MEDICAL DEVICES AND IN VITRO DIAGNOSTICS REGULATIONS

Key points for consumers

BEUC The European Consumer Organisation

The Consumer Voice in Europe

Why it matters to consumers

From basic care to life-saving treatments, around two million different types of medical devices shape patient and consumers' daily lives worldwide. The revision of the EU legislative framework in 2017 was a necessary step to enhance patient safety after past scandals across Europe like faulty breast implants illustrated that weak rules put consumers at real risk. Despite some enhanced coordination efforts between national authorities, the European Commission's current proposal to amend these rules risks reversing previous patient safety gains by simplifying rules too far.

Read our position paper

The table assesses the proposals with the following symbols, illustrating:

 what BEUC supports

 what can be improved

 what BEUC considers problematic

COMMISSION PROPOSAL	BEUC POSITION
SHORTAGES The proposal strengthens EU coordination to address shortages of critical devices and enables national authorities to request manufacturers' information on **any supply-chain risks and weaknesses**.	The proposal should go further to improve prevention and mitigation: • Manufacturers must develop **shortage prevention and management plans**. • Only defined exceptional circumstances (e.g. natural disaster, trade restrictions) should justify the absence of early **shortage reporting**, to prevent manufacturers from over-delaying their duties. • For better **public communication**, national user-friendly public databases should grant patients and healthcare professionals access to shortage information.
CONFORMITY CERTIFICATES' VALIDITY The proposal removes the safety re-assessment after five years by default, validating certificates unlimitedly in practice.	The EU should **maintain the first validity re-assessment after five years**. This will avoid over-relying on **less comprehensive** post-market **checks to** remove unsafe **or underperforming** devices from use. To simplify rules, this mandatory re-assessment could trigger unlimited validity, unless the authority deems the product does not fully comply with safety requirements.
SAMPLING AND WELL-ESTABLISHED TECHNOLOGIES[1] (WET) The Commission grants more flexibility on how notified bodies review some devices' performance and safety information during conformity assessments. This means that for WET and other devices, notified bodies will only have to assess one representative sample product's information, which risks overlooking potential issues.	The EU should **maintain the current conformity assessment approach** for medical devices and in-vitro diagnostics. Notified bodies should **review each high-risk WET** product's technical documentation. The Commission must consult the Medical Devices Coordination Group (national competent authorities) to create an **exhaustive list** of devices that meet the criteria for well established technologies. This will add legal clarity and harmonise the application of this concept.

[1] Devices with a simple, stable design, a long history of safe use, and well-known clinical performance

COMMISSION PROPOSAL	BEUC POSITION
ARTIFICIAL INTELLIGENCE (AI) The Commission proposes removing medical devices from the AI Act's strongest high-risk requirements, and get them regulated under sectoral laws legislation.	To protect patients, policymakers must regulate devices **under the AI Act's strictest high-risk requirements**. Sectoral legislation will decrease safety levels.
EQUIVALENT DEVICES Currently, manufacturers of implantable and high-risk medical devices may skip clinical trials if there is an 'equivalent' device on the market and share information among themselves. The proposal makes it easier for manufacturers to choose this route.	The EU should maintain its current equivalence rules, meaning an equivalent product must be the **same, not only similar when it comes to biological and clinical characteristics**. Manufacturers producing equivalent medical devices should have a contract granting full access to the original device's technical documentation, to verify that new devices meet the applicable safety and performance requirements.
IMPLANT CARD INFORMATION The Commission's proposal would allow making key information that **patients** receive directly on their **implanted medical devices accessible online only**.	To safeguard patient' safety and easy access to information, manufacturers must ensure that both, **paper and digital implant cards**, are available. Digital formats must be privacy-friendly.
INNOVATION To facilitate patients' timely access to **orphan and breakthrough devices,** the proposal can allow these devices to be placed on the market with limited clinical data. The proposal also introduces regulatory **sandboxes** to test innovative devices under flexible, time limited rules.	To combine patient safety and innovation: • Notified bodies must duly justify in their assessment reports any decision to allow a device on the market based on limited clinical data. • Manufacturers must provide the missing data through specific post market requirements. Regulatory sandboxes must: • Include strong safeguards, ethical principles, and close authority monitoring; • Only allow temporary adaptations, but never full "*waivers*" to the current rules.
POST-MARKET SURVEILLANCE The Commission is simplifying post-market surveillance rules: Periodic Safety Update Reports (PSURs), random on site audits, and damage compensation mechanisms.	• The co-legislators should tighten the rules on PSURs to avoid missing new data that is relevant for patients safety. PSURs should be prepared for all devices intended for self-testing. • Member States should set up user-friendly incident reporting systems to make it easier for patients to do so. • Authorities must remain able to randomly conduct unannounced audits at any manufacturer's site. • Manufacturers must ensure they have sufficient financial coverage to compensate consumers harmed by a defective device

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