



copy by e-mail:
cab-kyriakides-contact@ec.europa.eu

Commissioner Stella Kyriakides
European Commissioner for
Health and Food Safety
European Commission
Rue de la Loi / Wetstraat 200
1049 Brussels, Belgium

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Open letter: Urgent action needed to secure continued access to essential medical devices for children and for patients with orphan diseases

Dear Commissioner Kyriakides,

The undersigned representatives of European medical associations dedicated to child health and medical care write to you to request your urgent action in order to secure continued access of children and of patients of all ages with orphan diseases to essential medical devices.

The original goals of the EU Medical Device Regulation 745/2017 (EU MDR), i.e. to strengthen clinical evaluation and safety particularly of high-risk medical devices, are widely supported. However, the application of the EU MDR has hugely increased the time and cost associated with bringing medical devices to market or maintaining them on the market. As a result, manufacturers are withdrawing medical devices sold in smaller numbers from the EU market when the additional arising costs cannot be recovered. In contrast, they tend to continue marketing such devices in other jurisdictions. As a result, the paediatric and rare diseases community in the European Union currently faces the loss of essential medical devices that are indispensable for appropriate patient care. For example, balloons for performing the life-saving Rashkind manoeuvre in newborn infants with certain congenital heart defects have become unavailable, and a lack of sufficiently equipped hemodialysis machines for performing dialysis in young children with end-stage kidney disease has been reported. If this development is not corrected, many paediatric and orphan disease patients who can afford to do so, and who are fit for travel, may want to travel from the EU to e.g. Switzerland or the USA to get medical care.

The transition period for the EU Medical Device Regulation 745/2017 was originally supposed to end in 2024 but has been postponed until 2027 or 2028, depending on the risk classification of the medical device. However, this will not halt the disappearance of essential medical devices from the EU market, because further marketing requires an application to be submitted to a notified body by May 2024, and a contract to be in place between the device manufacturer and notified body by September



2024. We are being told that the costs of (re)certification by Notified Bodies form a critical financial barrier for manufacturers to (re)introduce devices on the EU market, particularly those devices that cater to small patient groups like children or patients with rare diseases, and thus offer less return on investment for manufacturers. To give you an example, a company with a single device received invoices of over €800,000 for conformity assessment which gives at most, 5 years market access. This is over 150 times the cost of a United States '510k' lifetime market clearance for the same device, which costs approximately €5,000. Larger medical device companies benefit from economies of scale, with regulatory costs likely to be less than 3% of revenue. For smaller companies, these costs are a much greater proportion of revenue and therefore they represent an existential threat.

Moreover, companies have indicated that their investment in the EU into research and development of improved paediatric and orphan medical devices in the EU will be markedly reduced, and if the situation remains unchanged many innovative small and medium enterprises may face the danger of going out of business, or may relocate to other countries outside of the EU.

Clinicians were among the first to raise the issue of 'disappearing' essential devices to regulators in October 2021, and groups such as the Biomedical Alliance have conducted multiple questionnaires to identify medical devices that have already been withdrawn, or are likely to be withdrawn. This is essential activity to characterise the impact of the problem on public health, but a more efficient and continuous monitoring must be put in place since clinicians usually become aware only months or even years after the commercial decision has been made to withdraw a product.

Another severe challenge arises because there is no continuous EU-wide monitoring mechanism that could identify last in class devices or devices that are about to disappear from the EU market. In response to a Parliamentary question in March (E-000205/2023(ASW)), the European Commission noted that it does not have at its disposal robust information about specific medical devices that have ceased to be supplied in the last 24 months. No one can say with certainty what will happen in the next 12 months, but reports available to clinicians indicate a high likelihood of losing significant numbers of essential medical devices. This will result in an avoidable risk of death and serious injury, not as a consequence of unsafe medical devices, but as a consequence of disappearance of devices due to unforeseen effects of the EU MDR.

Recently the representatives of 22 European medical associations dedicated to child health care have formulated their joint position on appropriate approaches for the clinical investigation and conformity assessment of high-risk medical devices for children as part of the EU-funded CORE-MD project (Guerlich K et al, Clinical Investigation and Evaluation of High-Risk Medical Devices for Infants, Children and Adolescents, submitted for publication). Based on these considerations, we propose the following policy decisions to the European Commission and the European Parliament:

- 1. The unintended consequences of implementing the EU Medical Device Regulation inducing unavailability of specific medical devices must be urgently corrected such that children and patients with orphan diseases will have continued access to medical devices that are needed for 'state of the art' health care**



2. An EU wide system should be established to monitor whether specific medical devices are about to disappear from the market, or have disappeared from the market.
3. An efficient and fast process needs to be implemented by which high-risk medical devices can be assigned a status of a “paediatric device” or an “orphan device”, for which a simplified, fast and low-cost conformity assessment can then be applied, similar to the strategies established in the USA (Humanitarian Device Exemption regulation). This process of assigning this status should be delegated to an EU Expert Panel with inclusion of competent paediatric experts.
4. For high-risk medical devices assigned a paediatric or orphan device status, conformity assessment with involvement of competent clinical and paediatric expertise should be completed within a short period of time and with a limited maximum fee, both defined by the EU, to proactively encourage to bring devices to the market also for small and particularly vulnerable patient groups. The conformity assessment for paediatric or orphan device status should either be delegated to a public body that can set low fees, or the fees charged by private notified bodies working for profit should be capped through subsidizing from the EU.
5. Until these required changes have been implemented in the EU, transition solutions need to be established to protect patients. For the interim period, high-risk paediatric or orphan medical devices that have been marketed in the EU for at least 3 years without reported problems should get automatic permission for continued use, and high-risk medical devices approved for use in paediatric patients or patients with orphan diseases under the US Humanitarian Device Exemption regulation should be permitted for market access in the EU, to prevent unavailability of devices that will endanger patient safety and well-being.

We ask you to kindly set up a meeting where we can discuss with you the serious shortages of medical devices for children that have already arisen at this time, the further threats that are expected, and the options for corrective steps that should be taken in the interest of protecting child health.

Yours sincerely,

Prof. Adamos Hadjipanayis, MD
President, European Academy of Paediatrics (EAP)
secretariat@epa paediatrics.eu





Prof. Gunhild Waldemar, MD
President, Biomedical Alliance in Europe
marieke.meijer@biomedeuropa.org



Prof. Berthold Koletzko, MD
Chair of the Board, Child Health Foundation –
Stiftung Kindergesundheit
info@kindergesundheit.de



Prof. Nico Blom, MD
President, European Association for
Paediatric and Congenital Cardiology (AEPC)
office@aepc.org



Ziyad M. Hijazi, MD, MPH
President, The Pediatric and Congenital
Interventional Cardiovascular Society (PICS)
zhijazi@me.com



Laura Reali, MD
President, European Confederation of
Primary Care Paediatricians (ECPCP)
president@ecpcp.eu



Silke Mader
Chair, European Foundation for the
Care of Newborn Infants (EFCNI)
info@efcni.org





Zsolt Bognar, MD
Chair, European Society for Emergency
Paediatrics (EUSEP)
europeanpem@eusem.org



Prof. Ullrich Baumann, MD
President, European Society for Paediatric
Gastroenterology, Hepatology and Nutrition
(ESPGHAN)
office@espghan.org



Daniele de Luca, MD
Medical President, European Society for
Paediatric and Neonatal Intensive Care (ESPNIC)
dm.deluca@icloud.com



Paulien Raymakers-Janssen
Nursing President, European Society for
Paediatric and Neonatal Intensive Care (ESPNIC)
p.a.m.a.raymakers-janssen@umcutrecht.nl



Prof. Dieter Haffner, MD
President, European Society for Paediatric
Nephrology (ESPN)
Haffner.Dieter@mh-hannover.de



Prof. Rukshana Shroff, MD
Chair, European Society for Paediatric
Nephrology (ESPN) Working Group Dialysis
Rukshana.Shroff@gosh.nhs.uk





Prof. Alberto Edefonti
Chair, European Pediatric Dialysis Working Group (EPDWG)
aedefonti@hotmail.com

Franz Schaefer, MD
President, International Pediatric Nephrology Association (IPNA)
Coordinator, European Rare Kidney Disease Reference Network (ERKNet)
franz.schaefer@med.uni-heidelberg.de



Prof. Kevin Rostasy, MD
President, European Paediatric Neurology Society (EPNS)
kevin.rostasy@uni-wh.de



Prof. Angelo Ravelli, MD
President, Paediatric Rheumatology European Association (PRoS)
elisapatrone@gaslini.org



Prof. Amulya K. Saxena, MD
Past President & Executive Board member, European Paediatric Surgeons' Association (EUPSA)
office@eupsa.info



Prof. Charles C. Roehr, MD
President, European Society for Paediatric Research (ESPR)
office@espr.eu





Prof. Serdar Tekgül, MD
President, European Society for
Paediatric Urology (ESPU)
president@espu.org



Prof. Alberto M. Pereira, MD
Coordinator, European Rare Disease Research
Coordination & Support Action consortium
(ERICA)
info@erica-rd.eu



Prof. Wout Feitz, MD
European Reference Network for rare urogenital
diseases and complex conditions (ERN eUROGEN)
Michelle.Battye@radboudumc.nl



David A. Pearce, PhD
Chair, International Rare Disease Consortium
(IRDiRC)
david.pearce@sanfordhealth.org



Stefania Arasi, MD
Chair, Pediatric Section Board, European
Academy of Allergy and Clinical Immunology
(EAACI))
stefania.arasi@opbg.net



Dr Donato Bonifazi
Coordinator, European Paediatric Translational
Research Infrastructure (EPTRI)
coordinator@eptri.eu





Prof. Paul Dimitri, MD
Coordinator, Medical Devices Research Platform,
European Paediatric Translational Research
Infrastructure (EPTRI)
paul.dimitri@nhs.net



Marielle W.H. Pijnenburg, MD
Head of Paediatric Assembly of the European
Respiratory Society (ERS)
m.pijnenburg@erasmusmc.nl



Prof. Piotr Szymański, MD
Chair Regulatory Affairs Committee,
European Society of Cardiology (ESC)
RegulatoryAffairs@escardio.org



Prof. Alan G Fraser, MD
Scientific Coordinator, CORE-MD EU
Horizon project grant 965246
FraserAG@cardiff.ac.uk

