

EPTRI POSITION NOTE

Revision of the Medical Device and *In vitro* Diagnostic Medical Device Regulations: Addressing the Specific Needs of Paediatric Populations

20 October 2026

Background

EPTRI is a pan-European research infrastructure that connects specialised units across Europe and globally, bringing together expertise in paediatric research, clinical development, regulatory science and stakeholder engagement to strengthen the paediatric research ecosystem and accelerate the development of innovative health solutions for children. Through its specialised network and its coordination of the EU4Health-funded, three-year project [OrphaDev4Kids \(EU4H-2023-PJ, No. 101161377; 2024–2027\)](#), EPTRI also has practical experience in addressing barriers to the development of medical devices (MDs) and *in vitro* diagnostic medical devices (IVDs) for paediatric and rare disease populations. Paediatric research infrastructures and European clinical networks can support evidence generation by facilitating multicentre collaboration, harmonised data collection and access to small, heterogeneous and geographically dispersed patient populations. Their expertise can contribute to the development of scientifically robust and feasible evidence-generation strategies throughout the device lifecycle.

In the context of the ongoing revision of the Medical Device Regulation (MDR) and *In Vitro* Diagnostic Medical Device Regulation (IVDR), EPTRI welcomes the opportunity to strengthen the regulatory framework addressing the specific needs of paediatric patients, while maintaining robust standards for safety, performance, clinical benefit and appropriate evidence generation. In particular, EPTRI considers that the current revision does not yet sufficiently recognise paediatric health and research as specific considerations within the medical device framework.

Paediatric medical devices address specific clinical and technological needs that are not always adequately captured by regulatory frameworks designed for broader patient populations. Children are not a homogeneous population, and differences in anatomy, physiology, psycho-emotional state, developmental stage, disease presentation and clinical needs may have direct implications for the design, adaptation, evaluation and use of medical devices. In addition, paediatric and rare disease populations are often small, heterogeneous and geographically dispersed, which makes evidence generation particularly challenging and limits the commercial incentives for manufacturers to invest in dedicated devices. This can hinder the timely development and availability of appropriate and innovative devices for children.

From a paediatric research perspective, these characteristics require regulatory approaches that take into account the specific needs of children and the conditions affecting them. Regulatory flexibility should therefore be accompanied by mechanisms that support appropriate evidence generation and scientific advice. Within the MDR/IVDR revision, EPTRI considers it important that regulatory

amendments are accompanied by appropriate consideration of paediatric needs, so that innovation and timely access can be supported without compromising safety, performance or clinical benefit. EPTRI's position is therefore focused on ensuring that the revised MDR/IVDR framework appropriately reflects the specific characteristics and needs of paediatric populations and provides a proportionate and predictable regulatory environment for the development and availability of medical devices and *in vitro* diagnostic medical devices for children.

EPTRI position: Key regulatory considerations

The European Commission presented on **16 December 2025** its [proposal for a Regulation](#) amending Regulations (EU) 2017/745 on medical devices (MDR) and (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), with the objective of simplifying the regulatory framework and reducing administrative burdens while maintaining a high level of public health and patient safety. The proposal, [COM\(2025\) 1023 final](#), follows the ordinary legislative procedure (2025/0404(COD)), under which the European Parliament and the Council act as co-legislators.

As of 1 October 2026, the proposal remains under examination by the European Parliament and the Council and has not yet reached the trilogue negotiation stage. The [European Parliament's Legislative Observatory](#) currently records the procedure as “awaiting Committee decision”.

At the European Parliament, the dossier is being handled by the Committee on Public Health (SANT). A [committee draft report \(PE787.987\)](#) was published on 30 June 2026, followed by amendments tabled in July. The Parliament currently indicates 14 December 2026 as the indicative date for the first-reading plenary sitting.

In parallel, the Council is continuing its technical examination of the proposal through its [Working Party on Pharmaceuticals and Medical Devices](#). Council discussions on the proposal continued throughout September 2026.

The next key steps are therefore the adoption of the Parliament's position, further work within the Council towards its position, and, subsequently, the opening of trilogue negotiations. The timing of final adoption remains dependent on the progress of these negotiations.

The revision of the MDR/IVDR provides an opportunity to introduce specific provisions addressing the regulatory and clinical development challenges associated with paediatric medical devices. EPTRI considers that such provisions should be incorporated within Article 52a (MDR) and Article 48a (IVDR) through a clear and coherent framework that recognises paediatric devices as a distinct category, while maintaining robust standards of safety, performance and clinical evidence.

EPTRI therefore recommends that the revised Article 52a (MDR) and Article 48a (IVDR) address four complementary aspects:

1. Establish a clear and needs-based definition of paediatric medical devices

The paediatric population encompasses distinct developmental stages, from neonates and infants to children and adolescents, with differences in anatomy, physiology and clinical needs that may directly affect the design, adaptation and evaluation of medical devices. These characteristics, together with

small and heterogeneous patient populations and limited commercial incentives, can make clinical evidence generation particularly challenging and support the need for a dedicated and clearly defined regulatory framework for paediatric medical devices and IVDs.

Paediatric and orphan medical devices may face similar structural barriers, including small and heterogeneous patient populations, difficulties in recruiting sufficient numbers of paediatric patients, limited availability of appropriate paediatric comparators, age- and development-related differences, and limited commercial volumes. Nevertheless, EPTRI considers that these two concepts should remain distinct from a regulatory perspective. As reflected in the proposed AM 470¹, linking paediatric devices to the orphan-device pathway would not necessarily capture the full range of devices for which paediatric-specific development challenges exist.

The orphan concept is primarily linked to the epidemiology of the relevant disease or condition and to the availability of alternatives and/or expected clinical benefit. In contrast, the paediatric concept relates to the intended population and to the specific challenges associated with developing and evaluating technologies for children. Requiring a paediatric device to meet the orphan criteria could therefore exclude devices that face significant paediatric-specific challenges but do not meet the epidemiological threshold for orphan designation.

A central element of the proposed framework is therefore the definition of a paediatric MD/IVD. Defining a paediatric device solely on the basis that it is intended for individuals below 18 years of age, as proposed by AM 261², could result in an excessively broad category. The definition should therefore ensure an appropriate balance between capturing real paediatric-specific challenges and avoiding an unnecessarily broad category in which any device intended for individuals below 18 years of age could automatically benefit from the full Article 52a/48a pathway.

In this respect, EPTRI's proposal does not rely solely on the age criterion. In addition to being intended for individuals under 18 years of age, the proposed definition requires that the device is expected to provide a clinical benefit taking into account both device-specific factors and patient population-specific factors. This definition covers both devices intended exclusively for children and those intended for broader populations where paediatric use entails specific considerations regarding device design or adaptation, clinical development, evidence generation, or evaluation.

This represents an important step towards ensuring that paediatric designation is linked not only to the age of the intended population but also to a relevant clinical need and the expected benefit, considering device-specific and patient population-specific factors. To ensure consistent application of the proposed definition, its implementation should be supported by paediatric-tailored device design, from design concept to validation, to guarantee the expected clinical benefit. These should take into account the device's intended purpose, its characteristics, the needs of the target paediatric population and the clinical context, while allowing for case-by-case assessment where appropriate.

The objective should not be to lower the level of evidence required for paediatric devices, but rather to ensure that evidence-generation strategies are scientifically appropriate and proportionate to the

¹ Amendments 374-615 Draft report PE787.987v01-00

² Amendments 132-373 Draft report PE787.987v01-00

device, its intended purpose, risk profile and the characteristics of the paediatric population, while supporting timely access to appropriate devices.

Unlike orphan medical devices, for paediatric devices the lack or scarcity of alternatives, as well as comparison with existing options or the state of the art, are not defining features of the category. These aspects should therefore not be considered defining criteria for the identification of paediatric devices, as they do not necessarily capture the specific challenges associated with paediatric development. Furthermore, given the European paediatric medical device landscape and country-by-country disparities in public access to such healthcare tools, bringing more options to the market, even if similar or equivalent, to treat, diagnose, or prevent diseases or conditions in the under-18 population could contribute to reducing disparities in access to appropriate diagnostic, treatment and preventive solutions for children across European healthcare systems.

The EPTRI position is reflected in the proposed introduction of a new Article 52a/48a(4), establishing the criteria for the designation of a device as a paediatric device.

2. Provide dedicated expert advice on paediatric clinical development and evidence generation

Manufacturers and prospective manufacturers should have access to paediatric scientific and regulatory advice from the early development stage, including before formal paediatric designation. Such advice should clarify the intended purpose, applicable regulation, risk classification, evidence needs and route for clinical investigation or performance study. EPTRI therefore proposes the amendments to Article 52a/48a(5) and (6), extending the expert-panel assessment and clinical development advice to confirmed paediatric devices. The proposed extension of the Article 52a/48a pathway to paediatric medical devices provides strong regulatory support to manufacturers through access to expert panel advice regarding their clinical development strategy and the appropriate non-clinical/analytical or clinical data required for the clinical/performance evaluation of the device, where conventional clinical/performance study designs may be difficult to implement due to small or heterogeneous paediatric populations or limited comparators.

3. Enable prioritised and proportionate conformity assessment, including rolling review

Establishing a clearly defined conformity assessment process for confirmed paediatric medical devices, including prioritised conformity assessment and rolling review where appropriate, could help mitigate prolonged assessment timelines. This approach would reduce the risk of delays in bringing critical paediatric technologies to patients.

Rolling review could similarly be useful where evidence and technical documentation are generated progressively. It may facilitate earlier regulatory interaction and allow issues to be identified and addressed during development rather than only at the final conformity assessment stage.

This principle is reflected in the proposed amendment to Article 52a/48a(7), introducing prioritised conformity assessment and rolling review for confirmed paediatric devices and a specific provision for the certification of paediatric devices where premarket clinical evidence is based on limited clinical data, subject to a favourable benefit-risk ratio. Prioritised assessment and rolling review should facilitate timely and iterative regulatory evaluation without reducing the substantive

requirements for conformity assessment. The adequacy of relevant clinical data during pre-market phase should be assessed on a case-by-case basis, taking into account the device's intended purpose, risk profile and applicable safety and performance requirements. Given the heterogeneity of the paediatric population, any residual uncertainties shall be addressed through an accurate and well-structured post-market clinical/performance follow-up plan, featuring clearly defined objectives and timelines to address the remaining gaps in the clinical/performance evaluation. The inclusion of paediatric devices under Article 52a/48a ensures that regulatory requirements are continuously updated through future adaptations and implementing measures, proposed in the amendments to Article 52a/48a(10) and (11). This would help ensure that the paediatric regulatory framework remains aligned with scientific and technological developments and the state of the art.

4. Support paediatric development through certification and development planning

When clinical evidence stems from limited or heterogeneous paediatric populations, the regulatory framework must facilitate a scientifically sound, proportionate evaluation while strictly upholding standard requirements for safety, performance, and clinical benefit.

The proposed amendment to Article 52a/48a(9) provides for certification of confirmed paediatric devices based on adequate pre-market evidence and a favourable benefit-risk ratio, subject to appropriate post-market clinical or performance follow-up. For *in vitro* diagnostic medical devices, the clinical benefit is typically indirect, being derived from the device's clinical utility and clinical performance, both of which are strictly dependent on the analytical performance. This means that the primary focus for demonstrating clinical benefit should be to establish scientific validity, fulfil all analytical performance requirements, and gather as much possible clinical performance data to minimize any unaddressed safety and performance requirements in the pre-market phase. Any remaining gaps must then be covered by a comprehensive post-market performance follow-up plan.

Considering the limited availability of devices specifically designed or adapted to address paediatric needs, Subsection 12 aims to foster the development of paediatric medical devices by encouraging manufacturers of adult devices to adapt their technologies.

A dedicated paediatric development plan would establish a structured framework to evaluate paediatric applications early in the product lifecycle. Such plans should primarily address categories or groups of adult-marketed devices with an identified clinical benefit in paediatric populations, but where dedicated design and development review, as well as evidence generation, are required. Their scope should be proportionate to the device's risk profile, intended paediatric use and existing evidence. Furthermore, implementation should clarify how relevant device categories or groups are identified, without automatically imposing identical development obligations on all devices marketed for adults. Ultimately, these plans should support design review, evidence-generation strategies, clinical investigations and necessary device development adaptations to address unmet paediatric needs while ensuring compliance with the General Safety and Performance Requirements (GSPRs).

This principle is reflected in the proposed introduction of Article 52a/48a(12), empowering the Commission to establish requirements for the preparation of paediatric development plans for relevant categories or groups of devices marketed for adults.

The proposal also includes fee relief for paediatric devices (AM 438 of Article 50-paragraph 2-MDR), on the rationale that certain paediatric devices target small patient populations and have limited commercial potential relative to their certification costs.

Overall, establishing a clear link between the intended paediatric population and expected clinical benefit helps ensure that the Article 52a/48a pathway is restricted to paediatric devices facing genuine development, conformity assessment, or market access barriers, thereby avoiding an overly broad application of the framework. The objective should be to reduce procedural and timing barriers associated with paediatric device development, without lowering the regulatory standards applicable to the demonstration of safety, performance and clinical benefit.

Proposed amendments

EPTRI PROPOSED AMENDMENT of ART.52-paragraph a-MDR	
<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
Conformity assessment of breakthrough devices and of orphan devices	Conformity assessment of breakthrough devices, of orphan devices and of paediatric devices
1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article.	1. For the conformity assessment of breakthrough devices, orphan devices and paediatric devices , for which a notified body is involved in the conformity assessment, the procedures laid down in Article 52 shall apply subject to the specific arrangements set out in this Article. (AM 464*)
2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.	2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.
3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.	3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives; (ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.

EPTRI PROPOSED AMENDMENT of ART.52-paragraph a-MDR

<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
/	4. A device shall be considered a paediatric device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition in subjects under 18; (b) the device is expected to provide a clinical benefit taking into account both device-specific factors and patient population-specific factors.
4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body.	5. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 shall provide an opinion as to whether the criteria set out in paragraph 2, 3 or 4 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 109 and shall be duly taken into consideration by the manufacturer and the notified body. (AM 471*)
5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device.	6. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2, 3 or 4 of this Article, the manufacturer of a breakthrough device, of an orphan device or of a paediatric device, as applicable, may request advice from the expert panels referred to in Article 106 regarding its clinical development strategy and appropriate preclinical or clinical data for the clinical evaluation of the device. (AM 477*).
6. For a confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines. The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The	7. For a confirmed breakthrough device, an orphan device, or a paediatric device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 52 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines. The notified body shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 5 or 6 (ex 4 or 5) and, where it does not follow such opinion or advice, it shall provide duly justified reasons.

EPTRI PROPOSED AMENDMENT of ART.52-paragraph a-MDR	
<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
notified body may ask the expert panel to clarify the opinion it has provided.	The notified body may ask the expert panel to clarify the opinion it has provided.
7. The notified body shall issue a certificate pursuant to Article 56 where the premarket clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.	8. For a confirmed breakthrough device or an orphan device, the notified body shall issue a certificate pursuant to Article 56 where the premarket clinical evidence, even if based on limited clinical data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.
/	9. For a confirmed paediatric device, the notified body shall issue a certificate pursuant to Article 56 where the premarket clinical evidence, even if based on limited clinical data, is deemed adequate, provided that the following condition is fulfilled: (a) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market clinical follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 56, such as a requirement for the manufacturer to conduct specific post-market clinical follow-up activities within a specified period of time.
8. The Commission is empowered to adopt delegated acts in accordance with Article 115 in	10. The Commission is empowered to adopt delegated acts in accordance with Article 115 in

EPTRI PROPOSED AMENDMENT of ART.52-paragraph a-MDR

<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.	order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices, orphan devices or paediatric devices at international level. (AM 492*)
9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3).	11. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices, orphan devices or paediatric devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). (AM 494*)
	12. The Commission may, by means of implementing acts, lay down requirements for the preparation of a paediatric development plan, for categories or groups of devices which are marketed for adults, but may have clinical benefit for paediatric patients. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 114(3). (**)
*Amendments of Draft report PE787.987v01-00 **A similar amendment was also proposed by the Biomedical Alliance in Europe in June 2026	

EPTRI PROPOSED AMENDMENT of ART.50-paragraph 2-MDR

<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3). Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of Recommendation 2003/361/EC the possibility	2. Notified bodies shall apply at least a 50 % fee reduction for manufacturers that are micro enterprises within the meaning of Recommendation 2003/361/EC and at least a 25 % fee reduction for small enterprises within the meaning of that Recommendation. They shall apply at least a 50 % fee reduction for manufacturers that apply for conformity assessment of an orphan device referred to in Article 52a(3) or a paediatric device referred to in Article 52a(4) of this Regulation or Article 48a(4) of Regulation (EU) 2017/746. Notified bodies shall provide manufacturers that are micro or small enterprises within the meaning of

EPTRI PROPOSED AMENDMENT of ART.50-paragraph 2-MDR

<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
to defer the payment of fees until the relevant conformity assessment activity is finalised.	Recommendation 2003/361/EC the possibility to defer the payment of fees until the relevant conformity assessment activity is finalised.

EPTRI PROPOSED AMENDMENT of ART.48-paragraph a-IVDR

<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
Conformity assessment of breakthrough devices and of orphan devices	Conformity assessment of breakthrough devices, of orphan devices and of paediatric devices
1. For the conformity assessment of breakthrough devices and orphan devices, for which a notified body is involved in the conformity assessment, the procedures laid down in Article 48 shall apply subject to the specific arrangements set out in this Article.	1. For the conformity assessment of breakthrough devices, orphan devices and paediatric devices , for which a notified body is involved in the conformity assessment, the procedures laid down in Article 48 shall apply subject to the specific arrangements set out in this Article. (AM 702*)
2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.	2. A device shall be considered a breakthrough device if it meets the following criteria: (a) it is expected to introduce in the Union a high degree of novelty with respect to the device technology, related clinical procedure or the application of the device in clinical practice; (b) it is expected to provide a significant positive clinical impact on patients or public health, for a life-threatening or irreversibly debilitating disease or condition, by either of the following: (i) offering a significant positive clinical or health impact compared to available alternatives and the state of the art; (ii) fulfilling an unmet medical need where there is an absence or insufficiency of available alternative options for that purpose.
3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives;	3. A device shall be considered an orphan device if it meets the following criteria: (a) it is intended for the treatment, diagnosis, or prevention of a disease or condition that presents in not more than 12 000 individuals in the Union per year; (b) at least one of the following criteria is met: (i) there are insufficient available alternatives;

EPTRI PROPOSED AMENDMENT of ART.48-paragraph a-IVDR	
<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.	(ii) the device is expected to provide a clinical benefit compared to available alternatives or the state of the art, taking into account both device-specific factors and patient population-specific factors.
/	4. A device shall be considered an in vitro paediatric device if it meets the following criteria: (a) it is intended for the diagnosis of a disease or condition in subjects under 18; (b) the device is expected to provide a clinical benefit taking into account both device-specific factors and patient population-specific factors.
4. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 of Regulation (EU) 2017/745 shall provide an opinion as to whether the criteria set out in paragraph 2 or 3 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 102 and shall be duly taken into consideration by the manufacturer and the notified body.	5. Upon a duly substantiated request by a manufacturer or a notified body, an expert panel referred to in Article 106 of Regulation (EU) 2017/745 shall provide an opinion as to whether the criteria set out in paragraph 2, 3 or 4 of this Article, as applicable, are fulfilled. That opinion shall be published on a dedicated website without disclosing any confidential information as referred to in Article 102 and shall be duly taken into consideration by the manufacturer and the notified body.
5. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2 or 3 of this Article, the manufacturer of a breakthrough device or of an orphan device, as applicable, may request advice from the expert panels referred to in Article 106 of Regulation (EU) 2017/745 regarding its performance evaluation strategy and appropriate analytical or clinical performance data for the performance evaluation of the device.	6. Where the opinion of the expert panel confirms the fulfilment of the criteria set out in paragraph 2, 3 or 4 of this Article, the manufacturer of a breakthrough device, of an orphan device or of paediatric device , as applicable, may request advice from the expert panels referred to in Article 106 of Regulation (EU) 2017/745 regarding its performance evaluation strategy and appropriate analytical or clinical performance data for the performance evaluation of the device. (AM 713*)
6. For a confirmed breakthrough device or an orphan device, as applicable, the notified body involved in the conformity assessment procedure set out in Article 48 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines. The notified body shall give due consideration to an	7. For a confirmed breakthrough device, an orphan device, or paediatric device , as applicable, the notified body involved in the conformity assessment procedure set out in Article 48 shall prioritise the conformity assessment of that device and apply, where appropriate, a rolling review with a view to reduce assessment timelines. The notified body

EPTRI PROPOSED AMENDMENT of ART.48-paragraph a-IVDR	
<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
opinion or advice provided by the expert panels in accordance with paragraph 4 or 5 and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided.	shall give due consideration to an opinion or advice provided by the expert panels in accordance with paragraph 5 or 6 (<i>ex 4 or 5</i>) and, where it does not follow such opinion or advice, it shall provide duly justified reasons. The notified body may ask the expert panel to clarify the opinion it has provided. (AM 715*)
7. The notified body shall issue a certificate pursuant to Article 51 where the premarket clinical evidence, even if based on limited clinical performance data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical performance data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as a requirement for the manufacturer to conduct specific post-market performance follow-up activities within a specified period of time.	8. For a confirmed breakthrough device or an orphan device, the notified body shall issue a certificate pursuant to Article 51 where the premarket clinical evidence, even if based on limited clinical performance data, is deemed adequate, provided that either of the following conditions is fulfilled: (a) the benefit of the immediate availability on the market of the device outweighs the risk associated with the fact that additional clinical performance data are still required; (b) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as a requirement for the manufacturer to conduct specific post-market performance follow-up activities within a specified period of time.
/	9. For a confirmed paediatric device, the notified body shall issue a certificate pursuant to Article 51 where the premarket clinical evidence, even if based on limited clinical performance data, is deemed adequate, provided that the following condition is fulfilled: (a) the benefit-risk-ratio of the device is favourable and the manufacturer commits to providing additional data from post-market performance follow-up activities. Where appropriate, the notified body shall limit the validity of the certificate and specify any conditions for or limitations to the certificate's validity in accordance with Article 51, such as a requirement for the

EPTRI PROPOSED AMENDMENT of ART.48-paragraph a-IVDR	
<i>Text proposed by the Commission</i>	<i>Proposed Amendment</i>
	manufacturer to conduct specific post-market performance follow-up activities within a specified period of time.
8. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices or orphan devices at international level.	10. The Commission is empowered to adopt delegated acts in accordance with Article 108 in order to amend this Article to adapt to technical or scientific progress or to take into account developments regarding conformity assessment of breakthrough devices, orphan devices or paediatric devices at international level. (AM 724*)
9. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices or orphan devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).	11. The Commission may, by means of implementing acts, lay down further details of the procedure for the conformity assessment of breakthrough devices, orphan devices or paediatric devices set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3). (AM 727*)
	12. The Commission may, by means of implementing acts, lay down requirements for the preparation of a paediatric development plan, for categories or groups of devices which are marketed for adults, but may have clinical benefit for paediatric patients. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 107(3).
*Amendments of Draft report PE787.987v01-00	

Conclusions

EPTRI calls for a regulatory framework that recognises the specific needs of paediatric MDs and IVDs and facilitates their development and availability, while preserving robust standards for safety, performance, clinical benefit and evidence generation.

EPTRI recommends that the ongoing MDR/IVDR revision consider a clear and meaningful definition of paediatric medical devices, proportionate eligibility criteria for dedicated regulatory support, enhanced scientific and regulatory advice, prioritised and proportionate conformity assessment, including rolling review where appropriate, and mechanisms facilitating the development or adaptation of existing devices for paediatric populations.

EPTRI also highlights the role of paediatric research infrastructures and European clinical networks in supporting evidence generation, and the importance of clear implementation criteria, appropriate post-market follow-up and a well-defined scope for paediatric development plans.

EPTRI considers that the proposed amendments to Article 52a/48a would provide a coherent framework addressing the main regulatory challenges associated with paediatric MDs and IVDs, while maintaining a clear distinction between paediatric and orphan devices. The proposed fee reduction under Article 50(2) would further support the implementation of this framework by addressing part of the economic barriers associated with conformity assessment.