

**PATIENTS AND DOCTORS CALL FOR URGENT INVESTMENT
TO ENSURE THAT THE EU MEDICAL DEVICES REGULATION IS IMPLEMENTED ON TIME**

OPEN LETTER TO EU HEALTH MINISTERS

It is now less than one year to 26 May 2020, when the new EU Regulation on Medical Devices (EU 745/2017) must be applied.

The Regulation mandates stronger safety requirements for high-risk medical devices, greater transparency of clinical evidence, and strengthened post-market surveillance.

Medical devices are vital for the prevention, diagnosis and treatment of disease. The successful implementation of the Regulation is a fundamental priority for patients and healthcare professionals requiring access to safe, innovative and effective technologies.

Progress has been slow. Limited regulatory capacity and manpower threaten the swift and effective implementation of the Regulation. Calls from the European Parliament to ensure that sufficient resources are dedicated within the European Commission have so far been ineffective; the number of dedicated regulatory staff in the Health Technology Unit in DG GROW¹ in Brussels is only 10.

This will be discussed by the Council of the European Union - EPSCO² on June 13-14.

Patients and healthcare professionals call jointly for European Union Member States to increase investment urgently, in order not to risk postponing implementation. By freeing up resources and boosting the capacity of the European Commission and national competent authorities it will be positive to speed up the designation of notified bodies, complete implementing legislative acts, ensure a fully functional Eudamed database and introduce the system of expert panels.

A realistic appraisal of progress is essential, and contingency plans must be transparent.

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¹ European Commission DG Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)

² Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO)