European Academy of Paediatrics
Paediatric Section of U.E.M.S

PRESS RELEASE

European experts warn about shortages of medical devices for children and give recommendations on clinical investigation and evaluation

https://onlinelibrary.wiley.com/doi/10.1111/apa.16919

Brussels, 18 August 2023 - Paediatricians across Europe have voiced serious concerns about the evolving shortages of medical devices in the European Union (EU) that are essential for treating sick children. Devices are withdrawn from the market due to markedly increased regulatory requirements and high costs of certifying devices under the revised EU Medical Device Regulation. Urgent action is therefore needed to protect the access to essential medical devices for children.

As part of the EU CORE-MD project (Coordinating Research and Evidence for Medical Devices), the European Academy of Paediatrics (EAP) hosted a high-level expert workshop at the Ludwig Maximilians University Munich, Germany. Experts developed recommendations on clinical investigation and on clinical evaluation of paediatric medical devices considered to be of "high-risk". Experts from a variety of paediatric clinical subspecialties and European paediatric associations, as well as from a regulatory authority and from the European Commission Directorate General Health and Food Safety contributed.

The paediatric experts agreed on key elements for clinical investigation and evaluation of high-risk medical devices for children:

- The establishment of a European expert panel with competent paediatric experts dedicated to paediatric medical devices is needed to advise on their evaluation
- Recommendations for a facilitated and low-cost evaluation of "orphan medical devices" used on only few patients as well as criteria for assigning an orphan medical device status were defined
- Full transparency and sharing of clinical evidence supporting the evaluation and certification of medical devices is called for, in the interest of patient safety
- Recommendations on approaches of clinical evaluation of medical devices in children were defined, considering ethical aspects and feasibility
- The establishment of European registries of paediatric patients and other patients with rare (orphan) diseases requiring medical devices is called for, to gather additional evidence after market access

The expert recommendations are published in Acta Paediatrica:
https://onlinelibrary.wiley.com/doi/10.1111/apa.16919

ENDS

European Academy of Paediatrics
Paediatric Section of UEMS
(European Union of Medical Specialties)
Secretariat: Paragon GP
18 Avenue Louis-Casai,1209 Geneva, Switzerland
+41 22 5330 948
secretariat@eapaediatrics.eu
www.eapaediatrics.eu

ABOUT THE EUROPEAN ACADEMY OF PAEDIATRICS (EAP)

The European Academy of Paediatrics (EAP; https://www.eapaediatrics.eu/) is the umbrella organization of national paediatric associations across Europe and of European paediatric subspecialty associations, and acts as the united voice of European Paediatrics and Child Health. It promotes the health of children and young people in Europe through improving standards in training, service and research.

About CORE-MD:

The EU-funded project "Coordinating Research and Evidence for Medical Devices" (https://www.core-md.eu/) reviews methodologies for the clinical investigation and evaluation of high-risk medical devices and translates expert scientific and clinical evidence for evaluating high-risk medical devices into advice for EU regulators, to achieve an appropriate balance between innovation, safety, and effectiveness.

Contact:

Kathrin Gürlich / Prof. Berthold Koletzko, Dr. von Hauner Children's Hospital, LMU Univ. of Munich, Germany, email: office.koletzko@med.lmu.de, phone: +49 89 4400 52826

European Academy of Paediatrics
Paediatric Section of UEMS
(European Union of Medical Specialties)
Secretariat: Paragon GP
18 Avenue Louis-Casai,1209 Geneva, Switzerland
+41 22 5330 948
secretariat@eapaediatrics.eu
www.eapaediatrics.eu