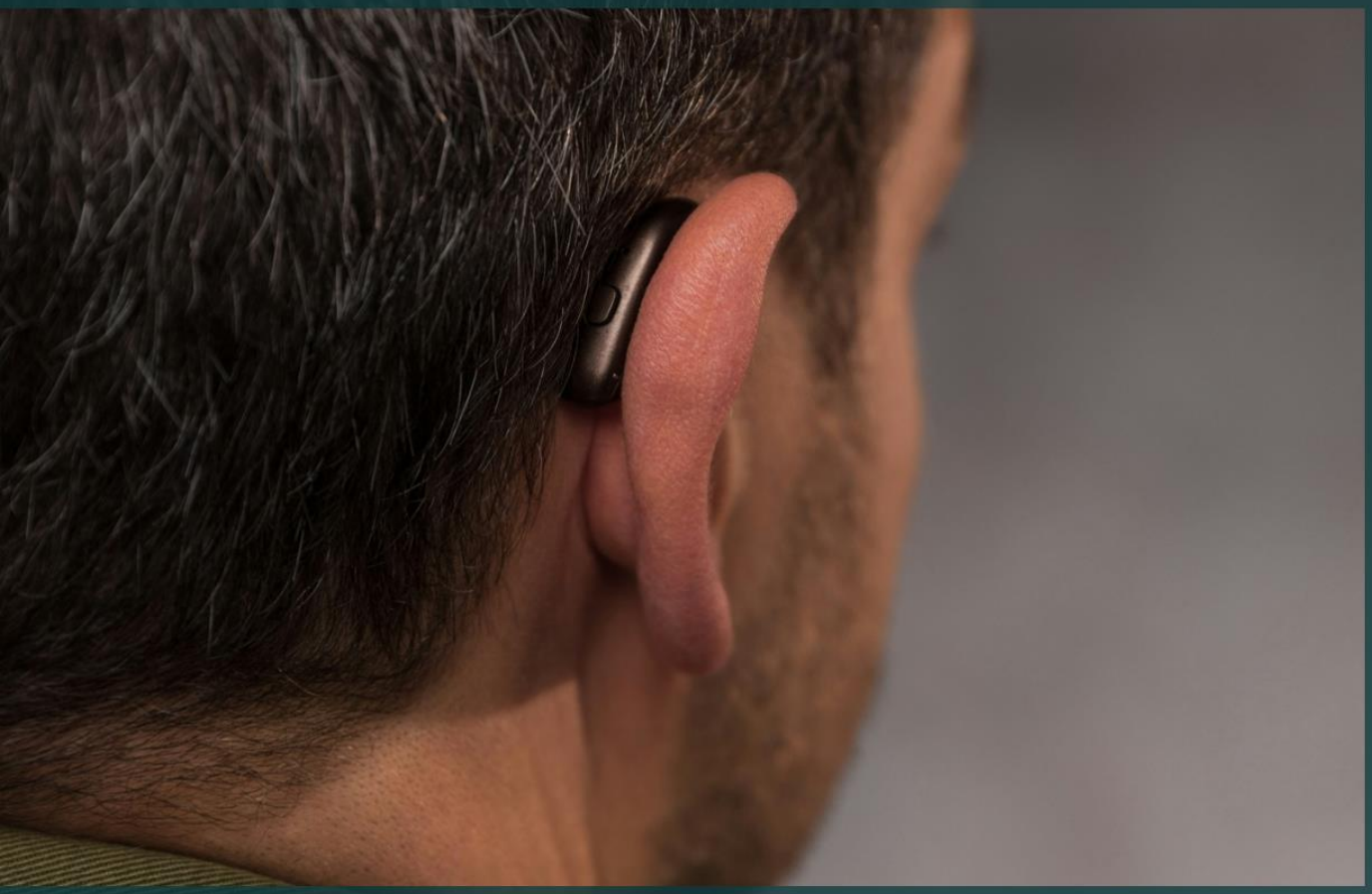
The Sound of Brussels

The monthly EU policy bulletin of the European Hearing Instrument Manufacturers Association (EHIMA)

November 2026



Hearing You

www.hearingyou.org
EHIMA's portal to hearing health in Europe

In Focus

MDR revision advances towards a year-end Council position as Parliament works towards its mandate

The revision of the EU Medical Devices Regulation continued to move forward in October, although the Council and European Parliament remain at different stages of the process.

In the Council, the Irish Presidency is aiming to secure agreement among Member States on a common position by the end of December. EU ambassadors broadly supported that timetable on 14 October, and national officials have continued technical discussions on a revised Presidency draft.

The European Parliament is less advanced. Its lead health committee has not yet adopted a report, meaning Parliament does not yet have a negotiating mandate. October also brought a change in the internal market committee, which is providing an opinion on the file, with Anna Cavazzini (Greens/EFA, Germany) replacing Maria Guzenina (S&D, Finland) as rapporteur.

The next step in the European Parliament is for the health committee to agree and vote on its position. A plenary vote is currently indicated for 14 December 2026, but this depends on the committee stage being completed in time.

November will therefore be an important month for both institutions. If the Council reaches a general approach in December, Member States would have a formal mandate for negotiations. Parliament must still complete its own position before interinstitutional talks on the final MDR revision can begin.

Commission prepares new equality-data recommendation with a focus on disability evidence

The European Commission is preparing a new Recommendation to improve the collection and use of equality data, with adoption expected in the third quarter of 2027. The non-binding initiative is intended to make information on discrimination and inequalities more available and comparable across the EU.

The work forms part of the wider Union of Equality agenda and follows the Commission's commitment to strengthen disability data, including more detailed indicators by type of disability. For hearing health, this could help address gaps in existing statistics: EU datasets can identify functional difficulties such as hearing, but the same level of detail is not consistently available across disability data.

The Commission's current approach also encourages Member States to combine official statistics with other evidence sources, including surveys, research and data from civil-society organisations and service providers.

Council agrees Digital Omnibus mandate, setting out its position on pseudonymised data and AI

The Council agreed its negotiating mandate on the Digital Omnibus on 21 October, establishing a common Member State position on proposed changes to EU data protection, privacy, data and cybersecurity rules. The European Parliament must now agree its own mandate before negotiations on the final legislation can begin.

On pseudonymised data, the Council keeps the existing definition of personal data but clarifies that data may fall outside the GDPR for a third party that cannot identify the person using means reasonably likely to be available to it. The text cites the European Health Data Space prohibition on re-identification as one example of a legal barrier that may be relevant to that assessment, while retaining safeguards and calling for further guidance.

The mandate also clarifies the treatment of scientific research and AI. Personal-data processing for AI may rely on legitimate interest where appropriate, but only after a case-by-case assessment. For incident reporting, the Council proposes national entry points supported by an EU information point and would extend the GDPR breach-notification deadline to 96 hours for breaches likely to create a high risk. The text remains subject to negotiations with Parliament.



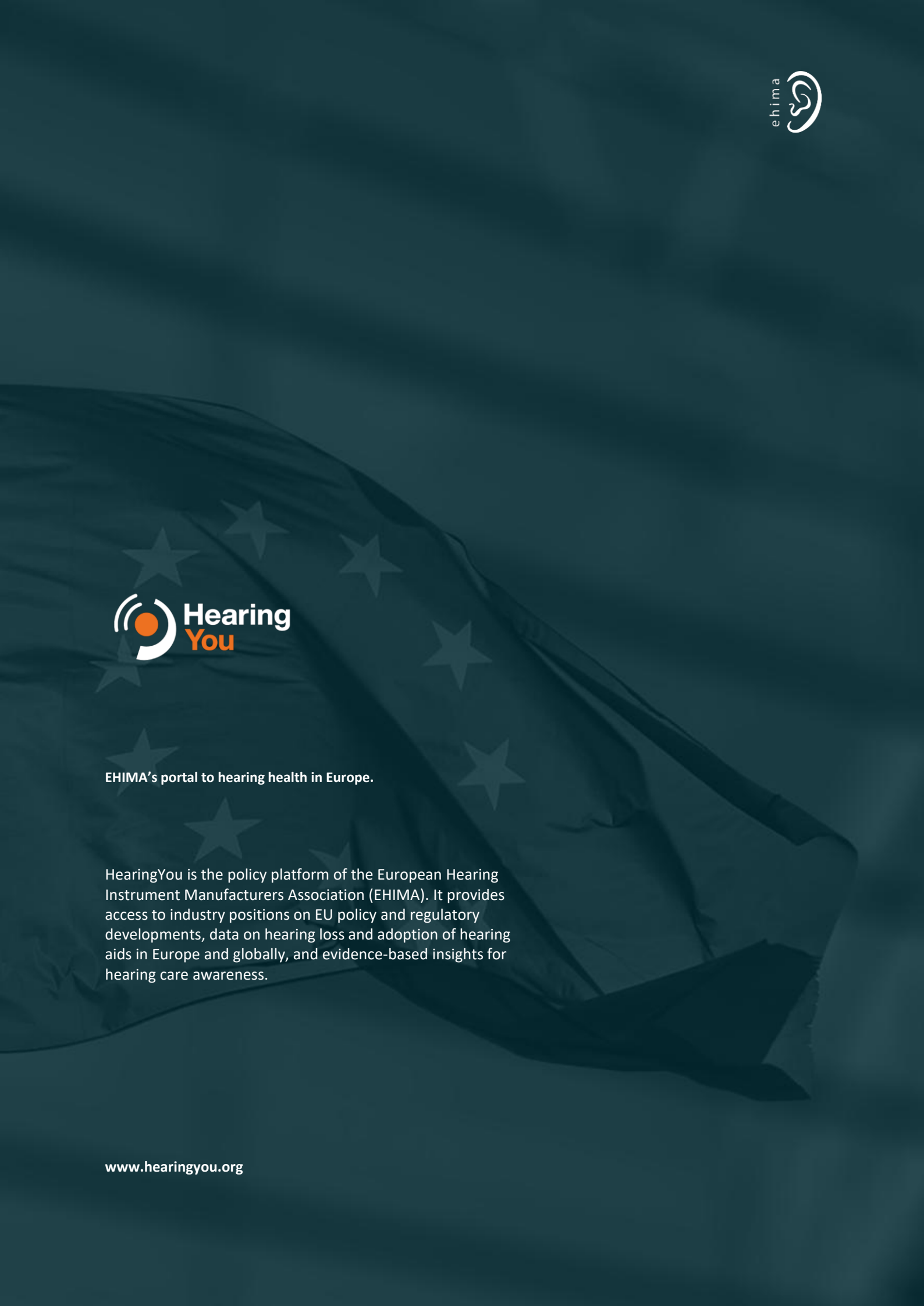
European Disability Forum highlights barriers to assistive technology access and calls for stronger EU coordination

The European Disability Forum published a review of assistive technology access across the EU on 22 October, comparing national systems and identifying a fragmented landscape for people who rely on assistive products and services.

The review points to several recurring barriers: restricted product choice linked to pre-approved lists; insufficient funding; limited information and expert advice for users and authorities; and gaps in maintenance and support. It also finds that differences in national rules and funding can make smaller markets less attractive to suppliers, reducing the range of solutions available.

The paper does not propose a single European provision system. Instead, it calls for stronger EU-level coordination through an Assistive Technology Single Market Action Plan, common principles for person-centred provision and measures to improve cross-border access. It also recommends action on procurement, the assistive-technology workforce and the evidence base.

The recommendations add to a wider EU debate about how to reduce fragmentation while leaving the organisation and financing of support systems largely at national level.



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.

www.hearingyou.org