Biomedical Alliance in Europe

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# Biomedical Alliance in Europe calls for urgent measures to ensure the continuing availability of essential medical devices

**Brussels:** The Biomedical Alliance in Europe, representing 36 medical and research societies, calls on Member States to take action and prevent a potential shortage of medical devices, ahead of the discussions during the EPSCO meeting on 14 June on the implementation of the Medical Devices Regulation.

Doctors and scientists across all medical specialties strongly support the aim of the EU Medical Device Regulation (EU 2017/745) (MDR) which has applied since May 2021, to improve the standards of clinical evidence for high-risk medical devices.

Unfortunately, there is a chance that essential medical devices may disappear from the market. Contributory causes include the fact that that the personnel and resources that were envisaged to be needed in order to deliver the requirements of the new Regulation have never been allocated within the European Commission, and that the capacity of the notified bodies to approve devices remains insufficient. It is increasingly apparent that there is a real risk that many medical devices may be taken off the market by manufacturers and become unavailable for patients who require them, unless special measures are taken urgently to avoid this.

Medical device manufacturers reported from a recent survey, that 27% of all medical devices may be made obsolescent or discontinued (source MedTech Europe). Notified bodies announced that new certificates of approval have been issued for only 1069 devices out of a total of around 25,000 that need to be certified under the MDR (source MDCG[1] meeting 19 May 2022). Medical devices for orphan or paediatric indications are particularly vulnerable to additional regulatory costs or delays, and although there is no European database to identify these products, the loss of even a small number of products can have major implications for health care across Europe.

This problem will be discussed by Ministers of Health in the EU at the meeting of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) on Tuesday 14 June 2022. The BioMed Alliance urges ministers to propose new measures to ensure that devices can remain available for patients. The members of the Alliance will support the European Commission in developing and implementing policies to prevent what could become a major clinical crisis.

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[1] Medical Device Coordination Group (of the European Commission with national device regulatory agencies)