The Sound of Brussels

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Hearing You

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In Focus

The MDR revision is moving forward, with early political divisions emerging over AI and simplification

The revision of the Medical Devices Regulation (MDR) has entered a new phase, with both the Council and the European Parliament beginning to define their positions on the European Commission's proposal. This marks an important step in the legislative process as the debate is moving from the Commission's initial simplification agenda towards the political choices that will shape the final rules.

The MDR is the EU's main rulebook for medical technologies, including hearing devices. A central question is now how artificial intelligence should be treated in this framework. The European Commission has proposed bringing AI-enabled medical devices more closely into the MDR system, with the aim of avoiding duplicate requirements under both the MDR and the EU's wider Artificial Intelligence Act.

The early debate shows that this approach is not yet settled. In the Council, several national governments appear to support the objective of avoiding unnecessary regulatory overlap, although some have also raised the need for further consideration of sector-specific AI and cybersecurity requirements. In addition, Member States have asked for more clarity on the role of the European Medicines Agency and expert panels in the MDR system.

The first signal from the European Parliament's Internal Market Committee (IMCO) points in a different direction. Its rapporteur, Maria Guzenina, proposes deleting the Commission's clause on AI-enabled medical devices, arguing that all AI should remain governed under the horizontal AI Act, warning that a separate sectoral regime for medical devices would create legal uncertainty and regulatory fragmentation.

Although both institutions continue to support the overall objective of simplifying the MDR, the first political positions demonstrate that important elements of the Commission's proposal remain contested. The coming stages of the MDR revision will be important for determining whether the final framework reduces duplication and improves predictability for medical technologies, including hearing devices, or whether the interaction between the MDR and AI Act remains complex.

AI Omnibus formally adopted as broader Digital Omnibus negotiations continue

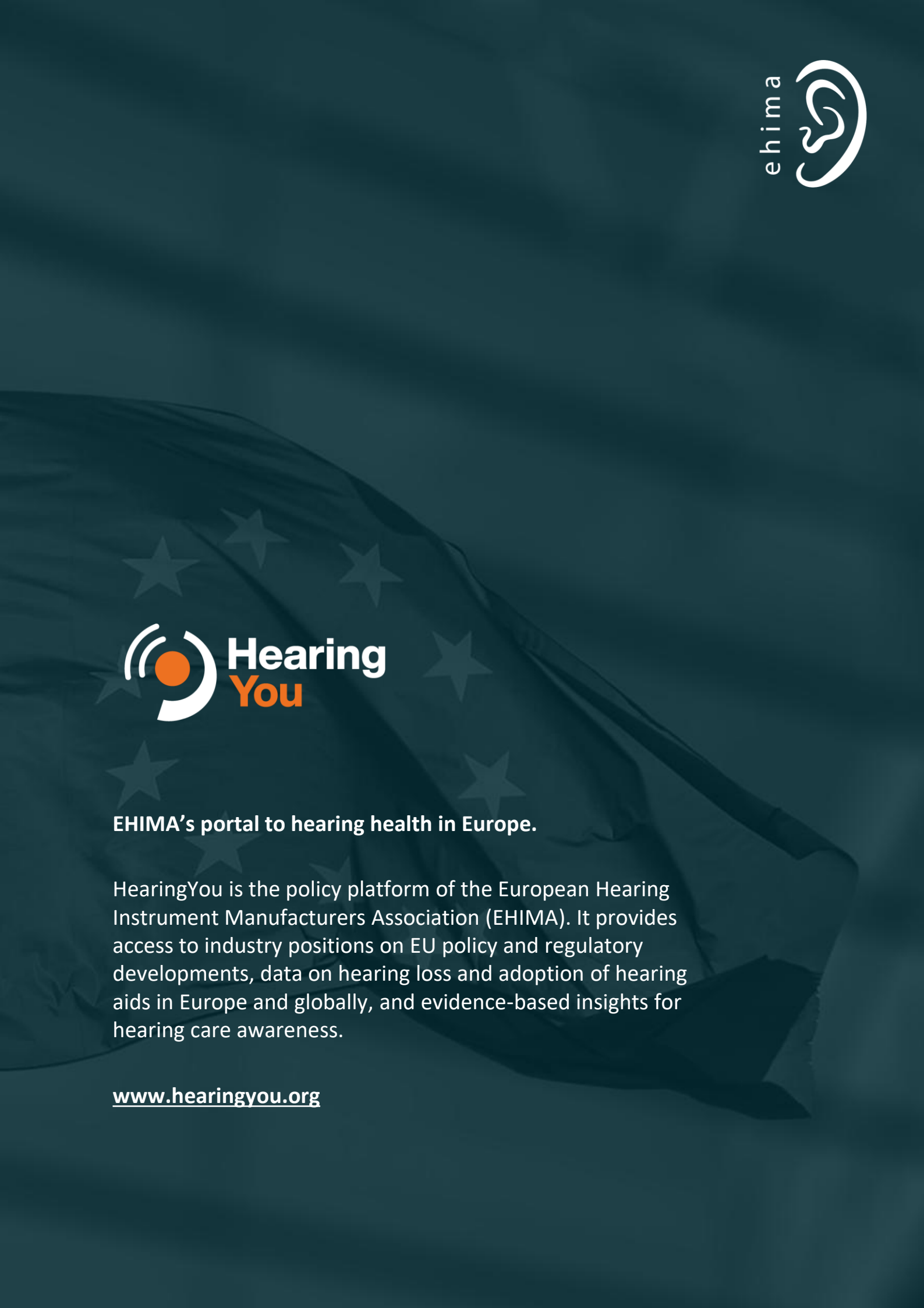
The AI Omnibus Regulation has now been formally adopted by the Council, completing the legislative process after the political agreement reached in May. The Regulation confirms that high-risk AI requirements will apply from 2 August 2028 to high-risk AI systems embedded in products, including medical devices. This means the headline timeline is now clear. However, the practical effect for medical technologies will still depend on implementation. The AI Omnibus Regulation also introduces a mechanism allowing the European Commission to limit the application of the AI Act where sector-specific legislation contains comparable AI requirements. In addition, the Regulation requires the European Commission to issue guidelines to help manufacturers apply the AI Act while reducing unnecessary regulatory burden.

For the hearing sector, one of the most relevant questions remains how the EU defines a "safety component" under the AI Act. Draft Commission guidance suggests that AI functionalities used purely for performance enhancement, convenience, service efficiency or processing optimisation would not constitute a safety component.

EU-China consultations open a new channel for managing trade tensions

The EU and China have launched the new Trade and Investment Consultations (TIC), creating a ministerial-level forum at a time when trade relations have become increasingly strained. The talks come against the backdrop of European concerns about Chinese industrial overcapacity, market access barriers and growing competition in high-value sectors such as cars, machinery, chemicals and life sciences. The consultations do not amount to a reset in EU-China relations, and no immediate regulatory changes or market access commitments were agreed. Their main value is procedural as they create structured workstreams on trade and investment balancing, export controls, intellectual property and WTO reform, alongside a monitoring mechanism to exchange data and track trade flows.

The opportunity is therefore to manage disputes before they escalate, particularly around critical raw materials, export restrictions and supply-chain predictability. For the hearing technology sector, the file is mainly relevant as part of the wider business environment for innovative European manufacturers, especially where supply chains, export controls and intellectual property protection are concerned.



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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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