The Sound of Brussels

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Hearing You

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In Focus

European Parliament backs MDR simplification, but key details remain contested

The revision of the Medical Devices Regulation (MDR) is moving forward in the European Parliament. Following the publication of Parliament's first draft position in June, Members of the European Parliament have now submitted their amendments, providing a clearer picture of where there is political agreement and where important differences remain.

There is broad support for the overall objective of simplifying the MDR and reducing unnecessary administrative burden. Renew and independent MEPs have proposed making reliance between notified bodies mandatory to avoid duplicate checks. MEPs are also calling for greater use of internationally recognised standards and closer cooperation with regulators outside the EU.

At the same time, Parliament appears more cautious about some of the European Commission's more far-reaching simplification proposals. One important example concerns the validity of medical-device certificates. The Commission proposed removing the current five-year expiry period, but most political groups favour retaining periodic reassessments for certain higher-risk products, including some Class III devices and implants.

The treatment of AI-enabled medical devices also remains politically contested. The Commission proposed bringing certain requirements for medical-device AI more directly into the MDR framework, with the aim of reducing overlap with the EU AI Act. Schenk's (EPP) draft report supports the transfer but several S&D and Green MEPs oppose it.

Another debate concerns so-called "well-established technologies". The Commission proposed a more flexible, criteria-based approach for determining which technologies qualify, rather than relying only on predefined lists. The Greens favour keeping a restrictive list-based system, while Schenk (EPP) supports the more flexible approach. The outcome will determine how broadly established medical technologies can benefit from more proportionate regulatory requirements.

The overall direction of the revision nevertheless remains focused on simplification. Parliament will now work towards compromises between the political groups, with a vote in the responsible committee expected in January 2027.

Digital Omnibus negotiations move towards a more cautious approach to GDPR reform

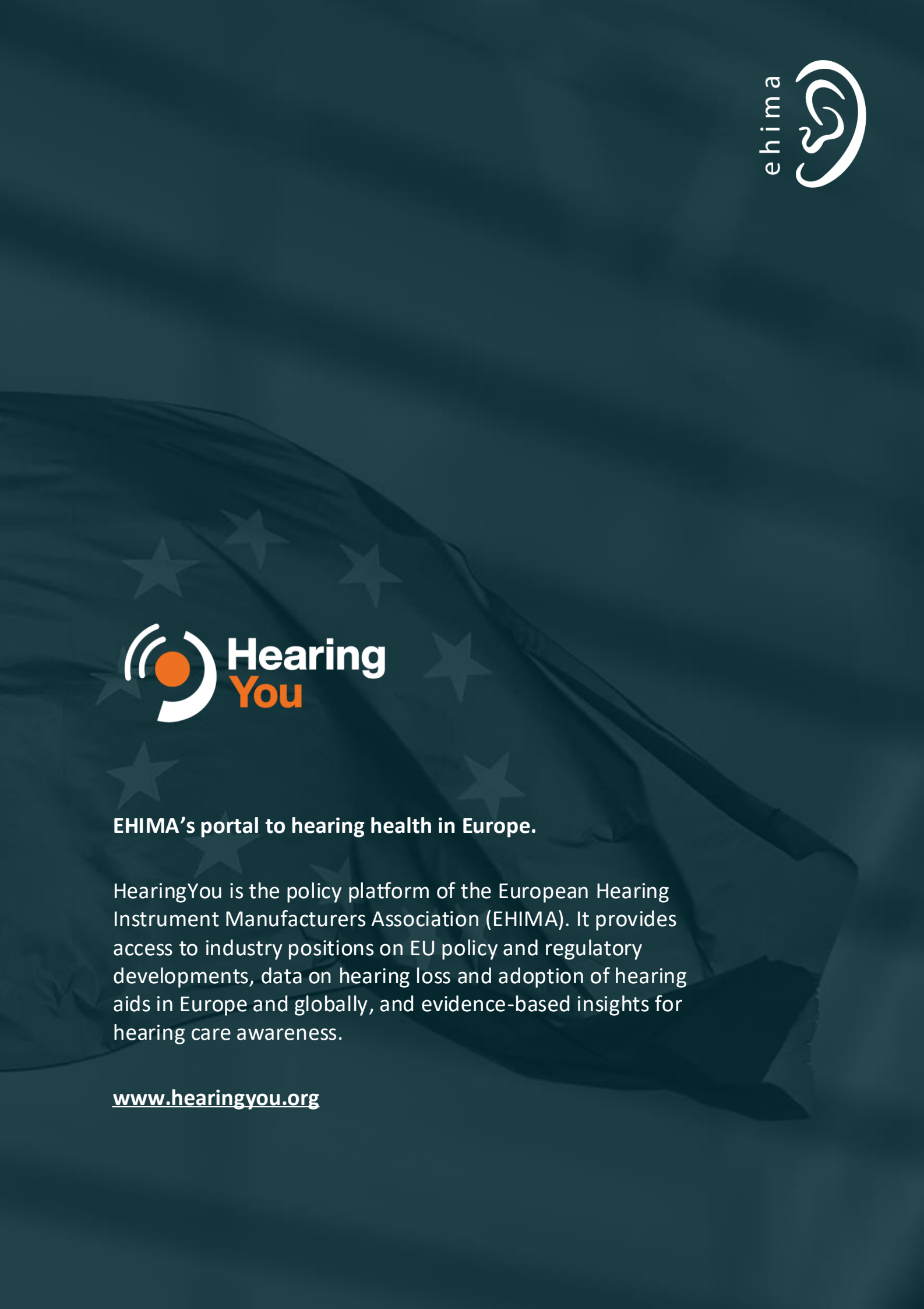
Negotiations on the EU's Digital Omnibus are continuing, with both EU Member States and the European Parliament taking a more cautious approach to changes to the General Data Protection Regulation (GDPR) than initially proposed by the European Commission.

The Digital Omnibus is intended to simplify several pieces of EU digital legislation, including the GDPR, the Data Act and the ePrivacy Directive. A central part of the current debate concerns pseudonymised data — data where identifying information has been removed or separated — and the conditions under which personal data can be used for the development and training of artificial intelligence systems.

The Commission had proposed making it easier to rely on "legitimate interest" as a legal basis for using personal data in AI development. Member States are favouring a more cautious approach, under which organisations would continue to assess on a case-by-case basis whether their legitimate interests justify the use of personal data.

A similar debate is taking place in the European Parliament. There is resistance to changing the GDPR's existing definition of personal data, although political groups remain divided over how far the Digital Omnibus should go in facilitating the use of pseudonymised data, scientific research and AI development. More than one thousand amendments were submitted in July, and compromise negotiations are expected to continue after the summer.

The emerging direction therefore points towards more targeted changes rather than a broad rewriting of the GDPR. In particular, the final rules will need to clarify when pseudonymised information can be considered no longer identifiable and how these provisions interact with other EU data rules. Negotiations continued through August, but neither the Council nor the European Parliament has yet agreed its final position.



EHIMA's portal to hearing health in Europe.

HearingYou is the policy platform of the European Hearing Instrument Manufacturers Association (EHIMA). It provides access to industry positions on EU policy and regulatory developments, data on hearing loss and adoption of hearing aids in Europe and globally, and evidence-based insights for hearing care awareness.

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