European cardiologists call for urgent action to prevent medical device shortages

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The European Society of Cardiology (ESC), which represents more than 100,000 health care professionals, today urges EU health ministers to prevent a shortfall of essential medical devices for cardiovascular

patients.

The call comes ahead of the Employment, Social Policy, Health and Consumer Affairs Council (EPSCO) meeting on 9 December, when ministers will discuss ongoing challenges in implementing the Medical Device Regulation (MDR) and the resulting risk of safe medical devices being removed from the EU market. Insufficient availability would have dire consequences for the diagnosis and treatment of cardiovascular patients, especially vulnerable groups including children and those with rare diseases.

Concerns about the transition to the MDR led the ESC, together with the Biomedical Alliance in Europe, to conduct a survey asking clinicians if devices they use are no longer on the market. ESC responses were the large majority (41%), with 21 EU countries and different subspecialties represented, ranging from pediatric cardiology to arrhythmology and cardiac surgery.

Results from ESC respondents:

- 49% have experienced issues with the availability of medical devices since the MDR was enacted.
- In 30% of cases the device was used to treat children and in 27% of cases patients with rare diseases.
- In 42% of cases the use of an alternative device was not as effective, so a reduction in the level of patient care was reported by 59% of respondents.

The devices reported as missing from the market included diagnostic and ablation catheters, some stents, and devices used in pediatrics. The reported causes for unavailability included manufacturers withdrawing products due to the length and cost of MDR recertification and, in parallel, disruptions of supply chain and delivery issues.

The ESC supports the MDR's aim to enhance patient safety by improving the standards of clinical evidence required for medical devices, and welcomes the measures suggested by the Medical Device Coordination Group (MDCG) to facilitate the transition to the MDR. However, the ESC believes that stronger action is needed to avert this added threat to public health while healthcare systems are still reeling from the COVID-19 pandemic.

The ESC invites the European Commission and Member States to consider extending the recertification deadline of 26 May 2024. During this additional period, notified bodies should be given extra capacity to process recertification applications, while manufacturers would have more time to adjust to the regulations and cope with supply chain problems. The ESC also asks regulators to explore the opportunity for joint procurement actions to counteract shortages.

In addition, the ESC encourages the adoption of specific regulatory provisions to support the development and certification of orphan devices and it supports the possibility of conditional approval pathways.

The ESC also highlights that scientific societies can play a key role in providing expertise and data on medical devices through running registries.

In parallel, the ESC believes that additional measures should be taken to support research and innovation in the medical device field in Europe to stop investments shifting to other markets, which would slow down innovation, affect independent research organizations and academia, and further limit patient access to novel medical devices.

As summarized by the Chairman of the ESC Regulatory Affairs Committee, Piotr Szymański, "solutions are urgently needed to mitigate the medical devices crisis, that threatens medical procedures, research

and innovation in Europe."

More information: Clinicians concerned about limited availability of medical devices (Dropbox PDF): www.dropbox.com/s/oox1zdka6b8usr7/Report%20survey%20results%20v3.pdf?dl=0

Provided by European Society of Cardiology