

*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

## Proposed amendments to the Digital Omnibus on AI

### Proposed amendments

The CPME feedback on the Digital Omnibus Package can be accessed [here](#) and the CPME policy on the deployment of AI can be accessed [here](#).

European doctors agree with several amendments proposed by the IMCO-LIBE draft report and the JURI draft opinion, in particular those that reinstate important provisions from the original AI Act (e.g. the responsibility of providers and deployers on AI literacy, clarify the interplay with other legislation warranting simplification), or that address new topics which reflect the rapid evolution of the use of AI (e.g. introducing agentic AI in the AI definition, banning the instrumentalization of AI for sexualised content without consent).

CPME strongly advocates for a clear and consistent approach to the AI Act, ensuring that ethics, safety and innovation go hand in hand. The use of electronic health records (EHRs) to train commercial AI systems raises significant ethical and legal questions. CPME calls on EU regulators to provide clarity on the applicable legislation, the authority responsible for oversight, and on how to prevent the treatment relationship from becoming an unpaid resource for commercial product development. The lack of a clear legal framework not only undermines European values such as personal data protection and trust in healthcare but also poses risks to the quality and safety of care.

European doctors advocate for a European blueprint and infrastructure that standardises digital safety and aligns innovation with European values.

**CPME calls on EU legislators to maintain medical devices (MD) and *in vitro* medical devices (IV MD) in Section A of Annex I of the AI Act and apply the requirements for high-risk AI systems set out in Chapter III, Section 2 of the AI Act.** Important safeguards on high-risk AI systems must remain applicable to MD and IVMD, such as human oversight, continuous monitoring of machine learning algorithms, datasets transparency, accuracy and robustness, as well as the assurance of data being sufficiently representative and of high-quality, tailored to healthcare. In addition, AI-specific risk management requirements to prevent and address potential harms from AI system failures or biases are only considered within the AI Act.

CPME’s proposed amendments are indicated in **bold italics and underlined font**

### Amendment 1

**New Amendment  
Proposal for a regulation  
Recital 4 a (new)**

<b>Agentic AI</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
	<b><u>(4a) Agentic AI constitutes a new category of artificial intelligence applications that can execute sophisticated real-world operations rapidly and with reduced human oversight. While conventional AI systems deliver outputs like forecasts, generated content, suggestions or judgments, agentic AI distinguish itself through its capacity to carry out concrete</u></b>

	<p><b><u>actions autonomously. To address this potential regulatory gap and provide legal clarity, it would be advisable to amend the definition to expressly include systems that execute autonomous actions under the jurisdiction of Regulation (EU) 2024/1689.</u></b></p>
<p><b>Justification</b></p>	
<p>As explained by the rapporteur of the JURI Committee, the current AI Act does not cover AI agents in the definition of AI. The AI definition addresses outputs and not actions. Since agentic AI might be used in the healthcare sector, with a fair degree of autonomy, it is of utmost important for patient safety, that this type of AI is covered by the AI Act.</p>	

## Amendment 2

**Amendment 3 IMCO-LIBE draft report  
Proposal for a regulation  
Recital 5**

<b>AI literacy</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<p>(5) Article 4 of Regulation (EU) 2024/1689 currently imposes an obligation on all providers and deployers of AI systems to ensure AI literacy of their staff. AI literacy development starting from education and training and continuing in a lifelong learning manner is crucial to equip providers, deployers and other affected persons with the necessary notions to make informed decisions regarding AI systems deployment. However, experience shared by stakeholders reveals that a one-size-fits-all solution is not suitable for all types of providers and deployers in relation to the</p>	<p><b><u>delete</u></b></p>

<p>promotion of AI literacy, <b>rendering such a horizontal obligation ineffective in achieving the objective pursued by this provision. Moreover, data indicate that imposing such an obligation creates an additional compliance burden, particularly for smaller enterprises, whereas</b> AI literacy should be a strategic priority, regardless of regulatory obligations and potential sanctions. <b>In light of that</b>, Article 4 of Regulation (EU) 2024/1689 should be amended to require the Member States and the Commission, without prejudice to their respective competences, to individually, collectively and in cooperation with relevant stakeholders encourage providers and deployers to <b>provide a sufficient level of</b> AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, <b>including</b> through offering training opportunities, providing informational resources, <b>and</b> allowing exchange of good practices <b>and other non-legally binding initiatives</b>. The European Artificial Intelligence Board ('Board') will ensure recurrent exchange between the Commission and Member States on the topic, while the Apply AI Alliance will allow discussion with the wider community. <b>This amendment is without prejudice to the broader measures taken by</b> the Commission and the Member States to promote AI literacy and competences for the wider population, including learners, students, and citizens at different ages and in particular through education and training systems.</p>	
<p><b>Justification</b></p>	
<p>The obligation for providers and deployers to ensure a sufficient level of AI literacy for their staff and persons operating with AI is an essential condition for the safe deployment of AI in healthcare, and should therefore be maintained. AI literacy should not be seen as a burden, but rather as helping to raise ethical and social awareness on AI benefits and risks.</p>	

Amendment 3

**Amendment 4 IMCO-LIBE draft report**  
**Proposal for a regulation**  
**Recital 6**

<b>Processing special categories of data for bias detection and correction</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<p>(6) Bias detection and correction constitute a substantial public interest because they protect natural persons from biases’ adverse effects, including discrimination. Discrimination might result from the bias in AI models and AI systems other than high-risk AI systems for which of Regulation (EU) 2024/1689 already provides a legal basis authorising the processing of special categories of personal data under Article 9(2), point (g), of Regulation (EU) 2016/679 of the European Parliament and of the Council<sup>6</sup> . Given that discrimination might result also from those other AI systems and models, it is therefore appropriate that Regulation (EU) 2024/1689 should provide for a legal basis for the processing of special categories of personal data also by providers and deployers of other AI systems and AI models as well as deployers of high-risk AI systems. The legal basis is established in compliance with Article 9(2), point (g) of Regulation (EU) 2016/679 Article 10(2), point (g) of Regulation (EU) 2018/1725 of the European Parliament and of the Council<sup>7</sup> and Article 10, point (a) of Directive (EU) 2016/680 of the European Parliament and of the Council<sup>8</sup> provides a legal basis allowing, where necessary for the detection and removal of bias,</p>	<p><b><i>Support the Council’s wording which is in line with EDPB-EDPS recommendation in its Joint Opinion 1/2026</i></b></p>

<p>the processing of special categories of personal data by providers and deployers of all AI systems and models, subject to appropriate safeguards that complement Regulations (EU) 2016/679, Regulation (EU) 2018/1725 and Directive (EU) 2016/680, as applicable.</p>	
<p>-----</p> <p><sup>6</sup> Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: <a href="http://data.europa.eu/eli/reg/2016/679/oj">http://data.europa.eu/eli/reg/2016/679/oj</a>).</p> <p><sup>7</sup> Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: <a href="http://data.europa.eu/eli/reg/2018/1725/oj">http://data.europa.eu/eli/reg/2018/1725/oj</a>).</p>	
<p><sup>8</sup> Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA (OJ L 119, 4.5.2016, pp. 89–131, ELI: <a href="http://data.europa.eu/eli/dir/2016/680/oj">http://data.europa.eu/eli/dir/2016/680/oj</a>).</p>	

<i>Justification</i>
<p>Allowing the processing special categories of personal data, in particular health data, for bias detection and correction by <u>all</u> providers and deployers of <u>non-high-risk AI systems</u> widely opens the material and personal scope for processing special categories of personal data, which can easily be prone to abuse and misuse. This can aggravate inequalities of more vulnerable individuals, causing patient harm. Should the inclusion of this recital be necessary considering new Article 4a by the co-legislators, CPME strongly supports the EDPB-EDPS recommendation in its Joint Opinion 1/2026 of 20 January 2026 to specify that these data may be used only in clearly circumscribed situations, where the risk of adverse effects caused by bias is sufficiently serious to justify processing special categories of data</p>

### Amendment 4

**New Amendment**  
**Proposal for a regulation**  
**Recital 9**

<i>Registration in EU database of low and medium risk AI systems</i>	
<i>Text proposed by the Commission</i>	<i>CPME proposed Amendment</i>
<p><b><i>(9) To streamline compliance and reduce the associated costs, providers of AI systems should not be required to register AI systems referred to in Article 6(3) of Regulation (EU) 2024/1689 in the EU database pursuant to Article 49(2) of that Regulation. Given that such systems are not considered high-risk under certain conditions where they do not pose significant risk of harm to the health, safety or fundamental rights of persons, imposing registration requirements would constitute a disproportionate compliance burden. Nevertheless, a provider who considers that an AI system falls under Article 6(3) remains obligated to document its</i></b></p>	<p><b><u>delete</u></b></p>

<p><b>assessment before that system is placed on the market or put into service. This assessment may be requested by national competent authorities.</b></p>	
<p><b>Justification</b></p>	
<p>This deletion is necessary to restore the obligation to register in an EU database low and medium AI systems where the provider self-exempted its AI system as high-risk, despite being referred to in Annex III of the AI Act. CPME agrees with the arguments put forward by EDPB-EDPS Joint Opinion 1/2026 where it argues that this amendment risks significantly decreasing accountability of providers of AI systems and could lead to undesirable incentives for providers to unduly invoke the exemption without critical analysis. The registration obligation ensures the transparency and traceability of AI systems.</p>	

### Amendment 5

**New Amendment**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 2 a (new)**

Regulation (EU) 2024/1689

Article 3 – point 1

Definition of AI system	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
	<p><b>(2a) In article 3, point 1 is replaced by the following:</b></p>
<p>(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, <b>or</b></p>	<p>(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content,</p>

decisions that can influence physical or virtual environments;	recommendations, decisions, <b><u>or autonomous actions and operations</u></b> that can influence physical or virtual environments;
<b>Justification</b>	
As explained by the rapporteur of the JURI Committee, the current AI Act does not cover AI agents in the definition of AI. The latter addresses outputs and not autonomous actions or operations. Since AI agents might be used in the healthcare sector, with a fair degree of autonomy, it is of utmost important for patient safety, that this type of AI is covered by the AI Act, alongside predictions, recommendations and decisions..	

### Amendment 6

#### Amendment 8 of the IMCO-LIBE draft report

#### Proposal for a regulation

#### Article 1 – paragraph 1 – point 4

Regulation (EU) 2024/1689

Article 4 – paragraph 1

<b>AI literacy</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<p><b>(4) Article 4 is replaced by the following:</b></p> <p><b>Article 4</b></p> <p><b>AI literacy</b></p> <p><b>The Commission and Member States shall encourage</b> providers and deployers of AI systems <b>to</b> take measures to <b>ensure a sufficient level of</b> AI literacy of their staff and other</p>	<p><del><b>The Commission and Member States shall encourage</b></del> Providers and deployers of AI systems <b>shall</b> take measures to <b>ensure a sufficient level of</b> AI literacy of their staff and other persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, <b>level of</b> education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the</p>

<p>persons dealing with the operation and use of AI systems on their behalf, taking into account their technical knowledge, experience, <b>level of</b> education and training and the context the AI systems are to be used in, and considering the persons or groups of persons on whom the AI systems are to be used.</p>	<p>AI systems are to be used.</p>
<p><b>Justification</b></p>	
<p>The obligation for providers and deployers to ensure a sufficient level of AI literacy for their staff and persons operating with AI is an essential condition for the safe deployment of AI in healthcare, and should therefore be maintained. AI literacy should not be seen as a burden, but rather as helping to raise ethical and social awareness on AI benefits and risks.</p>	

### Amendment 7

**Amendment 10 of the IMCO-LIBE draft report**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4a – paragraph 1

<p><b>Processing special categories of personal data</b></p>	
<p><i>Text proposed by the Commission</i></p>	<p><i>CPME proposed amendment</i></p>
<p>1. To the extent necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to appropriate</p>	<p>1. To the extent <b><i>strictly</i></b> necessary to ensure bias detection and correction in relation to high-risk AI systems in accordance with Article 10 (2), points (f) and (g), of this Regulation, providers of such systems may exceptionally process special categories of personal data, subject to</p>

<p>safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:</p>	<p>appropriate safeguards for the fundamental rights and freedoms of natural persons. In addition to the safeguards set out in Regulations (EU) 2016/679 and (EU) 2018/1725 and Directive (EU) 2016/680, as applicable, all the following conditions shall be met in order for such processing to occur:</p>
<p><b>Justification</b></p>	
<p>Reinstating the standard of ‘strict necessity’ from current Article 10(5) of the AI Act for the processing of special categories of personal data for the purpose of ensuring bias detection and correction is necessary. This amendment is in line with the EDPB-EDPS Joint Opinion 1/2026 of 20 January 2026.</p>	

### Amendment 8

**Amendment 11 of the IMCO-LIBE draft report**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 5**

Regulation (EU) 2024/1689

Article 4a – paragraph 2

<p><b>Processing special categories of personal data</b></p>	
<p><i>Text proposed by the Commission</i></p>	<p><i>CPME proposed amendment</i></p>
<p>2. Paragraph 1 may apply to providers and deployers of other AI systems and models and deployers of high-risk AI systems where necessary and proportionate if the processing occurs for the purposes set out therein and</p>	<p><b><u>delete</u></b></p>

<p>provided that the conditions set out under the safeguards set out in this paragraph.;</p>	
<p><b>Justification</b></p>	
<p>Allowing the processing special categories of personal data, in particular health data, for bias detection and correction by <u>all</u> providers and deployers of <u>non-high-risk AI systems</u> widely opens the material and personal scope for processing special categories of personal data, which can easily be prone to abuse and misuse. This provision can rather aggravate inequalities of more vulnerable individuals, causing patient harm. Should the inclusion of this provision found necessary by the co-legislators, CPME strongly supports the EDPB-EDPS recommendation to specify that these data may be used only in clearly circumscribed situations, where the risk of adverse effects caused by bias is sufficiently serious to justify processing special categories of data.</p>	

### Amendment 9

**New Amendment**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 6**

Regulation (EU) 2024/1689

Article 6 – paragraph 4

<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<p><b>(6) in Article 6(4), paragraph 4 is replaced by the following:</b></p>	<p><b><u>delete</u></b></p>
<p><b>4. A provider who considers that an AI system referred to in Annex III is not high-risk shall document its assessment before that system is placed on the market or put into service. Upon request of national competent</b></p>	

<p><b>authorities, the provider shall provide the documentation of the assessment.;</b></p>	
<p>Justification</p>	
<p>This deletion is necessary to restore the obligation to register in an EU database low and medium AI systems where the provider self-exempted its AI system as high-risk, despite being referred to in Annex III of the AI Act. CPME agrees with the arguments put forward by EDPB-EDPS Joint Opinion 1/2026 where it argues that this amendment risks significantly decreasing accountability of providers of AI systems and could lead to undesirable incentives for providers to unduly invoke the exemption without critical analysis. The registration obligation ensures the transparency and traceability of AI systems.</p>	

### Amendment 10

**New Amendment**

**Proposal for a Regulation**

Regulation (EU) 2024/1689

New Article 17a – Designation of an AI officer

<p>Designation of an AI Officer</p>	
<p><i>Text proposed by the Commission</i></p>	<p><i>CPME proposed amendment</i></p>
<p>-</p>	<p><b><u>1. The provider of a high-risk AI system, including a general-purpose AI system, and the deployer of AI systems referred to in Article 50, shall designate an AI officer in any case where the AI system or model may present systemic risks or is likely to have a harmful</u></b></p>

	<p><i><u>impact on health, safety, or fundamental rights.</u></i></p> <p>2. <i><u>The AI officer shall have the following tasks:</u></i></p> <p>a) <i><u>To monitor compliance of the policies of the provider and of the deployer with this Regulation;</u></i></p> <p>b) <i><u>To provide advice to the provider and the deployer for the purpose of this Regulation;</u></i></p> <p>c) <i><u>To cooperate with national competent authorities and market surveillance authorities and act as their contact point.</u></i></p> <p><i><u>A group of undertakings may appoint a single AI officer provided that the AI officer is easily accessible from each establishment.</u></i></p>
<p><b><i>Justification</i></b></p>	
<p>Similar to accountants for corporate governance or data protection officers for GDPR, the role of an AI officer for both providers of high-risk systems and deployers can offer additional safeguard for compliance with obligations under the AI Act. This role could ensure internal compliance of companies with the AI Act, in particular when processing special categories of data for bias detection and correction, or for producing AI outputs, or for disclosing or making personal data available to third parties. This officer could facilitate the work of the market surveillance authorities at several instances, being the point of contact for competent authorities, creating more trust in the market environment. Finally, an AI officer could ensure compliance with the obligations of deployers of AI systems, such as those in Article 26 of the AI Act.</p>	

Amendment 11

**New Amendment**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 12 b (new)**

Regulation (EU) 2024/1689

Article 41 – paragraph 1 – introductory part

<b>Implementation timelines</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<p>1. The Commission <b>may</b> adopt, implementing acts establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled:</p>	<p><b>(12b) In Article 41, the introductory wording is replaced by the following:</b></p> <p>‘1. The Commission <b><u>shall</u></b> adopt, implementing acts <b><u>by 2 December 2027</u></b> establishing common specifications for the requirements set out in Section 2 of this Chapter or, as applicable, for the obligations set out in Sections 2 and 3 of Chapter V where the following conditions have been fulfilled.’</p>
<b>Justification</b>	
<p>Pursuant to Article 41(1)(a) and (ii) of the AI Act, the European Commission may adopt implementing acts establishing common specifications when harmonised standards are not delivered within the deadline. These are then repealed once the harmonised standards are in place (Article 41(4) of the AI Act). This amendment ensures fixed timelines, offering stability to the internal digital market.</p>	

Amendment 12

**New Amendment**

**Proposal for a regulation**

**Article 1 – paragraph 1 – point 14**

Regulation (EU) 2024/1689

Article 49 – paragraph 2

<b>Registration of AI systems</b>	
<i>Text proposed by the Commission</i>	<i>CPME proposed amendment</i>
<b><i>(14) in Article 49, paragraph 2 is deleted;</i></b>	<b><u>delete</u></b>
<b><i>Justification</i></b>	
<p>This deletion is necessary to restore the obligation to register in an EU database low and medium AI systems where the provider self-exempted its AI system as high-risk, despite being referred to in Annex III of the AI Act. CPME agrees with the arguments put forward by EDPB-EDPS Joint Opinion 1/2026 where it argues that this amendment risks significantly decreasing accountability of providers of AI systems and could lead to undesirable incentives for providers to unduly invoke the exemption without critical analysis. The registration obligation ensures the transparency and traceability of AI systems.</p>	

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