BEUC The European Consumer Organisation

The Consumer Voice in Europe

Recommendations

For a targeted revision of EU medical devices rules

October 2025

Why it matters to consumers

Consumers use a wide range of medical devices in their daily lives to walk, keep their heart beating, or check their glucose levels for instance. If the performance of these products is low, they can disrupt consumers' health and quality of life.

Ensuring that devices are safe, effective, and available for consumers contributes to the EU's healthcare quality. This calls for better pre-market assessment and market surveillance in the EU, and adequate shortage prevention and mitigation measures. It also means that consumers should have access to clear information and adequate shortage and safety reporting mechanisms to communicate with public authorities.

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The European Consumer Organisation, BEUC, herewith provides comments on the European Commission's plans to revise the regulations on medical devices (MDR) and in vitro diagnostics (IVDR).

Ensuring access to safe and effective medical technologies is essential for delivering high-quality healthcare. The 2017 revision of the EU rules on devices and IVDs was necessary to reinforce public trust in the approval and post-market surveillance systems for these products. BEUC strongly welcomed the increased focus on consumer protection in the new regulations.

While we acknowledge the efforts made over the last years by the Commission and the Medical Devices Coordination Group to implement the MDR and IVDR, the extended transition periods means that consumers have not yet reaped the full benefits they can bring.

In addition, in recent years, there has been growing attention to the shortage and withdrawal of medical devices, the root causes of which are not always clear. While this issue affects different types and classes of products, availability problems seem more acute for devices intended for paediatric use and rare diseases. Moreover, public communication on shortages is far from optimal. BEUC members have also reported about unsafe aligners sold online and concerning business practices in this sector – highlighting the need for close oversight (see here and here).

BEUC has been supportive of the European Commission's evaluation of the regulations to assess whether identified challenges can be addressed within the current legal framework – or some changes are needed.

As the Commission outlines its plans to revise the legislation, we call for an evidence-based approach that places consumers at the centre by ensuring the following:

BEUC RECOMMENDATIONS

Consumer safety

1 Maintain at least the safety standards set by the 2017 revision, and ensure adequate post-market surveillance and response - irrespective of the various sales channels, including online marketplaces; national competent authorities should have greater oversight capacity. Facilitate that consumers can easily and effectively report safety incidents to competent authorities across Member States.

Evidentiary requirements and transparency

2 Strengthen evidentiary requirements (high quality clinical investigations) and enhance transparency, aligning with the more robust transparency standards set by the Clinical Trials Regulation[1]. Mandate the publication of clinical evaluation reports and clinical assessment evaluation reports.

Coordination

3 Facilitate implementation by enhancing coordination between national competent authorities, the European Commission, notified bodies, expert panels and EMA. Guarantee that the reinforced structure is led by public authorities.

Safe use device instructions

4 Ensure that devices come together with written information on their safe use; electronic information should complement, not replace, the paper version of the instructions for use. Digital tools must be privacy friendly.

Shortage prevention and communication

5 Introduce measures that contribute to shortage prevention, improved mitigation, and effective public communication; require Member States to set up user-friendly databases with information on the devices marketed in their

[1] Trial protocols should be published at the time of decision on trial authorisation. For completed trials, summary results should be published no later than 12 months after the trial ends (6 months for paediatric trials) – and in any case, before the device enters the market.

country and any shortages. Facilitate consumer-friendly reporting mechanisms across Member States.

Privacy

6 Guarantee that health apps and AI systems used for medical purposes safeguard data privacy and security, while ensuring reliability and transparency.

Alignment with other EU legislation

7 Ensure adequate alignment with other relevant EU legislation, such as the general pharmaceutical legislation (e.g., to address gaps regarding borderline products), the Regulation on Health Technology Assessments, and the Regulation reinforcing the EMA's role in crisis preparedness and management for medicines and devices.

In addition, we call for any simplification exercise to focus on facilitating the implementation of the legislation and the attainment of a high level of health protection for patients and consumers.