



Biomedical Alliance in Europe

PRESS RELEASE

FOR RELEASE ON 29 November 2022

Time is running out: BioMed Alliance calls for urgent measures to improve the availability of essential medical devices

Brussels: The [Biomedical Alliance in Europe](#), representing 36 medical and research societies, calls again on Member States to propose concrete actions in order to prevent a critical shortage of medical devices. Continuing challenges for the implementation of the EU Medical Devices Regulation (MDR) will be discussed by health ministers during the EPSCO meeting on 9 December.

The BioMed Alliance reiterates its [concerns](#) that essential medical devices are disappearing from the European market. Clinicians and researchers across all medical specialties strongly support the aim of the EU Medical Devices Regulation to improve the standards of clinical evidence for high-risk medical devices, but many legacy devices that are safe are at risk of being taken off the market due to unforeseen circumstances.

The organisation conducted a [survey](#) of clinicians (created with ESC & EFORT) where 53% of all respondents indicated that they already experience issues with reduced availability of medical devices – especially those used to treat children or patients with rare diseases. They stated that this adversely impacts patient care. Reported causes for devices becoming unavailable include decisions by manufacturers (based e.g. on regulatory considerations or the high costs of recertification) and the limited capacity of notified bodies to conduct recertifications. Other reasons given were the continuing impact of the COVID-19 pandemic, shipping problems, and interruptions to global supply chains.

Healthcare professionals and researchers represented by the BioMed Alliance fear that problems will increase ahead of the deadline of 26 May 2024 when a large group of devices on the market must be in conformity with MDR. Failure to recertify needed devices will negatively impact care for European patients, and particularly for vulnerable groups such as children and people living with rare diseases. EU Member States, the European Commission, the European Parliament, notified bodies and manufacturers must act now to avert this looming crisis for European healthcare.

The BioMed Alliance believes that a variety of measures is necessary. It will support an **extension of the recertification deadline of 26 May 2024**, on condition that standards for clinical evidence are maintained. Added time should be used by policy makers to rectify issues that inhibit full implementation of the MDR, including the **capacity of notified bodies** and the need for a **special framework to support the development and certification of orphan medical devices**. **Manufacturers** should also use the extra time to send in applications of sufficient



Biomedical Alliance in Europe

quality as soon as possible. At the same time, the **Medical Device Expert Panels** should play a greater role in the early dialogue with manufacturers, and **registries** should be used to support certification with conditions for market surveillance, as they already provide a wealth of information on the safety of devices and their impact on clinical outcomes. Policy makers should also consider setting up **conditional approval** procedures in exceptional circumstances to serve as a measure of last resort for devices that are at risk of disappearance and are used to treat life threatening conditions.

Professor Alan Fraser, Chairman of the Regulatory Affairs Committee of the BioMed Alliance, said *“Medical device regulators and Notified Bodies must work together and transparently to ensure that essential medical devices remain available. Manufacturers of devices that are used infrequently need to acknowledge their social responsibilities to patients, and apply the pathways that are proposed for keeping legacy products on the market. Medical societies can support these initiatives by providing data from registries on the clinical performance of existing devices.”*

ENDS