

Solutions must be communicated in a transparent manner and must include careful monitoring and reporting on patient safety as well as involvement of the patient community.

Patients using medical devices should be fully informed and should be encouraged to report any unexpected problems they may encounter with their devices to their national authorities. **EPF calls for Member States' authorities to engage in regular dialogue with patient organisations in their country to ensure information flow and quick regulatory attention to any emerging concerns by patients**.

ABOUT EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 78 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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