Biomedical Alliance in Europe

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Time is running out: doctors call on the European Commission to address limited availability of medical devices, particularly for children

Brussels: The Biomedical Alliance in Europe, representing 36 medical and research societies, calls on the European Commission to implement concrete actions in order to prevent a critical shortage of medical devices, particularly for children and people living with rare diseases. In a letter written by a number of prominent experts that was sent to Commissioner Kyriakides today, the Alliance expresses its growing fear that Europe is on the track to a potential public health crisis, where essential medical devices may disappear from the EU market. The letter was based on discussions within the CORE-MD project and is also signed by a number of prominent European health organisations. It reflects the urgent concerns of healthcare professionals that they are not always able to provide the same standard of care due to shortages. It is only a matter of time before patients, and particularly children, experience serious consequences of the unavailability of devices or may even have a higher risk of mortality.

Since the implementation of the Medical Devices Regulation (EU 2017/745), clinicians have experienced that certain essential and lifesaving devices have already disappeared from the market, and others are expected to be withdrawn in the near future. The BioMed Alliance raised awareness on this pressing issue through two press releases in June and November 2022, and has conducted a survey amongst clinicians which showed that 53% of all respondents had experienced that one or more devices had become unavailable since the application of the MDR. A variety of reasons were considered responsible, but the result often had an adverse impact on patient care and particularly in vulnerable groups such as children, patients with rare diseases, and patients in need of non-standard sized implants.

Based on experiences and contacts with clinicians within the organisation and manufacturers, BioMed Alliance has noted that the costs of (re)certification by Notified Bodies form a significant to critical financial barrier for manufacturers to (re)introduce devices on the EU market, particularly those devices that cater to small patient groups and thus offer less return on investment for the industry. Excessive invoicing has made the transition from the device directives to the MDR exceptionally costly and in some cases financially prohibitive. There may have been extremely conservative interpretation and (over)application of the new requirements.

Other persisting issues are notified body capacity, and very limited opportunities for dialogue (especially early dialogue) between manufacturers and notified bodies or regulatory agencies. All these factors can lead to decisions by manufacturers to withdraw their devices from the EU market.

At the same time, BioMed Alliance also reiterates that manufacturers must take their responsibility to ensure that a wide range of devices is available for the care of the full variety of patients. The Alliance agrees that this group needs to ensure that the applications are submitted in time and with a high level of clinical evidence. In addition, experts have noticed that in the case of implants in odd sizes, more and more manufacturers withdraw standard devices and offer to produce custom-made devices, at a higher cost.

BioMed Alliance very much welcomes the establishment of the MDCG Orphan Devices Taskforce, but has experienced that the measures taken so far, including the extension of the MDR transition period, are not yet enough to fully address the issues. Healthcare professionals believe that urgent action must be taken to ensure the continued availability particularly of Orphan Devices, ‘last in class’ devices, and implants and devices in different sizes catering to all patient groups.

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BioMed Alliance calls on policy makers to take a variety of steps to address the unintended consequences of the MDR on the availability of devices now including:

- Establish some form of a continuous monitoring system/list of last in class devices allowing for a better collection of data and identification of essential devices about to disappear from the market
- Promote the possibility and facilitate the implementation of national and EU-wide derogations for devices that are about to disappear from the market and play a critical role in EU healthcare as an interim emergency measure (article 59 MDR)
- Facilitate the use of registries to provide clinical evidence for the evaluation of devices
- Quickly develop special procedures, schemes and incentives with the involvement of clinicians (e.g. through the MDCG Orphan Devices Task Force) to facilitate the development and certification of orphan medical devices and in vitro diagnostics

About BioMed Alliance:

The Biomedical Alliance in Europe (BioMed Alliance) is the result of a unique initiative of 36 leading European medical societies that together include more than 400,000 researchers and health professionals.

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