# The Sound of Brussels

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

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Hearing You

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# In Focus

## MDR revision moves forward as Parliament backs broad simplification, with AI emerging as the key dividing line

The revision of the Medical Devices Regulation (MDR) has reached an important new stage. On 30 June, European Parliament rapporteur Oliver Schenk presented his draft negotiating position, setting out Parliament's first detailed response to the European Commission's proposal. Overall, the draft strongly supports the Commission's objective of simplifying the MDR and reducing regulatory burden, particularly for lower-risk medical devices. It retains several important elements of the Commission proposal, including removing the five-year validity period for certificates, simplifying clinical evidence requirements and formally recognising the concept of "well-established technologies".

The report also proposes changes aimed at making the regulatory system more predictable. Manufacturers would have a stronger role when national authorities disagree over the classification of a device. Where a manufacturer and notified body disagree over classification, an independent expert panel could issue a binding decision. The draft also seeks to reduce duplication in conformity assessments by requiring notified bodies to recognise documentation already assessed by another notified body and focus their review on critical safety and performance elements.

At the same time, the rapporteur proposes retaining some requirements that the Commission had sought to simplify. These include liability provisions for manufacturers and authorised representatives, implant cards for well-established technologies and an initial post-market safety update for certain Class II devices.

The proposal has, however, encountered opposition from Social Democrat and Green MEPs. Their concern is that moving these requirements into the MDR could weaken the horizontal safeguards established under the AI Act. Several European healthcare organisations have also raised concerns about this approach.

So far, there has been no fundamental challenge in Parliament to the broader objective of simplifying the MDR. The AI/MDR interface therefore looks set to become the main issue to resolve when negotiations resume after the summer. MEPs can now table amendments to the draft report, after which the rapporteur will seek to build a majority around a final parliamentary position. A vote is expected around the end of 2026 or beginning of 2027.

## WHO strengthens the role of hearing care in dementia risk reduction

The World Health Organization (WHO) has updated its global guidelines on reducing the risk of cognitive decline and dementia, giving hearing care a more prominent role than in its previous guidance. For the first time, the WHO says that hearing aids may be offered to adults with hearing loss as part of efforts to reduce the risk of cognitive decline and dementia. This represents a change from its 2019 guidance, which concluded that there was insufficient evidence to recommend hearing aids for this purpose.

The new recommendation remains conditional. The WHO stresses that evidence for a direct causal relationship between hearing loss and dementia remains weak and that further research is needed to determine whether hearing aids can alter the trajectory of cognitive decline. However, the WHO points to the wider relationship between hearing health and healthy ageing. Hearing loss can contribute to social isolation, poorer mental well-being and reduced physical activity, which are themselves recognised risk factors for dementia. The updated guidance therefore places hearing care within a broader healthy-ageing approach rather than recommending hearing aids solely as a dementia-prevention measure. It complements existing WHO recommendations on hearing screening and personalised hearing interventions for older adults.

## AI Act deadline for high-risk systems in medical devices confirmed for August 2028

The relevant requirements will apply from 2 August 2028, including for high-risk AI systems embedded in regulated products such as medical devices. Earlier proposals to link the deadline to the availability of technical standards were dropped in favour of a fixed date.

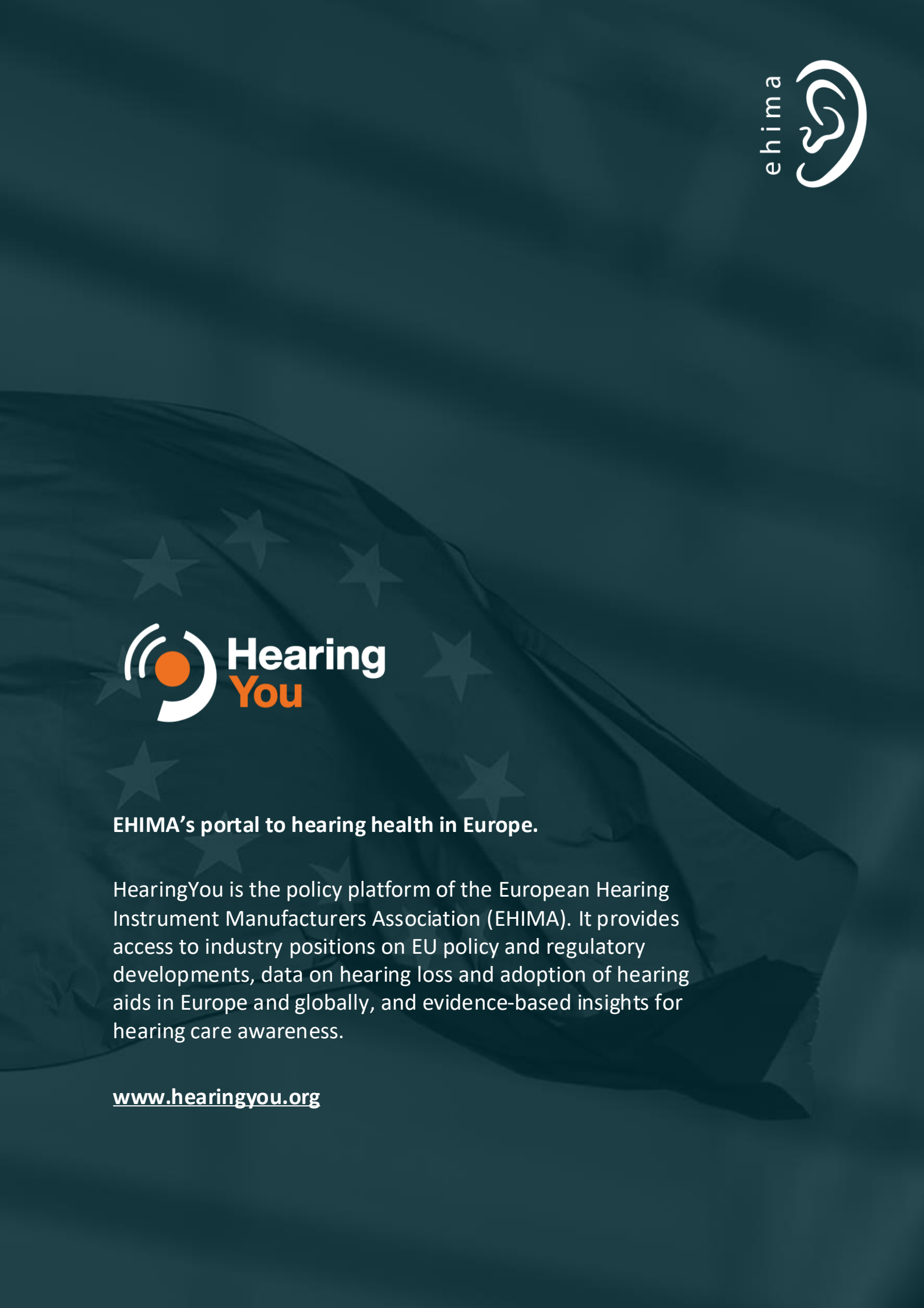
The practical impact on medical devices will also depend on the ongoing MDR revision, which could change how AI-enabled medical devices are regulated. In addition, recent European Commission guidance on the definition of high-risk AI suggests that functionalities focused on areas such as performance optimisation, rather than safety, may fall outside these requirements. The publication of the Omnibus Regulation nevertheless provides greater certainty on the overall implementation timeline: the August 2028 deadline is now formally established in EU law.

## ENISA sets out cybersecurity guidance for healthcare procurement

The EU Agency for Cybersecurity (ENISA) has published new guidance to help hospitals and other healthcare providers integrate cybersecurity into procurement decisions. The non-binding guidance reflects the growing dependence of healthcare systems on connected devices, cloud services, AI and data-intensive technologies, alongside an increase in cyber threats targeting healthcare infrastructure.

ENISA recommends considering cybersecurity throughout the procurement lifecycle. Before purchasing a product or service, healthcare providers are encouraged to assess cybersecurity risks, interoperability and suppliers' security practices, and to include appropriate cybersecurity requirements in contracts. During procurement, providers should consider areas such as access controls, encryption, software development practices and suppliers' previous handling of cybersecurity incidents. Once a technology is in use, ENISA recommends continued monitoring, timely software updates and patches, clear incident-response responsibilities and secure disposal of devices containing patient data.

The guidelines form part of the EU's wider effort to strengthen the cyber resilience of healthcare and other critical infrastructure.



**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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