ESPGHAN
European Society for Paediatric
Gastroenterology, Hepatology and Nutrition

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AVAILIBILITY OF PAEDIATRIC MEDICAL DEVICES (MD) IN THE EU: Current Landscape and Identified Issues.

CONTEXT

In 2017, the EU established a new regulatory framework for medical devices (EU 2017/745) aimed at improving the security and quality of healthcare for patients, protecting public health, and unifying requirements and conditions of the market across Europe. This new Medical Devices Regulation (MDR) became applicable on May 26th, 2021, with a transition period defined until May 26th, 2024, during which all medical devices currently available on the market must undergo conformity assessment by reputable *notified bodies,* created for this purpose. There are currently almost 22,000 MDs on the EU market with valid certificates issued under the *previous* Council Directives, which took place from 1990 to 1993, and all of these devices must receive a new registration following the 2017 MDR if they wish to continue operating after the transition period (ending May 26th 2024). MDs to be installed for the first time on the EU market undergo the same procedure to verify compliance with the 2017 MDR.

As of October 2022, notified bodies had received 8,120 applications from manufacturers for new certification, and only 1,990 had been issued. This means that 6130 applications are still pending. Furthermore, there are still 13,880 MDs with an "old" certificate for which manufacturers have yet to apply, and these devices must be certified and receive CE. This number does not include any potential new MDs.

PROBLEMS

1. The 2017 MDR is extensive, demanding, and expensive.

2. There is an insufficient number of notified bodies created to date, and their members require training, while financial resources remain unclear. If they continue at the same number and pace, it is projected that by the end of the transition period (May 26th 2024), only a further 7000 MDs could receive a certificate (22,000 are on the market with "old" certificates).
3. Manufacturers may not have sufficient resources or time to initiate and complete the conformity process within the provided transition period.
4. Manufacturers may turn to more open markets such as Canada, the USA, and other parts of the world where legislation is less demanding and the process is much cheaper.
5. Sales of paediatric and orphan MDs are much lower than those for adults and have a lower "cost-benefit" profile for manufacturers, who may not even apply for them.

The problems mentioned above could result in the following expected outcomes:

A. An acute shortage of medical devices on the EU market.
B. A decrease in the quality of healthcare.
C. Inappropriate and unsatisfactory new developments in the area of MDs, and a lack of the best new products on the EU market available for patients.
D. All of the above will be significantly more serious with respect to paediatric patients - an acute shortage of essential MDs could result in serious medical problems and have a damaging impact on the health of the paediatric population within the EU.

RESPONSE TO 2017 MDR – A PROPOSAL OF EU FOR AMENDMENTS, January 2023

Specialty and subspecialty medical societies, including the BioMed Alliance, EU expert bodies, the Medical Devices Coordination Group (MDCG), patient organizations, and MD manufacturers have all issued statements, provided documents, and initiated activities to present problems and initiate amendments to the 2017 MDR.

On January 6th 2023, a proposal for an amended Regulation of the EU on MDs was issued (2023/0005 COD). The most important amendment is the extension of the transition period from

May 26th 2024, until December 31st 2027, for high-risk devices (class III and class IIb) and until December 31st 2028, for medium and low-risk devices. This means that an extra 3-4 years are provided to finalise the new certification process, i.e., the conformity assessment process. *This new proposal also contains all the necessary adjusting articles that will enable the MDs with valid certification* according to the "old" MDR to stay on the market.

DOES THE NEW EU PROPOSAL of January 2023 RESOLVE THE PROBLEM OF PAEDIATRIC MDs?

While the proposed amendments to the EU regulation provide an additional 3-4 years for the transition period and allow MDs with valid certification to continue operating on the EU market until the end of 2028, the challenges with paediatric MDs will persist. The costs and time associated with the demanding and expensive legislative procedures may still discourage manufacturers from applying, resulting in the unwanted consequences listed above.

ACTIVITIES TO IMPROVE THE PROSPECT OF PAEDIATRIC MD

Activities undertaken in March and April 2023:

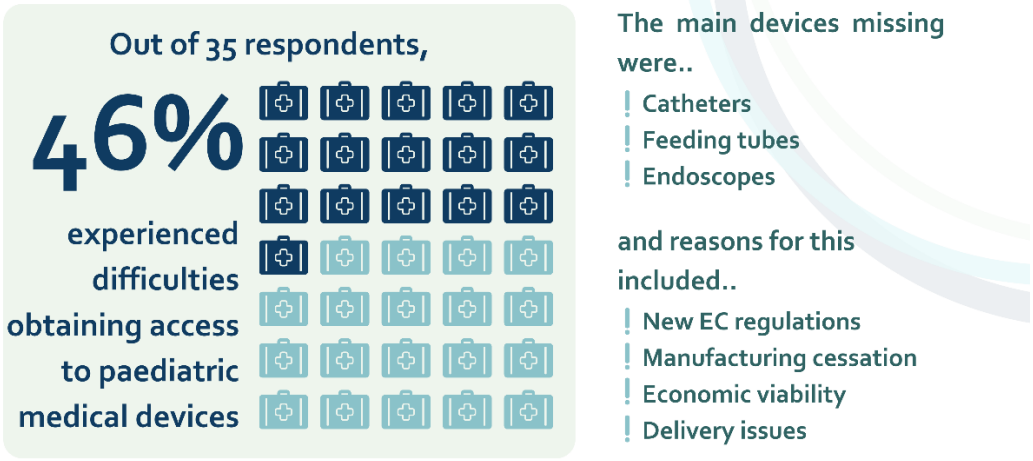
1. *Participation in the CORE-MD project (an EU Horizon 2020 project):*

The CORE-MD project reviews methodologies for the clinical investigation and evaluation of high-risk medical devices to establish recommendations that provide an appropriate balance between clinical efficacy, safety, and innovation. This is achieved through literature searches, onsite and online meetings, and document creation, all of which have already been completed.

2. *Creation of a network with the national presidents of general paediatric societies:*

Presidents of National PGHN and general paediatric societies were contacted and addressed.

3. *Survey to assess the extent of MD problems among the members of ESPGHAN Committees, Working Groups (WGs), and Special Interest Groups (SIGs) gave the following results:*



- 46% of 35 respondents experienced a problem with obtaining access to MDs.
- Most of the missing MDs belong to endoscopy and parenteral nutrition (PN) accessories.
- The problem has been encountered in the last 12 months.

The most common named reasons for the shortages are new EC regulations, problems with delivery, and stopped manufacturing for unclear causes.

Other important information obtained in the survey are presented in Appendix 1-3.

PLAN FOR FUTURE ACTIVITIES

The future activities aim to:

A. Develop short-term solutions to avoid the acute loss of necessary MDs within the member states and, more importantly, across the EU.
B. Obtain improved amendments to the current legislation (MDR) to create a protected niche for paediatric and orphan MDs, similar to the status of orphan drugs.

Some of the planned activities are:

1. Raise awareness among paediatric specialty/subspecialty medical associations on the problem and foster continuous lobbying, preferably both individually and jointly.

2. Increase pressure on organizations such as the Biomedical Alliance and Medical Devices Coordination Group (MDCG).
3. Coordinate activities with patient and parent organizations on the EU level.
4. Establish a network of EU MPs that will support this activity and future activities that require the EU parliament's involvement. This implies, but is not limited to, (a) engaging MPs on the national level, (b) creating a list of physicians who are currently MPs, and (c) searching for EU members' state representatives within the MDCG.

This report has been prepared by:

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References

1. EU regulation on medical devices – EU 2017/745
2. MDCG position paper of August 2022 (2022-14)
3. Biomedical Alliance in Europe documents:
   - Report on the survey
   - Press releases with respect to the problem of MDs
4. Pediatric cardiology statement printed in Pediatric Cardiology 2023;44:271-79
5. CORE-MD Project documentation & papers
6. EU proposal for amending regulation 2017/745, 2023/0005(COD)

Appendix 1: Results of Question 5 "What was the main application of the device(s)?"

Response	Count
Central Venous Catheter	1
System for home PN	1
Freja g-j tubes	1
Pump to deliver liquid enteral feeds into feeding tube	1
Central venous catheter for iv application of parenteral nutrition, fluids and medication	1
To collect cytokine profiles via sweat	1
Endoscopy	1
Broviac cathéter for home parentéral nutrition	1
Anal manometry probe	1
PEG buttons, PEG-J buttons	1
PEGJ (15 cm length of the jejunal extension)	1
Endoscopic retrograde cholangiography	1
iv- access, Catheters, Pain sensors	1
ERCP neonatal scope	1
Banding device to fit in <10kg children for treatment of oesophageal varices	1
Interventional radiology	1

Appendix 2: Results of Question 6 "Please list the name(s) of the manufacturer(s)/ companies and the Ref. Number of the device(s)"

Response	Count
Vygon	2
Cook	2
Bard	1
BD bodyGuard disposable microSet	1

Freka	1
Freego feeding pumps (Abbott)	1
7fr bard Hickman central venous catheter	1
Fujifilm endoscopes	1
Promedia Medizintechnik	1
Avanos	1
Kimberly-Clark	1
Olympus	3
Medstorm	1
No information given/available	2

Appendix 3: Results of Question 8 "If known, please list the reason(s) for the shortage/unobtainability of the device".

Response	Count
EC rule	1
Due to new regulation there was a safety alert. finally this is resolved and delivery is continued again	1
National supply shortage	1
MHRA backlog / lack of approval	1
All devices are available in the hospital theatre but the access to them for pedGIs is limited due shortage of anaesthetists in the hospital. Due to that shortage, we compete on daily basis for a slot with neuro-, thoraco- and cardiosurgrons, general surgeons, orthopaedics etc so, endoscopies compared to others are the last needed. Three months ago a new legislation allows the private performance of interventions in the evening and the weekends but the Ministry's explanatory of the law document is still pending.	1
Stop manufacturing	2
Problems with delivery	1
Economically not viable - according to manufacturer, please find our publication on this issue in JPGN: Endoscopic Retrograde Cholangiopancreatography in Infants: Availability Under Threat: A Survey on Availability, Need, and Clinical Practice in Europe and Israel. Koot BGP, Kelly DA, Hadzic N, Gonzales E, Hierro L, Davenport M,	1

Keil R, Fockens P, Baumann U. J Pediatr Gastroenterol Nutr. 2020 Aug;71(2):e54-e58. doi: 10.1097/MPG.0000000000002752.	
MRD certificate pending, no longer available due to rentability	1
Never available in the past	1