



PRESS RELEASE

EAP – EUROPEAN ACADEMY OF PAEDIATRICS urges urgent action to protect access to essential medical devices for children and patients with orphan diseases.

“The letter highlights the need for immediate action, as the transition period for the EU MDR has been extended but fails to address the disappearing devices.”

Brussels, 27 June 2023 - The European Academy of Paediatrics (EAP) and 22 other European associations dedicated to child health and medical care are joining forces to address the critical issue of maintaining access to essential medical devices for children and other patients with orphan diseases. In an open letter to Commissioner Kyriakides, the EAP calls for urgent action to prevent the loss of crucial medical devices necessary for optimal patient care.

While the EU Medical Device Regulation 745/2017 (EU MDR) aimed to improve the evaluation and safety of high-risk medical devices, its implementation has unintentionally resulted in increased time and costs for manufacturers. For example, one company received invoices of over €800,000 for conformity assessment for a single device for giving at most, 5 years market access. This is over 150 times the cost of a United States lifetime market access cost same device of approximately €5,000. For medical devices for children sold only in small numbers, manufacturers cannot recover such high regulatory costs, therefore, such products are withdrawn from the market even though they are essential for adequate treatment of children with specific disorders.

The EAP highlights the need for immediate action. The transition period for the EU MDR has been extended, but this will not halt the disappearance of essential medical devices for children from the EU market, because further marketing requires a contract to be in place between the device manufacturer and notified body by September 2024, with very high costs. Additionally, the absence of a comprehensive EU-wide monitoring mechanism hampers the identification of devices at risk of disappearing from the market. The EAP calls for the establishment of an efficient monitoring system to protect public health.

To address these issues, the EAP proposes the following policy decisions to the European Commission and the European Parliament:

1. Correct the unintended consequences of the EU Medical Device Regulation to ensure continued access to essential medical devices for children and patients with orphan diseases.
2. Establish an EU-wide monitoring system to track devices that may disappear from or have disappeared from the market.
3. Delegate the assignment of "paediatric device" or "orphan device" status to an EU Expert Panel with competent paediatric experts, enabling simplified and cost-effective conformity assessments similar to the US Humanitarian Device Exemption regulation.





4. Expedite the conformity assessment process for high-risk devices with paediatric or orphan device status, involving clinical and paediatric expertise, and implementing a capped maximum fee to incentivize the introduction of devices for small patient groups.

The complete letter, along with the supporting societies, is available at:

https://www.eapaediatrics.eu/wp-content/uploads/2023/06/Letter-Kyriakides_Med-Devices-signed-260626.pdf

The EAP urges Commissioner Kyriakides to schedule a meeting to discuss the urgent shortages of medical devices for children, anticipated threats, and necessary corrective actions to safeguard child health.

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ABOUT THE EUROPEAN ACADEMY OF PAEDIATRICS (EAP)

The European Academy of Paediatrics (EAP / formerly Council of European Specialists in Paediatrics, CESP) was founded in 1961. Its members include national paediatric societies from over 41 countries across Europe (28 European Union (EU) countries, 4 European Economic Area (EEA) countries and 9 non-EU countries) as well as all 14 UEMS recognised European paediatric subspecialty societies and observer Countries.

EAP/EBP- European Board of Paediatrics also is the official Section of the European Union of Medical Specialists that is formally linked with the European Commission and Member States Institutions and is responsible for developing European training standards in paediatrics and paediatric subspecialties and the EBP-EAP Exam.

The European Academy of Paediatrics coordinates the only European Research Network in paediatric primary care since 2008. With over 2000 members and several papers published the EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network) is a practice-based research network that was established in 2009. It consists of paediatric practitioners in European and Mediterranean countries and research consultants from Europe in collaboration with the EAP and AAP PROS.

EAP has two Permanent Councils (Primary, Secondary - Tertiary Care) and six Strategic Advisory Groups:

- Ethics established in 1997 with over 30 papers published on ethical issues,
- Rare diseases - already involved in the EU Commission Expert Group on Rare Disease,
- Vaccination - strongly supporting harmonization among national immunization programmes in Europe as well as optimization of vaccination coverage in collaboration with ECDC, EU Commission, DG Santé and other stakeholders,
- Adolescent medicine and Medicines for children producing evidence-based documents and up to date information on relevant aspects of paediatrics,
- Medicines for Children, established several years ago, restarted in 2018,
- Choosing Wisely has been established in December 2018.
- Young EAP is by far the largest network of national junior paediatric representatives: twenty-four countries are currently represented within Young EAP. EAP represents the European Geographic region within the International Pediatric Academy- IPA world.

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