MEP Heart Group Meeting

Addressing the Shortage of Medical Devices for Cardiovascular Disease Patients in the EU

Wednesday 28 June 2023 10:00 – 11.30

Overview

On 28 June 2023, the MEP Heart Group co-chairs (MEP) Brando Benifei (S&D, Italia), Maria Carvalho (EPP, Portugal), in collaboration with Member of the European Parliament Radka Maxová (S&D, Czechia), hosted the MEP Heart Group meeting on Shortage

of Medical Devices for Cardiovascular Patients in the EU.

The event on medical device shortages was driven by the critical need to address a pressing issue that impacts healthcare systems and patient well-being.

Key take-aways

- Medical devices play a vital role in diagnosing, treating, and monitoring cardiovascular diseases, improving patient outcomes and quality of life. The shortage of medical devices, particularly in paediatric cardiology, poses a significant concern and threatens patient care and safety.

- The implementation of the EU Medical Devices Regulation poses challenges in ensuring access to medical devices. The latest extension of the transitional period provides temporary relief, but comprehensive strategies are required to address the underlying issues.

- There is a need for prioritising cardiovascular health at the European level in all areas through multidisciplinary cooperation, making cardiovascular health a priority for the upcoming 2024 parliamentary term.

- Gender differences in cardiovascular disease (CVD) must be acknowledged, with a focus on improving the diagnosis, treatment and care of CVDs in women. Equally, there is a lack of research on CVDs in paediatric patients. An increased representation of women and children in clinical trials is desirable to address the unique challenges they face in accessing appropriate medical devices.

- The lack of predictability in the regulatory environment is driving medical device manufacturers towards regions with more stable and predictable regulations which poses a risk of device shortages across Europe.

- Financial support and actions are necessary to enhance capacity for certification at national level, through so-called notified bodies, monitor implementation progress, support innovation, and strengthen coordination among stakeholders.

Interventions

In her welcoming remarks, MEP Radka Maxova (S&D, Czechia) mentioned that there is a deep concern about the impact of the shortages of medical devices, which not only affect the overall population but also exacerbate gender differences in cardiovascular diseases (CVDs).

Dr Charmaine Griffiths, European Heart Network President, and British Heart Foundation CEO outlined the role of medical devices (MD) for CVD patients.

As CVD accounts for 1 in 4 deaths, medical devices play a critical role in diagnosing, treating, and monitoring CVD, improving outcomes and enhancing the quality of life for patients.

She emphasised the impact of the shortage of medical devices in paediatric cardiology, stressing that it has a phenomenal effect on young patients. To address these challenges, collaboration among policymakers, industry stakeholders, and patient advocates to collectively tackle the shortage of medical devices is needed.

Stefan Hofer[1], Head of the Department of Anesthesiology, Intensive Care Medicine, Emergency Medicine (Westpfalz Klinikum, Kaiserslautern), and affected father outlined the patient perspective by drawing attention to the alarming situation of hospitals in Germany that are running out of crucial medical devices, like balloon catheters for the care of newborn babies but also basic medication, for example, aspirin. There are approximately 9,000 children born every year in Germany with congenital cardiovascular diseases, however, the number is deemed too small to be of interest to the industry.

From the patient's perspective, there is a need for clarity, transparency, and decisive action to address the shortages of medical devices in paediatric cardiology.

MEP Brando Benifei (S&D, IT), MEP Heart Group Co-chair introduced the topic of challenges associated with ensuring the safety and efficacy of medical devices in the EU.

Limited access to medical devices is not only a concern in low-income countries but also a pressing issue in high-income nations. Despite advancements in technology and healthcare systems, many individuals, especially vulnerable populations and specialised areas such as paediatrics, still struggle to obtain necessary medical devices.

To effectively address this problem, the root causes of limited access need to be addressed. Affordability, availability, and regulatory barriers all play crucial roles in shaping the current landscape. Merely extending deadlines for compliance, while providing temporary relief, does not address the underlying issues or ensure optimal patient care.

[1] Stefan Hofer Presentation

Peter Bischoff-Everding (DG Sante D3) informed the audience about EU-level actions to address the risk of shortages of medical devices[2].

The EU Medical Devices Regulation and In Vitro Diagnostic Regulation were adopted by the Council and EP in 2017, with the MDR becoming applicable in 2021. In March 2023, an amendment to the MDR was introduced, extending the transitional period until the end of 2027 or 2028, depending on the risk class of the device.

Several bottlenecks emerged, particularly with the redesignation process for notified bodies responsible for assessments. This process took longer than expected, causing delays in the certification of medical devices.

Comprehensive and collaborative actions, such as enhancing notified body capacity, promoting tailored solutions for high-risk devices and providing financial support through EU funding programs, can help mitigate medical device shortages, improve regulatory processes, and enhance patient access to safe and effective medical devices.

Kai Rüenbrink, German Heart Foundation gave the perspective of a national Heart Foundation in this debate[3].

The implementation of the EU Medical Devices Regulation has presented significant challenges in ensuring access to medical devices, particularly in terms of affordability, availability, and quality. The disappearance of medical devices from the market is a concerning trend, particularly those intended for the treatment of rare diseases or paediatric patients. The majority of medical device manufacturers in Europe are small and medium-sized enterprises, often lacking the necessary resources and expertise to navigate the complex regulatory landscape. The cost and duration of assessment for compliance with the EU MDR are considerably higher in the EU compared to countries like the USA and Canada, posing additional challenges for manufacturers.

Recognising the need for action, the EC proposed a review of the EU MDR. Despite some progress, the overall capacity of conformity assessment bodies, known as "notified bodies", remains insufficient to meet the current demands. As of October 2022, there have been 8,120 applications for MDR certification, but only 1,990 certificates have been issued.

Panel Discussion

During the panel discussion, - Oliver Bisazza (MedTech Europe CEO), Peter Bischoff-Everding (European Commission), Kai Rüenbrink and Stefan Hofer (German Heart Foundation) engaged

[2] Peter Bischoff-Everding Presentation

[3] Kai Rüenbrink Presentation

in a dialogue to explore policy solutions and strategies to tackle the medical device shortage for cardiovascular disease (CVD) patients.

MedTech Europe's CEO expressed concerns about the unintended consequences of the EU MDR and emphasised the need for action. While timeline extensions have been implemented, they have not adequately addressed the underlying challenges faced by the industry, such as compliance costs, lengthy assessment timelines, confusion regarding requirements, and a lack of predictability. Addressing these issues is crucial for improving access to medical devices and preventing them from being diverted to regions with more predictable regulations.

Furthermore, participants highlighted the need to address the impact of the MDR on paediatric patients and urged the current European Commission (EC) and European Parliament (EP) not to pass the responsibility to the next mandate.

The panel discussion also focused on how stakeholders can support the EC in their work. The Commission expert emphasised the importance of providing relevant best practices, data, and experiences related to innovative medical devices and the challenges of obtaining certification. He noted that any alternative pathways for innovation would require changes in legislation, which requires consensus among the 27 member states and more than 700 MEPs.

In her closing remarks, MEP Carvalho (co-chair of the MEP Heart Group) underlined the need for increased attention and priority to cardiovascular diseases (CVD) at the EU level. She stressed that CVD should receive equal attention and resources as other types of diseases, emphasising the significance of prioritising prevention, treatment, and management of CVD for the overall well-being of EU citizens.

Written by EHN Secretariat

ANNEX

- Stefan Hofer Presentation
- Peter Bischoff-Everding Presentation
- Kai Rüenbrink Presentation