

How stakeholder pressure and institutional priorities can shape AI legislation – The case of AI Act Annex I under the Digital Omnibus on AI

By Jakub Skórczynski

When the AI Act entered into force in August 2024, not many could have foreseen that it would be subject to reform in 2026. The reform was part of EU's broader revisiting of recent legislative initiatives in the digital domain as part of EU's Digital Package.¹ With "simplification" as a key driver for the Digital Omnibus on AI, the European Commission proposed to change the AI Act.² The proposed changes encompassed, for example, the revision of the requirement on AI literacy and the postponement of the requirements on high-risk AI systems. Among these changes, and amid the trilogue, a push towards a bigger focus on sectoral exemptions from the AI Act could be observed.

Behind amendments to the AI Act lies a question: who ultimately influences the direction of EU AI legislation? This article presents two

distinct ways in which external and internal policy objectives have had and can have an influence on the reform of AI Act.

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The structure of the article

The article is structured by firstly addressing input from external stakeholders as an example of how they can influence the trilogue. Thereafter, the article considers internal policy objectives within the European Commission as drivers of change and the interaction between different entities within the Commission. Lastly, the article is concluded by giving an insight to why legal professionals dealing with digital legislation can have a benefit from considering the above matters.

The external aspect – When stakeholders influence the member states in trilogue.

In the beginning of May 2026, news outlets specialised in EU policy affairs reported on the fierce negotiations on the role of sectoral legislation in relation to the subsequent publication of the political agree-



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ment between the European Parliament and the Council of the EU on the Digital Omnibus on AI.³

In the late stages of the negotiations of the Digital Omnibus on AI a push towards a sectoral outlook on AI was strongly supported by

1 European Commission, 'Simpler EU digital rules and new digital wallets to save billions for businesses and boost innovation*' (2025) <https://ec.europa.eu/commission/presscorner/detail/en/ip_25_2718> accessed 31-08-2026

2 Regulation (EU) 2026/1744 of the European Parliament and of the Council of 8 July 2026 amending Regulations (EU) 2024/1689, (EU) 2018/1139 and (EU) 2023/1230 as regards the simplification of the implementation of harmonised rules on artificial intelligence (Digital Omnibus on AI), 2025/0404 (COD)

3 See for example: Pieter Haack, 'Germany set to secure win for industry in AI talks' *Politico* (06-05-2026) <<https://www.politico.eu/article/germany-eu-ai-law-machinery-exemption-industrial-rewrite/>>, Maximilian Henning, 'EU clinches AI reform deal centring on machinery cuts' *Euractiv* (07-05-2026) <<https://www.euractiv.com/news/eu-clinches-ai-reform-deal-centring-on-machinery-cuts/>> or Jedidiah Bracy, 'EU agrees to amend AI Act, clarifies overlap with machinery rules' *IAPP* (07-05-2026) <<https://iapp.org/news/a/eu-agrees-to-amend-ai-act-clarifies-overlap-with-machinery-rules>>

Germany, despite the sight of the provisional agreement being just beyond the horizon. In early April 2026, Chancellor Friedrich Merz made a statement at an industrial fair in Hannover, where he voiced his support of a “[...] *push to ease the regulatory burden in the EU on AI and, where possible, to exempt industrial AI from the current regulatory straitjacket*”.⁴ The commitment aligned with the arguments of several German industrial giants and, later, with a plea from seven leading EU industry actors.⁵ As reported by Politico, the initiative encompassed a broader push to prioritise sectoral regulation of AI rather than the horizontal regulation of the AI Act. The reasoning behind such approach was to minimise the risk of “*double obligations, overlapping requirements and legal uncertainty*”.⁶ It was suggested that the sectoral legislation should be moved from Section A of the Annex I to the Section B, which would significantly impact the scope of the AI Act. In a practical perspective, this would mean that legislation encompassed by the dual conformity assessment, including inter alia legislation on manufacturing, toys, and medical devices, would be moved to solely be covered by the sectoral legislation.⁷ A very similar approach was seen in a study com-

missioned by Bertelsmann Stiftung in November 2025.⁸ The authors argued that the ‘*bifurcation*’ between Annex I, Section A and Section B led to ‘*significant implementation challenges*’.⁹ It was highlighted that products regulated in Section A, and thus already subject to New Legislative Framework (NLF) were placed under direct application of AI Act. At the same time, products subject to Annex I, Section B, such as, for example, automotive, aviation and transportation products, were not subject to the NLF, whereby the AI Act governance principles were meant to be incorporated into existing sectoral legislation, but the AI Act would not be directly applicable in this context. This approach could thus indicate a high level of complexity, arising from the diverging scopes of applications, particularly relevant for undertakings working with both types of products.

The final version of the Digital Omnibus on AI has implemented the suggested change related to the Machinery Regulation in Annex I, Section B. The recitals refer to the “specific nature”¹⁰ of machinery and its corresponding sector. However, this change shows that even a late push made by the stakeholders can effectively affect the outcome of the legislative act, such as the AI Act.

The internal aspect – Diverging interests within the Commission or “Turf battles”?

The above changes were, however, not the sole efforts to alter parts of the AI Act in favour of sectoral legislation. In December 2025, as the legal community continued to assess the ramifications of the recently published Digital Omnibus on AI, an interesting development arose.

The Directorate-General for Health and Food Safety (DG SANTE) presented the proposal for a regulation to simplify rules on medical and in vitro diagnostic devices.¹¹ The proposal presented somewhat of a “backdoor” alteration of the AI Act, by proposing to move Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulations (IVDR) from the AI Act, Annex I, Section A to AI Act, Annex I, Section B. Similarly, to the recent developments of Machinery Regulation, it was indicated that the status quo led to uncertainty. Representatives of European trade associations indicated inter alia that “*The AI Act created significant interplay issues with the MDR and IVDR, with different definitions and concepts applying to the same product (how to assess risk, substantial modification, etc.), which would have created friction*”.¹² This argument was however disputed by AI professionals such as Adam Leon Smith, who argued that it is common for NLF legislation to overlap “*In such a case, the issue of overlap might be resolved by giving preference to the more specific Union harmonisation act. For example, the Machinery and Low Voltage regulations often both apply to the*

4 ‘Germany’s Merz says industrial AI needs less stringent EU regulation’ *Reuters* (31–08–2026) <<https://www.reuters.com/business/germanys-merz-says-industrial-ai-needs-less-stringent-eu-regulation-2026-04-19/>>

5 ASML, *ASML CEO Christophe Fouquet co-signed opinion piece with European technology companies* (2026)

6 Pieter Haeck, ‘Germany faces resistance in push to weaken AI rules’ (21–04–2026) <<https://www.politico.eu/article/germany-stronger-ai-deregulation-brussels-eu-opposition/>>

7 Luca Bertuzzi, *EU policymakers fall short of agreeing on AI Act amendments* (2026) or see the same authors LinkedIn post about the topic <<https://lnkd.in/p/eukFRUKC>> (29-04-2026)

8 Philip Hacker, Robert Kilian and Jana Costas, “*Simplifying*” *European AI Regulation - An Evidence-based Study*, 2025)

9 Ibid, p. 39

10 Regulation (EU) 2026/1744, Digital Omnibus on AI, recital 42

11 Proposal for a regulation amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and in vitro diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I, 2025/0404 (COD)

12 Julien Chasserieu, *Barely a month after the AI omnibus was presented, another major AI Act amendment just got proposed through the revision of the MDR and IVDR, changing the way the EU AI regulation will apply to medical devices with AI capabilities*. (2026) published on LinkedIn <<https://lnkd.in/p/e9Z-d9r9x>>



Illustration: Coulorbox/ ChatGPT

same product”.¹³ The author not only criticised the approach but also highlighted that alterations to the existing framework could have significant implications, for example for the process of developing harmonised standards, due to the potential withdrawal of stakeholders in medical devices.

However, this can lead to another question, which is: How can it be that DG SANTE tried to reform the AI Act by presenting its own proposal for a different legislative act, while the negotiations on the AI Omnibus were ongoing? The answer to this question will remain unresolved in the article, but it leads us to considering a broader question of cooperation within the European Commission.

The internal cooperation within the European Commission.

The tasks within the European Commission are split among com-

missioners and the administrative apparatus consisting of more than 30 Directorates-General (DG) and 20-service departments.¹⁴ As argued by Blom-Hansen, Finke and Senninger, the sheer size of the organisation leads to an unavoidable fragmentation due to a further division to separate departments and ministries with the aim to solve tasks at a specialised level.¹⁵ The different DGs within the European Commission are responsible for different policy areas, by pursuing a number of tasks encompassing implementation and management of EU policy and legislation.¹⁶ To exemplify, the Directorate-General for Communications Networks, Content and

Technology (DG Connect) was the DG responsible for a significant part of the work on the AI Act, and the Directorate itself consists of number of sublevel departments.¹⁷ The political responsibilities of the DG Connect encompasses among others pursuing the goals of promoting digitalisation of the EU, promoting technological sovereignty and enforcement of the rulebook for online platforms and AI.¹⁸ It is relevant to highlight that, the European Commission has formalised

13 Adam Leon Smith, *DG SANTE proposal threatens to undermine both the EU AI Act, and the New Legislative Framework itself* (2025)

14 Jens Blom-Hansen, Daniel Finke and Roman Senninger, ‘Coordination in European Commission’ in Gijs Jan Brandsma (ed), *Handbook on European Union Public Administration*, (Edward Elgar Publishing 2024), p. 239

15 Ibid

16 European Commission Directorate-General for Communication, ‘Organisation of the European Commission’ (2026) <https://commission.europa.eu/about/organisation_en> accessed 31-08-2026

17 Publications Office of the European Union, ‘Directorate-General for Communications Networks, Content and Technology (CNECT)’ (2026) <<https://op.europa.eu/en/web/who-is-who/organization/-/organization/CNECT/CNECT>> accessed 31-08-2026

18 European Commission Directorate-General for Communication, ‘Communications Networks, Content and Technology’ (2026) <https://commission.europa.eu/about/departments-and-executive-agencies/communications-networks-content-and-technology_en> accessed 31-08-2026

rules of procedure¹⁹ and that if a DG submits a proposal, it is usually followed by an inter-service consultation process, giving other relevant DG's the possibilities to comment.²⁰ However, as highlighted in scientific literature, there are examples questioning whether this coordination is always effective.²¹ Several articles have illustrated the conflictual tendencies within the Commission, for example when the DG's work in "silos" which affects the effectiveness of work due to lacks in coordination²², or the legislative process within Commission is occasionally subject to internal frictions, due to diverging interdepartmental interests.²³ With such instances in mind, it is possible that DG SANTE, in the case of the suggested changes to the AI Act, pursued its own ambitions for legislative change by placing medical devices in the AI Act, Annex I, Section B.

Conclusion: What's in it for legal practitioners?

This article briefly illustrates two of many ways in which policy objectives and politics affected the dialogue regarding the Digital Omnibus on AI. On the one hand, negotiations can be significantly affected by pursuing policy goals promoted by stakeholders in the industry or interest groups, for example within civil society or business, as illustrated by the German example.

On the other hand, there are also policy goals within the EU institutions. The example of DG SANTE and its suggested changes to the AI Act can serve as an illustrate example of diverging priorities within the EU Commission itself. This peculiarity often goes unnoticed by legal practitioners, since it is not as evident as the influence of external actors, and the EU is generally a highly capable and well-functioning organisation given its size, influence and power.²⁴

However, raising awareness on the potential tensions when regulating AI or other digital technologies, can have an impact on legal professionals within the field. The legal practitioners must navigate a complex landscape in which both horizontal (cross-sectoral) and sector-specific regulatory frameworks coexist. Each framework is driven by distinct policy objectives, and it is important to remember that EU is not a monolith. A perspective limited to horizontal IT legislation may not adequately address the legal elements and policy of sectoral legislation, such as within the medical technology sector. Similarly, an undue emphasis on sector-specific sources may lead to a distorted per-

ception of overarching regulatory frameworks in cross-sectoral legislation. A holistic approach that considers the contextual elements of policy and legal objectives can be essential, particularly for legal professionals seeking to better predict the overall development of digital legislation.

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19 Rules of Procedure of the Commission [C(2000) 3614], L 308

20 Blom-Hansen, Finke and Senninger, 'Coordination in European Commission', p. 245

21 The chapter 'Coordination in European Commission' by Blom-Hansen, Finke and Senninger in the "Handbook on European Public Administration" presented a nuanced list of different research articles both indicating that the work within the EU Commission is effective but also examples on articles stating the opposite, see p. 246 – 249.

22 Sevasti Chatzopoulou, 'Resilience of the Silo Organizational Structure in the European Commission' (2023) 61 JCMS: Journal of Common Market Studies

23 Miriam Hartlapp, Julia Metz and Christian Rauh, *Which Policy for Europe?: Power and Conflict inside the European Commission*, (Oxford University Press 2014) and Christian Rauh, 'One agenda-setter or many? The varying success of policy initiatives by individual Directorates-General of the European Commission 1994–2016' (2021) 22 European Union Politics

24 Just to illustrate the European Commission alone, employs around 32.000 permanent and contract employees: European Commission Directorate-General for Communication, 'Commission staff' (2026) <https://commission.europa.eu/about/organisation/commission-staff_en> accessed 31-08-2026

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