

The Sound of Brussels

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In Focus

The European Commission's State of the Union doubles down on simplification and puts health at the centre of its industrial AI agenda

The 2026 State of the Union address set out a broad political direction for the next phase of the Commission's mandate: a more competitive Europe, less administrative burden for business, stronger strategic autonomy and faster deployment of new technologies in the real economy.

The speech did not announce new hearing-specific or medical device-specific legislation. Its relevance for the hearing industry lies in the priorities it confirms. Regulatory simplification remains central. President von der Leyen said the Commission's omnibus packages are expected to cut annual administrative burdens by around EUR 17 billion, and called on Member States to avoid "gold-plating" EU rules with additional national requirements.

This matters for a sector already working through overlapping medical device, digital, data and sustainability rules. The Commission's commitment to a "simplicity-by-design" approach may shape the climate around ongoing files, including medical device reform, digital simplification and the review of public procurement rules.

Artificial intelligence was the most concrete health-related element. The Commission presented the AI Act as the EU's regulatory guardrail, but shifted emphasis towards deployment. Health was identified as one of five priority sectors for industrial AI, alongside transport, agri-food, advanced manufacturing, and defence and space. Further initiatives for AI in health are expected in November.

The speech also placed renewed emphasis on supply-chain resilience and critical raw materials. A European Corporation on Critical Raw Materials was announced to support joint procurement and stockpiling. For the hearing industry, the practical relevance will depend on whether future initiatives cover medical technology, batteries or electronic components.

The overall message is therefore one of policy direction rather than immediate regulatory change. The coming months will show how the European Commission translates simplification, industrial AI and resilience into concrete proposals.

Public procurement reform gives public buyers more room to use quality, innovation and “Made in Europe” criteria

On 9 September, the European Commission proposed a major revision of EU public procurement rules. The proposal would replace three existing directives with a single regulation, creating one EU rulebook for public buyers and reducing fragmentation between horizontal and sector-specific rules.

The reform would also shift public purchasing further away from price-only award decisions. Under the proposal, contracting authorities would have to include ecological, social, innovation, supply-security or local-preference criteria, with these factors receiving a minimum weighting of 30%. For labour-intensive contracts, the weighting would rise to 50%.

The “Made in Europe” element is not framed as an outright exclusion of non-European suppliers. Instead, the proposal gives public buyers more room to reward supply security and local preference, while preserving equal treatment for suppliers from countries covered by relevant trade agreements. A new Innovation Procedure would allow public buyers to define a challenge and invite the market to test solutions.

Digital Omnibus talks sharpen around pseudonymised data and AI

Council negotiations on the Digital Omnibus moved into more sensitive territory in September. A revised Irish Presidency compromise seeks to clarify when pseudonymised information may fall outside the GDPR for a specific recipient, where that recipient cannot reasonably identify the individual.

The text does not create a general exemption for pseudonymised data. Whether the GDPR applies would depend on the actual possibility of re-identification, including whether identification is impossible, legally prohibited or would require disproportionate time, cost and effort. The draft points to the European Health Data Space as one context where re-identification may be legally prohibited.

The Presidency text also addresses AI development. It suggests that processing personal data for the development and use of AI systems may, where appropriate, rely on legitimate interest, subject to the existing GDPR balancing test and safeguards such as transparency, the right to object and privacy-preserving techniques. The text remains under negotiation.



EU-India FTA advances with tariff gains for hearing devices, but no procurement chapter

On 11 September, the European Commission submitted the EU-India Free Trade Agreement for signature and conclusion. The agreement would reduce or eliminate tariffs on 96.6% of EU goods exports to India, with the Commission estimating potential customs-duty savings of up to EUR 4 billion annually for European exporters.

Medical technology is among the sectors expected to benefit. EU exports of optical, medical and surgical equipment to India currently face tariffs of up to 27.5%. For hearing instruments, the final gains differ by product line. Hearing aids under HS 90214090 would fall from a 13.8% agreement base rate to 3.75%, while frequency-modulated hearing aid systems under HS 90214010 would become duty-free from year 11. Parts and accessories under HS 90219010 would be liberalised from year 8.

The agreement also includes simplified customs procedures, self-certification of origin and a dedicated EU-India Working Group on Conformity Assessment. This may help address technical barriers over time, but it does not provide automatic recognition of EU MDR certification or mutual recognition of medical device conformity assessments. Notably, the final agreement does not include a public procurement chapter. European suppliers therefore do not gain new treaty-based access guarantees for Indian public-sector healthcare tenders through this FTA. The agreement still requires EU and Indian ratification before it can enter into force.



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