

Open Joint Letter on the Digital Omnibus on AI Preserving the Scope and Integrity of the AI Act

Brussels, 8 April 2026

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Ahead of the upcoming trilogue negotiations on the AI Omnibus proposal, we – organisations representing **civil society, consumers, doctors, hospitals and healthcare services, conformity assessment bodies (CABs) and academia**, wish to express our **concerns** about current proposals that would **weaken the scope and effectiveness of the EU Artificial Intelligence Act**.

The AI Act is the result of several years of legislative work and careful compromise rooted on fundamental rights, consumer protection, safety and trust. It establishes a framework designed to ensure that AI systems used in the EU are subject to appropriate safeguards while providing clarity for actors operating in the Single Market. Preserving this balance is essential to ensure that AI technologies placed on the market remain trustworthy and that consumers are effectively protected.

The European Commission's proposal promised targeted **simplification, not deregulation**. As trilogue negotiations begin, we are concerned that the proposal and the negotiating positions from the European Parliament and the Council respectively still risk reopening core elements of this framework, crucially weakening the AI Act. Simplification should not come at the expense of consumer protection, product safety, children's rights and fundamental rights.

We are particularly concerned with the EP proposals affecting **Annex I of the AI Act**, namely the removal of **Section A**. Annex I plays a **technical but essential role**, ensuring that AI systems embedded in products regulated under sector-specific EU legislation **remain appropriately covered by the AI Act's high-risk framework**, enabling a coherent link between horizontal AI requirements and existing EU product legislation.

Removing or weakening this link risks **creating a significant loophole, excluding a wide range of industrial and consumer AI systems from the direct scope of the AI Act**. The AI Act was designed to regulate **AI-specific risks which are not explicitly addressed in other sector-specific legislation**. Such an outcome would significantly undermine the AI Act's implementation and its safeguards designed to protect consumers, while also creating legal uncertainty about which AI systems remain subject to the framework.

A clear example of the potential consumer harms of this change is the **healthcare sector**, as **medical devices and in vitro medical devices would be removed from the scope of the AI Act**. As **European doctors, hospitals and healthcare service organisations** have shown¹, medical devices increasingly incorporate AI functionalities that can influence diagnosis, treatment decisions or patient monitoring. However, sectoral guidance already acknowledges that **current sectoral frameworks do not explicitly address risks specific to AI systems**². Ensuring that these systems remain clearly covered by the AI Act's governance framework is therefore essential to maintain patient safety and public trust in digital health technologies.

Another significant example **concerns the toy industry**, as this change would **remove toys with AI systems as safety components** from the high-risk classification in the AI Act. This would create a **structural gap in protecting children** whilst undermining the recently adopted EU framework on toy safety by removing a primary mechanism for addressing AI-related risks in toys³.

More importantly, such a change would **fail to deliver the simplification promised** by the AI Omnibus. On the contrary, it risks **leading to greater complexification and fragmentation**. Weakening the horizontal approach established by the AI Act would require **amending around twelve separate pieces of EU legislation** to reintroduce AI-related requirements on a sector-by-sector basis and establish a growing reliance on sector-specific rules and secondary legislation to address AI risks across different industries. This would create a **fragmented, more complex governance landscape** with diverging requirements across sectors, **increasing legal uncertainty** for authorities, businesses and consumers alike.

At a time when the EU seeks to strengthen trust in AI and reinforce its technological sovereignty, preserving trust in a coherent and effective framework for AI governance is essential.

We therefore call on EU legislators to **preserve the integrity and scope of the AI Act and maintain Annex I, including Section A**, avoiding changes that would weaken consumer protection and product safety, or introduce unnecessary complexity and uncertainty into the EU governance of AI.

We remain at your disposal to engage constructively to ensure that the implementation of the AI Act delivers on its objectives: protecting consumers, fundamental rights whilst supporting responsible innovation, and maintaining trust in the European digital ecosystem.

Yours sincerely,

¹ Open letter to safeguard safe, transparent, and accountable AI for Medical Devices and In Vitro Medical Devices CPME and HOPE, <https://www.cpme.eu/api/documents/adopted/2026/03/cpme-hope.open.joint.letter.digital.omnibus.ai.md.pdf>

² Joint Artificial Intelligence Board and Medical Device Coordination Group Document, Interplay between the Medical Devices Regulation and the In Vitro Diagnostic Medical Devices Regulation and the Artificial Intelligence Act, https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en

³ Recital 15, Toy Safety Regulation (Regulation EU 2025/2509): "Toys with AI systems as safety components that require third-party conformity assessment are classified as high-risk AI systems under the AI Act".



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- Center for Democracy and Technology (CDT Europe)
- Corporate Europe Observatory
- CPME – Standing Committee of European Doctors
- Danes je nov dan
- Digitalcourage
- ECNL - European Centre for Not-for-Profit Law
- EDRi – European Digital Rights
- Equinet
- European Disability Forum (EDF)
- European Network Against Racism (ENAR)
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- HOPE - European Hospital and Healthcare Federation
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