CONSUMER RECOMMENDATIONS

BEUC The European Consumer Organisation

The Consumer Voice in Europe

Revision of the EU medical devices regulations

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The European Consumer Organisation (BEUC) is the largest organisation promoting the general interests of Europe's consumers. Founded in 1962, it proudly represents more than 40 independent national consumer organisations from over 30 European countries. Together with our members, we inform EU policies to improve people's lives in a sustainable and fair economy and society.

Publication date 22 May 2026
Contact: health@beuc.eu
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Reference: BEUC-X-2026-048

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WHERE DO WE STAND IN THE LEGISLATIVE PROCESS?

- **On 16 December 2025, the European Commission published a legislative proposal for the revision of the EU regulations on medical devices and in vitro diagnostics. The European Parliament and the Council are expected to adopt their positions in 2026.**
- **In our October 2025 public consultation response, we called on the Commission to ensure that any simplification exercise does not compromise patient safety.**

MAIN RECOMMENDATIONS

1. **Conformity assessments:** conformity assessment certificates should initially be valid for up to 5 years. Following positive re-assessment they could become valid for an unlimited duration, unless the notified body decides to issue another time-limited certificate. The EU should maintain current approaches for conformity assessment, and the Commission should adopt a list of 'well established technologies'. The medical devices regulations should be kept in Section A of the AI Act, as was decided during the AI Omnibus negotiations.

2. **Clinical evidence:** the use of 'equivalence' to demonstrate compliance with safety and performance requirements should not be made easier, as this could compromise the quality of clinical evidence. For self-tests, there should be more stringent clinical evidence requirements. The Medical Devices Coordination Group (MDCG) should engage with the Health Technology Assessment (HTA) Coordination Group on evidentiary requirements and other topics of common interest.

3. **Innovation and devices for specific population groups:** manufacturers of 'breakthrough' and orphan devices should face specific post-market obligations; Sandboxes should come with stronger safeguards.

4. **Post-market surveillance:** Periodic Safety Update Reports (PSURs) should be updated more frequently than proposed by the Commission. Member States should facilitate user-friendly means for consumer reporting of safety incidents, and unannounced audits in manufacturers' sites should not need to be 'for cause'. The person responsible for regulatory compliance appointed by a manufacturer should be permanently available regardless of the company's size. Manufacturers must be capable to compensate consumers and patients for damages caused by defective devices.

5. **Product information and transparency:** the digital version of an implant card should complement, rather than replace, the paper format. These cards should be handed to patients

for all types of implantable devices. The EU should maintain at least the scope of devices for which manufacturers should develop at Summary of Safety and Clinical Performance (for medical devices) and a Summary of Safety and Performance (for in-vitro diagnostics). There should be additional transparency requirements on assessment reports and clinical studies.

6. **Device shortages:** Member States should set up public databases on shortages, and manufacturers be required to develop prevention plans.

7. **Patient and consumer engagement:** The MDCG should establish a dedicated working party to consult with patient, consumer, and healthcare professional organisations

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INTRODUCTION

Consumers and patients use a variety of medical devices in their daily lives. These range from hearing aids to contact lenses and dental and orthopaedic implants. Ensuring that medical devices and in vitro diagnostics are safe and perform well is crucial to improve health outcomes and people's quality of life.

In 2017, the EU legislative framework for devices was strengthened following some safety scandals.[1] The new Regulations on Medical Devices (MDR) and In Vitro Diagnostics (IVDR) enhanced the oversight of notified bodies, introduced stronger requirements on clinical evidence and post-market surveillance, as well as more transparency through EUDAMED.[2]

Despite continued efforts over the years from the European Commission and Member States to implement the Regulations, extended transition periods have prevented consumers from reaping their full benefits, such as greater transparency. In fact, EUDAMED may only become fully functional in 2027. In parallel, there have been reports of shortages and withdrawals of medical devices, without a clear understanding of the root causes. Availability problems have been reported particularly for some types of devices, such as for rare diseases.

BEUC supported the targeted evaluation launched by the Commission in 2024, to identify elements of the MDR and IVDR that work well, as well as any remaining challenges. The December 2025 legislative proposal to revise the Regulations includes several welcomed measures, particularly:

- Greater coordination between notified bodies and with the Medical Devices Coordination Group (MDCG).
- Requirement for Member States to ensure that competent authorities have enough technical, financial, and human resources to implement both Regulations.

[1] BEUC, *European Parliament vote: PIP scandal calls for stronger EU action* [Press release], 14 June 2012
[2] EUDAMED is a central platform for the exchange of information on devices between manufacturers, the Commission, competent authorities, and notified bodies. It is composed of six modules: 1. Actor registration, 2. Unique Device Identification (UDI) and device registration, 3. Notified bodies and certificates, 4. Clinical investigations and performance studies, 5. Vigilance and post-market surveillance, and 6. Market surveillance. It also consists of a public interface.

- More coordination amongst competent authorities on the regulatory status of products, including borderline cases.
- Greater role from the European Medicines Agency (EMA) in addressing device shortages beyond crisis situations.
- Specific scientific advice pathways for breakthrough and orphan devices.
- In case of online sales, new requirements for suppliers to provide certain information in the offer itself (e.g., manufacturer's details, instructions for use).

However, we are concerned about the scope and extent of the proposed simplification. The Commission's proposal goes beyond measures that would facilitate compliance with the safety requirements of the Regulations. In fact, some of the changes weaken both the pre-market assessment of devices and post-market surveillance, with their cumulative effects representing a step backwards. This applies to both to medical devices and in-vitro diagnostics (IVDs), a sector in rapid transformation. Over the last years, and particularly since the COVID-19 pandemic, the market for direct-to-consumer testing has expanded rapidly. The potential for consumer harm from poor quality self-tests is significant. False negative results may lead to missed diagnosis and skipped screening tests, while false positives can cause unnecessary worry and further testing. Instead of strengthening evidentiary requirements, the Commission's proposal goes in the opposite direction. This and other proposed measures do not make the regulations future proof, as they will fail to ensure a high level of consumer protection in light of new market trends.

In this briefing, we propose several improvements to the legislative proposal to ensure much needed public trust in the safety and performance of devices placed on the market.

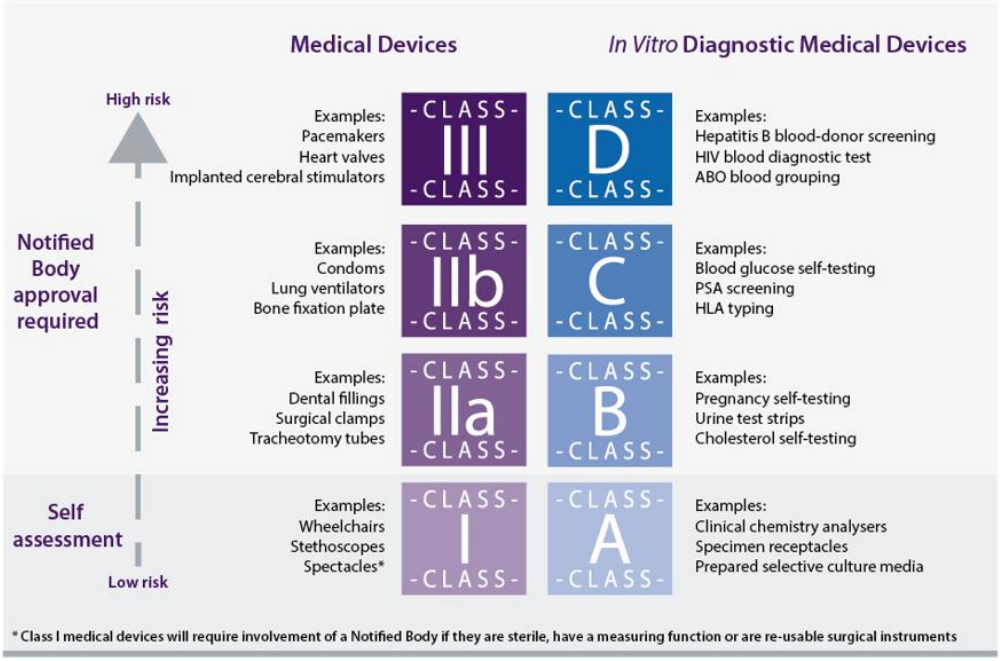

Figure from Payne, S., and Hall, A., *What is the IVDR? [Briefing]*, March 2018 (Adapted from the MHRA handbook). Available also on EUPATI's website here

PART 1 – KEY RECOMMENDATIONS

1.Conformity assessments

1.1. Validity of certificates

Under the current rules, the conformity certificates for medical devices and IVDs issued by notified bodies have a validity of up to five years. Manufacturers need to seek renewal thereafter on a recurring basis. Re-certification offers re-assurance that devices on the market continue to meet safety and performance requirements.

The Commission's proposal to remove the default maximum validity period of certificates risks increasing the chance of overlooked problems. We call for ensuring that re-assessment occurs at least once for each conformity assessment procedure. In addition, the proposal for notified bodies to conduct 'periodic reviews' of data gathered by the manufacturer's post-market surveillance system should be more prescriptive. We are concerned that neither the provisions on periodic reviews in the text nor in the Annex provide sufficient clarity on the process and frequency.

Recommendation

- Maintain the temporary validity (up to 5 years) of certificates. Following a positive re-assessment, the validity of certificates could become unlimited, unless the notified body decides on justified grounds to proceed with a time-limited certificate (point 47, amending Article 56 MDR and section 4.11 Annex VII; point 33 amending Article 51 IVDR and section 4.11 in Annex VII).
- Require the Commission to adopt an implementing act clarifying the frequency and modalities of the newly proposed periodic review requirement.

1.2. Representative sampling and Well-established technologies

The current legislation already provides some flexibility for manufacturers in conformity assessments - in some cases, the technical documentation does not have to be assessed by notified bodies for every individual device. This applies to some classes or types of devices (e.g., class IIb implantable devices considered "well-established technologies"), where the conformity assessment involves the review of the documentation of at least one representative device per generic device group, or at least one representative device for each device category.

The Commission proposes introducing further flexibility, which raises general concerns. We are particularly worried that class III well-established technology (WET) devices could, in the future, be placed on the market without prior review of their product-specific technical documentation. Given the high-risk profile of class III devices, we suggest maintaining a high level of regulatory scrutiny for all

types of devices in this group. We also call for preserving the current approach for other medical device classes as well as for IVDs.

In addition, we recommend developing an exhaustive list of WET devices, to ensure legal clarity and a harmonised application of the WET concept across the EU.

Recommendation

- Specify that the Commission *"shall, following consultation with the MDCG"* identify and publish an *"exhaustive list"* of devices that meet the criteria for well-established technologies (point 3, replacing Article 3 MDR). Devices that have been assessed for inclusion in the WET list, but have been rejected, should be mentioned in a separate list.
- Remove from the proposal the possibility for class III WET devices to benefit from an assessment of the technical documentation of one representative device per generic device group (point 43, amending Article 52 MDR).
- Maintain the current approach to conformity assessment for other medical devices and IVDs i.e., do not support the proposed flexibilities for class IIb and IIa medical devices, and IVDs class C and B (point 43, amending article 52 MDR; point 29 amending article 48 IVDR and point 6 in Annex II, amending Annex IX).

1.3. AI Act and medical devices

The AI Act's harmonised, risk-based horizontal framework ensures that AI systems placed on the EU market are subject to appropriate safeguards regardless of the sector they operate. It ensures that companies develop and deploy AI systems in a manner that upholds fundamental rights, consumer protection, safety and public trust.

When it comes to devices, the AI Act addresses the growing embedding of AI solutions into all types of medical devices, by regulating the AI-specific aspects and potential risks that sectoral legislation does not explicitly address and are key to ensuring safe and high-quality health care (e.g., bias mitigation, data training and validation).[3]

As part of the Digital Omnibus on AI, the European Commission proposes moving the MDR and IVDR from section A to section B of the AI Act. This would mean that the AI components of devices would no longer be directly regulated by the AI Act and subject to its high-risk requirements. Instead, they would be fall under tertiary legislation under the medical devices' regulations which do not provide similar safeguards. This could lead to serious regulatory gaps with direct and concerning consequences for consumers.

[3] CPME and HOPE, *Open letter to safeguard safe, transparent, and accountable AI for Medical Devices and In Vitro Medical Devices* [Letter], 10 March 2026

This proposal has already been discussed and freshly rejected by EU legislators. Co-legislators reached a provisional agreement on the AI Omnibus and rightly decided to maintain the AI Act rules applicable to AI-enabled medical devices. There is no justification for reintroducing this question in the context of the MDR revision. This process must not become an avenue to contradict a decision that already happened.

Recommendation

The MDR and IVDR should be kept in Section A of the AI Act, Annex I.

2. Clinical evidence

2.1. Clinical studies and equivalence

Today, manufacturers of implantable devices and class III devices may avoid conducting a clinical investigation (trial) if they demonstrate 'equivalence' to another device, including a device marketed by another manufacturer. This exemption is subject to some conditions. For example, the two manufactures must have a contract granting full access to the technical documentation of the first device. This helps verify that the applicable safety and performance requirements are met.

We are concerned that the Commission's proposal reduces requirements for clinical investigations and makes it easier to use the 'equivalence' route, as clinical evidence for high-risk medical devices has been found insufficient in many instances.[4] For the same reasons, we are also concerned about allowing a greater use of equivalence for demonstrating clinical performance for IVDs, and about insufficient requirements for the conformity assessment of self-tests.

Recommendation

- Maintain the current the conditions in Article 61(5) of the MDR that the manufacturer of an equivalent device must meet, to be exempted from conducting a clinical investigation (point 52, amending Article 61, paragraph 5).

- Keep the current requirement for demonstration of equivalence i.e., it should only be possible for devices that share the '*same*' materials or substances (biological characteristic) and '*same*' clinical condition or purpose, not '*similar*' (point 12 in Annex I of the EC proposal on the MDR, amending Annex XIV).

- For IVDs, clarify the concept of equivalence in a narrow and well-defined manner. As a rule, for self-tests at least, manufacturers should conduct a clinical performance study involving the intended population (add new requirement in point 10 in Annex II of the EC proposal on the IVDR,

[4] Fraser A, Buccheri S, Byrne R et al. Recommended methodologies for clinical investigations of high-risk medical devices—Conclusions from the European Union CORE–MD Project, The Lancet Regional Health – Europe, 2025; 58

amending Annex XIII section 1.2.3.). The conditions for possible exemptions should mirror those outlined in the MDR.

2.2. Cooperation with health technology assessment bodies

When the MDR and IVDR were adopted, there was no advanced framework of cooperation on health technology assessment (HTA) in the EU. Since 2025, HTA bodies from all Member States have come together to do joint clinical assessments for certain technologies under the HTA Regulation.

To ensure timely patient access to devices that bring added value, there should be a better alignment between the MDR, the IVDR and the HTA Regulations.

Recommendation

The Medical Devices Coordination Group should ensure appropriate consultation and exchange of information with the HTA Coordination Group on matters of common interest, such as on clinical evidence generation and the concept of 'well established technologies' (new addition in Article 103 MDR).

3. Innovation and devices for specific population groups

3.1. Breakthrough and orphan devices

The current regulations do not include specific provisions to facilitate access to devices for rare diseases, for which there have been availability-related challenges in the last years.

To address this, the Commission proposes introducing a specific pathway for scientific advice and conformity assessment for orphan devices, and for technologies introducing a high degree of novelty ('breakthrough'). Expert panels sitting at the EMA would be entrusted to issue an opinion on whether a specific device falls in one of those categories, and notified bodies should take it into account. This new pathway would allow manufacturers to place devices on the market with limited clinical data. We welcome these provisions but consider that stronger post-marketing requirements are necessary to ensure that manufacturers provide additional data.

Recommendation

- Require that if notified bodies accept limited clinical data for a 'breakthrough' or an orphan device, this is duly justified in their assessment report.
- Conformity assessment certificates for breakthrough and orphan devices shall go hand in hand with conditions to ensure that the manufacturer provides the additional data referred to in

paragraphs 7b of Article 52a (MDR) and 7b of Article 48a (IVDR), such as a requirement to conduct specific post-market clinical follow-up activities within a specified period of time, particularly for requested studies (point 44 inserting new Article 52a in MDR; point 30 inserting Article 48a in IVDR).

These recommendations should be read in conjunction with our proposals in point 1.1 on the validity of certificates.

3.2. Sandboxes

The European Commission introduces the possibility of establishing 'regulatory sandboxes'. This would allow for the testing and validation of new (innovative) products in an environment that is controlled and time-limited, yet with more flexible regulatory conditions. The legislative proposal needs some improvements to safeguard patients' safety. Co-legislators must ensure that sandboxes are not a shortcut to avoid regulation and are closely monitored by competent authorities throughout their duration.[5]

Recommendation

- A regulatory sandbox should allow for temporary adaptations – but not "*waivers*" - to the requirements set out in the regulations; it should operate fully in line with ethical principles. The national competent authority should closely monitor the sandbox throughout its duration (point 50 inserting new Article 59b in MDR; point 36 inserting new Article 54b in IVDR).
- The European Commission should, in consultation with Member States' competent authorities and based on their feedback, publish an annual report on the implementation and results of national and Union regulatory sandboxes. Such report should go hand in hand with a layperson summary (add new Article 59c in MDR; new 54c in IVDR with transparency measures).

4. Post-market surveillance

4.1. Periodic Safety Update Reports

Today, the manufacturers of class IIb and class III devices must prepare a periodic safety update report (PSUR) and update it at least once a year. PSURs provide a summary of the analysis of the post-market surveillance data gathered. The same applies to IVDs class C and D. For class IIa devices (e.g., hearing aids) manufacturers must update it at least every two years.

The Commission proposes that manufacturers update the PSUR less frequently; for class III and IIb devices, as well as for IVDs C and D, it would be updated in the first year after the certificate is issued,

[5] BEUC, When innovation means progress. BEUC's views on innovation in the EU [position paper], November 2019

and then every two years or *"when there is a significant change in the benefit-risk determination or in the acceptability of undesirable side-effects/erroneous results"'*. Regarding class IIa devices, the Commission proposes updating the certificate only *"when necessary"*.

We find the new approach too permissive, particularly in light of the Commission's proposal to eliminate the re-assessment of devices by default. We are also concerned with letting manufacturers determine if there is a significant change in benefit-risk for PSURs to be updated – this provision gives too much discretion to entities with direct commercial interests.

Recommendation

- For class III and class IIb devices, require that the PSUR is updated at least annually until the certificate becomes unlimited in time and every two years thereafter or earlier if post-market information suggests a "~~*significant* "~~*change"* in the benefit-risk determination or in the acceptability of undesirable side-effects (point 67 amending Article 86 MDR). The same should apply to IVDs D and C, and also to all devices intended for self-testing (point 53 amending Article 81 IVDR).
- For class IIa devices, the manufacturer should update the PSUR in the first two years after placing the device on the market or earlier, and thereafter, if post-market information suggests a "~~*significant* change~~"' in the benefit-risk determination or in the acceptability of undesirable side-effects.
- For orphan or breakthrough medical devices and IVDs, the PSUR should be updated at least annually until the certificate becomes unlimited in time. After that, according to the class to which the device belongs.
- In addition, the revised legislation should allow the notified body or a competent authority to require, at any time and for any of these classes of devices, an updated PSUR from the manufacturer. The grounds for such requests could be outlined in an implementing act.
- We support the Commission's proposal to require manufactures to update the PSUR of legacy orphan devices at least annually (point 95, adding new paragraphs in Article 120 MDR; point 78 in Article 110 IVDR).

4.2. Consumer and patient reporting of safety incidents

Both, the MDR and the IVDR, mandate Member States to take appropriate measures, such as targeted information campaigns, to encourage and enable healthcare professionals, users and patients, to report suspected serious incidents. However, the regulations do not explicitly require setting up 'user-friendly' reporting systems. The ongoing revision brings an opportunity to improve these processes for consumers and patients, and reporting levels.

Recommendation

Require Member States to facilitate reporting through the provision of alternative reporting formats in addition to user friendly web-based formats (new addition in Article 87 paragraph 10 MDR, and Article 82 paragraph 10 IVDR).

4.3. Audits

Based on important learnings from safety scandals, the current legislation improved oversight. Notified bodies must conduct random unannounced audits on-site at least once every five years and, if needed, of the manufacturers' suppliers and subcontractors.

The Commission's proposal to limit unannounced audits to 'for cause' situations in the future – triggered only by post-market surveillance concerns or request from competent authorities - is a step backwards. Waiting until signals are available before being able to carry out unannounced inspections unfortunately means that consumers and patients may have already been harmed.

Recommendation

Maintain the current obligation for notified bodies to randomly perform unannounced audits on the site of the manufacturer and, where appropriate, of the manufacturer's suppliers and/or subcontractors (Annex IX, section 3.4 MDR; and Annex IX section 3.4 IVDR).

4.4. Regulatory compliance

The Commission's proposal to remove the detailed qualification requirements of the person appointed by a manufacturer/authorised representative to ensure regulatory compliance raises safety concerns; there is a risk that the responsible person may not be sufficiently qualified to ensure compliance.

We are also concerned that SMEs relying on an external expert for such a task would only be required to ensure the expert is available, instead of *"permanently and continuously"* available. If serious issues arise, it is important to react quickly, regardless of company size.

Recommendation

Maintain the list of formal qualifications that the person responsible for regulatory compliance must have, as well as the current obligations for SMEs (point 13 amending Article 15 MDR and point 13 amending Article 15 IVDR).

4.5. Compensation in case of damage to consumers

The MDR and IVDR require manufactures to have measures in place to provide sufficient financial coverage in case of damage caused by a defective device, in a way that is proportionate to the risk class, type of device, and enterprise size.

The Commission's proposal deletes this provision, as well as the requirement for competent authorities to facilitate access to device-related documents to a potentially injured patient or user, or other parties affected by the damage caused by a device believed to be defective. The Commission has not justified these concerning deletions in the published proposals.

Recommendation

Maintain the current provisions in paragraphs 14 and 16 of Article 10, MDR, and in paragraphs 13 and 15 of Article 10, IVDR. Manufacturers must always be able to compensate consumers for damage their devices may have caused.

5. Product information and transparency requirements

5.1. Implant card

Manufacturers of implantable devices must provide patients with an 'implant card' with information that allows a clear identification of the device. For example, its name, unique device identifier (UDI), and the manufacturers' name and contact details.

The Commission's proposal to facilitate that manufacturers can make this information available only in digital form risks undermining the rights of patients who have limited digital skills or limited access to digital tools. Both means of information should be complementary.

We also consider that patients should receive an implant card for all implantable devices that are well-established technologies.

Recommendation

- Specify that digital means of information should complement, but not replace, paper formats (point 16, amending Article 18 MDR). Require that digital technologies ensure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and do not allow the identification, profiling or tracking of individuals, nor be used for commercial purposes including for advertising or marketing activities.
- Delete the exemption of implantable WET devices in point 16b of the Commission's proposal and in paragraph 3 of the MDR.

5.2. Summary of safety and clinical performance

For standard implantable devices and for class III devices, manufacturers must draft a summary of safety and clinical performance (SSCP). It includes relevant information such as any contra-indications and warnings, the description of the device, and an overview of the clinical evidence supporting it. This document must be publicly available in EUDAMED.

The proposal to remove the obligation to develop and publish an SSCP for class IIa implantable devices and WET devices is an unacceptable step backwards. Reducing the level of transparency undermines consumers' right to information and public trust in the system. The same goes for the Commission's proposal to reduce the scope of class C IVDs for which manufacturers must draw up and make publicly available a Summary of Safety Performance (SSP). Ideally, co-legislators should expand the transparency measures.

Recommendation

- Maintain the current requirements on SSCP in terms of scope (i.e., standard implantable devices and class III devices) and writing style (i.e., understandable to patients) – point 24 amending Article 32 MDR.
- Keep the current obligations for manufacturers in relation to the SSP, specially regarding the established scope and writing style. Expand the obligation to all devices intended for self-testing (point 22 amending Article 29 IVDR).

5.3. Assessment reports, study 'protocols' and results

Currently, the legislation does not mandate the publication of the Clinical Evaluation Assessment Report (CEAR) from notified bodies for the medical devices they assess. Lack of transparency prevents a clear understanding of the rationale for conformity assessments and hinders public scrutiny on those evaluations – unlike in the pharmaceutical regulatory framework. The same occurs for IVDs.

Recommendation

- Require the publication of the CEAR, together with a layperson's summary, at time of publication of the conformity assessment certificate in EUDAMED (new addition in section 4.6, Annex VII MDR referring to Article 33).
- The same requirement should apply for IVDs, in relation to the Performance Evaluation Assessment Report (new addition in section 4.6, Annex VII IVDR).

Regarding clinical investigations, it is important to ensure that summary results of clinical trials – whether positive or negative - are published within one year of the end of the trial and to mandate the publication of trial protocols, similarly to medicines.[6] [7] Greater transparency on trials supports medical research and enables more informed decisions by trial participants and patients. This also applies to IVDs regarding performance studies (falling in the scope of Article 58).

Recommendation

- Require the publication of the summary of the clinical investigation immediately after the sponsor has submitted it to the Member State in which the trial was conducted (i.e., within one year of the end of the trial regardless of study outcomes). It must be publicly available by the time the device is registered and before it is placed on the market, in all cases. For paediatric clinical investigations, summary results should be submitted and published 6 months after the end of the trial, similarly to medicines (amend Article 77 MDR).[8]
- Mandate the publication of clinical investigation plans at the time of trial application decision, as requested for medicines (new requirement in Articles 72 and 73).
- Mirror these recommendations in the IVDR (new requirements in Articles 68, 69 and 73 IVDR).

6. Shortages

6.1. Shortage prevention

Shortages of medical devices are a widespread issue today. A recent survey from community pharmacists shows that 60% of responding countries experienced shortages in 2025, affecting all classes of medical devices.[9] Similarly, another survey found that that medical devices shortages pose a significant challenge: 53% of hospital pharmacists reported that they hinder the delivery of best care to patients.[10]

The Commission's proposal includes the possibility of requiring manufacturers to share information on supply chain risks and weaknesses for certain devices. While this is a positive step, this measure alone

[6] European Commission, *European Medicines Agency and Heads of Medicines Agency, Revised CTIS Transparency Rules*, 5 October 2023

[7] The WHO recommends that for every clinical trial, summary results are publicly reported within 12 months of study completion. However, the MDR allows a two-year publication delay for the summary results of devices that do not end up being (timely) registered.

[8] These recommendations are without prejudice to the current requirements for earlier reporting and publication in the event of early termination or temporary halth of the trial.

[9] PGEU, *PGEU Medicine Shortages Report 2025*, 2026

[10] EAHP, *EAHP 2025 Shortages Survey Report*, November 2025

is insufficient to prevent shortages. What is needed is that manufacturers identify any risks early on and adopt proactive and concrete measures to address such vulnerabilities.

Recommendation

Require the manufacturers of medical devices that fall in the scope of Article 10a to develop shortage prevention and management plans; the content of such plans should be defined through an implementing act (new addition in Article 10a MDR and 10a IVDR).

6.2. Reporting the interruption or discontinuation of devices

Under current rules, manufacturers must report a temporary supply disruption or discontinuation when this could lead to serious harm or a risk of serious harm to patients or public health. Such information must be reported at least six months in advance of the anticipated situation.

The Commission proposes that, where it is not possible to report with such advanced notice, the manufacturer notifies "without undue delay" when they become aware of the anticipated interruption or discontinuation. To avoid abuses, we propose specifying that this should be exceptional and that manufacturers must justify the reason that prevented earlier notification to the competent authority.

Recommendation

Specify that where it is not possible to report a disruption or discontinuation of the supply six months in advance, the manufacturer must do so without undue delay *"as soon as it becomes aware of the anticipated interruption or discontinuation where exceptional circumstances directly related to the supply interruption or discontinuation, which shall be duly identified and substantiated to the competent authority concerned, prevented the manufacturer from complying with the deadline"* (new addition in Article 10a MDR, and Article 10a IVDR).

6.3. Public communication on shortages

The current legislation does not mandate Member States to inform patients and consumers about the shortage of medical devices. Consumers, patients, and healthcare professionals need this information however to manage shortages effectively and plan appropriate alternatives.

Recommendation

Mandate Member States to set up user-friendly public databases that inform patients, consumers, and healthcare professionals on the discontinuation or interruption of devices notified under Articles 10a of the MDR and IVDR.

7. Patient and consumer engagement

The revision of the MDR and IVDR brings an opportunity to strengthen engagement with patients, consumers, and healthcare professionals, while preventing conflicts of interest. We strongly recommend establishing a specific platform for exchange and discussion between competent authorities and stakeholders, similar to the European Medicines Agency's working parties.

Recommendation

Mandate the MDCG to establish a working party composed of representative umbrella organisations of patients, consumers, and healthcare professionals (Article 103 MDR).

ENDS