MEDECINS EUROPEENS
EUROPEAN DOCTORS

AMENDMENTS

The European Doctors (CPME) represent 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.

CPME Suggested Amendments to the JURI Draft Opinion on the Proposal laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)

European Doctors welcome the rapporteur's new articles on the right to lodge a complaint, on a trustworthy AI as well as on the initiative of re-establishing the High-Level Expert Group on AI.

CPME understands the concern of promoting innovation in Europe and to not overburden SME's, but these should not be at the cost of patient safety. Therefore, we oppose the removal of the quality management system (QMS). In healthcare, this stance would be detrimental to the overall quality of AI[1] and could have consequences on a future liability scheme. Research shows that without a QMS there is an increasing risk of product or service liability in operations.[2] A specific regime for SMEs and start-ups could be envisaged without eliminating QMS altogether.

On transparency and provision of information to users, European Doctors stress the importance of knowing in advance of any circumstances that could have an impact on the expected level of accuracy, robustness, cybersecurity of the AI system, and thus lead to health risks for their patients. In fact, European Doctors support full disclosure of serious incidents and malfunctions by providers of AI systems to patients and users.

[1] Dadario, N. B., Nicholas, P., Henkin, A., Sin, B., Dyer, K., Sughrue, M. E., & Doyen, S. (2022). The Z-Shift: A Need for Quality Management System Level Testing and Standardization in Neuroimaging Pipelines. 1 Years, 43(3), 319. According to the authors: "companies (developing any clinically used pipelines, whether as a medical device or not) should invest in building a fit-for-purpose verification and validation framework under a QMS that would facilitate the discovery and elimination of faults in a systematic manner."

[2] Stimson. W, Using the QMS to Manage the Risk of Liability, February 2013 Conference: International Conference on ISO 9000, <https://www.researchgate.net/publication/267332733_Using_the_QMS_to_Manage_the_Risk_of_Liability> ; Goodden, R.,How a good quality management system can limit lawsuits, 2001, Quality Progress. 34. 55-59.

CPME highlights the need to develop the role of the AI auditor, an independent and, preferably, external person to the organisation, whose professional conduct is subject to supervision by the EU or national authority. The auditor would provide an accurate report on the reliability and trustworthiness of the AI system. Good audit quality contributes to the orderly functioning of markets by enhancing the integrity and efficiency of AI systems. We foresee those statutory auditors fulfilling a particularly important societal role, as do now account auditors.

European Doctors stress that Annex III is not complete. It should include the use of AI i) for determining insurance premium and claim assessments, ii) for assessing medical treatments and iii) for health research, as certain systems cannot be deployed without clear validation (e.g. AI systems on emotion recognition for alcohol addiction, violent behaviour, potential misbehaviour, among other related to emotions and behaviour as there can be misuse leading to discrimination and harm). The Commission's yearly assessment for amendment of Annex III should be made public.

Finally, the new obligation for users to carry out a "trustworthy technology assessment" can be challenging to implement as it will depend on the level of the digital competence of each individual. European Doctors further stress that the JURI opinion should not overburden healthcare professionals (users) with additional protocols and administrative reports. Moreover, measures to mitigate consequences of AI biases, such as gender bias, ethnic bias, age bias, or any type of population biases, including the prevalence bias (a priori probability) should be taken by the provider as it strongly influences the value of any data-driven model.

Proposed amendments

Proposal for a regulation – Article 3 – paragraph 1 – point 44 – introductory part

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
(44) 'serious incident' means any incident that directly or indirectly leads, might have led or might lead to any of the following:	(44) 'serious incident' means any incident that directly or indirectly leads~~, might have led or might lead~~ to any of the following:	**(**44) 'serious incident' means any incident ***or malfunction*** that directly or indirectly leads ~~,~~ ~~might have led or might lead~~ to any of the following:
Justification *A 'serious incident' should also include malfunction, which could occur without being a faulty system (foreseen in AM 55).*		

Proposal for a regulation – Article 4 a (new) – paragraph 3

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
-	**(3) Providers and users of high-risk AI**	**(3) Providers ~~and users~~ of high-risk AI**

	systems shall complete a trustworthy technology assessment, in compliance with paragraph 1 and as part of the requirements under Article 16(a) and 29(4).	**systems shall complete a trustworthy technology assessment, in compliance with paragraph 1 and as part of the requirements under Article 16(a) and 29(4).**
Justification *The implementation of a "trustworthy technology assessment" depends on the level of the digital competence of each individual. The AIA Act should not overburden healthcare professionals (users) with additional protocols and administrative reports.*		

Proposal for a regulation – Article 10 – paragraph 5 – point vi (new)

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems, the providers of such systems may process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including technical limitations on the re-use and use of state-of-the-art security and privacy-preserving measures, such as pseudonymisation, or encryption where anonymisation may significantly affect the purpose pursued.	5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection and correction in relation to the high-risk AI systems the providers of such systems may **also** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including: (…)	5. To the extent that it is strictly necessary for the purposes of ensuring bias monitoring, detection**,** ***mitigation*** and correction in relation to the high-risk AI systems the providers of such systems may **also** process special categories of personal data referred to in Article 9(1) of Regulation (EU) 2016/679, Article 10 of Directive (EU) 2016/680 and Article 10(1) of Regulation (EU) 2018/1725, subject to appropriate safeguards for the fundamental rights and freedoms of natural persons, including: (…) ***(vi) measures for mitigating consequences of AI biases, such as gender bias, ethnic bias, age bias, or any type of population biases, including the prevalence bias.***
Justification *Biases mitigation is a major challenge in AI. The Regulation should include the need for providers to mitigate consequences of AI biases, such as gender bias, ethnic bias, age bias, or any type of population biases, including the prevalence bias (a priori probability) which strongly influences the value of any data-driven model.*		

Proposal for a regulation – Article 10 – paragraph 6

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that those high-risk AI systems comply with paragraph 2.	-	6. Appropriate data governance and management practices shall apply for the development of high-risk AI systems other than those which make use of techniques involving the training of models in order to ensure that those high-risk AI systems comply with paragraph 2. ***Those practices shall include, where appropriate, the need to consult statutory AI auditors or conduct an AI audit by independent external auditors.***
Justification *The Regulation should call for independent oversight over AI systems to enhance the degree of confidence of the public. Good audit quality contributes to the orderly functioning of markets by enhancing the integrity and efficiency of AI systems. Statutory auditors will fulfil a particularly important societal role, as it does now account auditors. The EU should not accept a system where companies act first and apologise later.*		

Proposal for a regulation – Article 12 – paragraph 4

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum: deleted (a) recording of the period of each use of the system (start date and time and end date and time of each use); (b) the reference database against which input data has been checked by the system;	deleted	***4. For high-risk AI systems referred to in paragraph 1, point (a) of Annex III, the logging capabilities shall provide, at a minimum:*** ***(a) recording of the period of each use of the system (start date and time and end date and time of each use);*** ***(b) the reference database against which input data has been checked by the system;*** ***(c) the input data for which the search has led to a match;***

(c) the input data for which the search has led to a match; (d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).		***(d) the identification of the natural persons involved in the verification of the results, as referred to in Article 14 (5).***
Justification *The automatic recording of events of high-risk AI is necessary to effectively mitigate the risks for health, safety and fundamental rights. This paragraph should be reinstated.*		

Proposal for a regulation – Article 16 – paragraph 1 – point b

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
(b) have a quality management system in place which complies with Article 17;	deleted	***(b) have a quality management system in place which complies with Article 17. The specific needs of small and medium-sized enterprises shall be taken into account;***
Justification *In healthcare the use of high-risk AI systems need to be supported by a robust quality management system in order to ensure that the provider ensures real and genuine compliance with the regulation. This obligation needs to be reinstated and a specific regime for SMEs and start-ups could be envisaged.*		

Proposal for a regulation – Article 17

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
[…]	deleted	***Reinstate Article 17 in full.***
Justification *High-risk AI systems need to be developed under a robust quality management system to guarantee genuine compliance with the draft regulation. In healthcare, there should be incentives for providers to report serious incidents and malfunctions, techniques and procedures for quality control and quality assurance or to set up an accountability framework, among other. Article 17 needs to be reinstated as it outlines common sense practices which every company needs to consider to be credible and to reduce liability risks.*		

Proposal for a regulation – Article 64 – paragraph 2

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.	deleted	2. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2 and upon a reasoned request, the market surveillance authorities shall be granted access to the source code of the AI system.
Justification *In case of complaints, medical regulators need to have access to the algorithm, while respecting trade secrets. This provision needs to be reinstated.*		

Proposal for a regulation – Article 83 – paragraph 1

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned. The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.	-	~~***1. This Regulation shall not apply to the AI systems which are components of the large-scale IT systems established by the legal acts listed in Annex IX that have been placed on the market or put into service before [12 months after the date of application of this Regulation referred to in Article 85(2)], unless the replacement or amendment of those legal acts leads to a significant change in the design or intended purpose of the AI system or AI systems concerned.***~~ The requirements laid down in this Regulation shall be taken into account, where applicable, in the evaluation of each large-scale IT systems established by the legal acts listed in Annex IX to be undertaken as provided for in those respective acts.

Justification *The EU should not accept a system where companies act first and apologise later. A transitional period of 24 months is sufficient in this fast-changing sector as foreseen by Article 85(2).*

Proposal for a regulation – Article 83 – paragraph 2

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.	2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject **to substantial modification as defined in Article 3(23)** in their design or intended purpose.	***~~2. This Regulation shall apply to the high-risk AI systems, other than the ones referred to in paragraph 1, that have been placed on the market or put into service before [date of application of this Regulation referred to in Article 85(2)], only if, from that date, those systems are subject to significant changes in their design or intended purpose.~~***
Justification *The EU should not accept a system where companies act first and apologise later. A transitional period of 24 months is sufficient in this fast-changing sector as foreseen by Article 85(2).*		

Proposal for a regulation – Article 84 – paragraph 1

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation.	-	1. The Commission shall assess the need for amendment of the list in Annex III once a year following the entry into force of this Regulation. ***Such assessment shall be made public and take into account the criteria of Article 7(2).***
Justification *The assessment made by the Commission in relation to the need of amending Annex III, needs to be made public. Such assessment should be based on the criteria of Article 7(2) in order to allow civil society to properly comment and provide input.*		

Proposal for a regulation – Annex III – paragraph 1 – point 1 – point a a (new)

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendment*
-	-	***(aa) AI systems intended to be used for emotion recognition in health research, such as alcohol addiction, violent behaviour and potential misbehaviour.***
Justification *Certain AI systems used for emotion recognition and behaviour cannot be deployed without clear validation as there can be misuse leading to discrimination and harm (e.g. AI systems on emotion recognition for alcohol addiction, violent behaviour, potential misbehaviour which can be used in health research).*		

Proposal for a regulation – Annex III – paragraph 1 – point 5 – point c a (new)

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
-	-	***(ca) AI systems intended to be used for the purpose of determining insurance premium and claim assessments;***
Justification *AI systems used for determining insurance premium can pose a risk of harm to health and safety or a risk of adverse impact on fundamental rights of patients. The proliferation of data about patients/citizens allows insurers to consider a wider array of personal and behavioural data, including genetic data where citizens have no control, making it easier to identify high-risk characteristics in individuals, resulting in refusing insurance cover or increasing prices of insurance policies (ex. premiums for home insurance policies in the Netherlands increasing considerably).* [3] *It also facilitates 'cherry-picking' of low-risk citizens and is thus discriminatory.*		

[3] In this sense see German Data Ethics Commission, 'Opinion of the Data Ethics Commission, <https://www.bmjv.de/SharedDocs/Downloads/DE/Themen/Fokusthemen/Gutachten_DEK_EN.pdf?__blob=publicationFile&v=2>, p. 11.

Proposal for a regulation – Annex III – paragraph 1 – point 5 – point c b (new)

Commission proposal	*JURI Draft Opinion*	*CPME suggestion for amendments*
-	-	***(cb) AI systems intended to be used for medical treatment assessments.***
Justification *AI systems used for assessing medical treatments can pose a risk of harm to health and safety or a risk of adverse impact on fundamental rights of users. There are cases of misdiagnosis or underdiagnosis.*[4] [5]		

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Seyyed-Kalantari, L., Zhang, H., McDermott, M.B.A. *et al.* Underdiagnosis bias of artificial intelligence algorithms applied to chest radiographs in under-served patient populations. *Nat Med* **27,** 2176–2182 (2021). https://doi.org/10.1038/s41591-021-01595-0.

[5] Helbing D, Beschorner T, Frey B, Diekmann A, Hagendorff T, Seele P, Spiekermann-Hoff S, van den Hoven J, Zwitter A. Triage 4.0: On Death Algorithms and Technological Selection. Is Today's Data- Driven Medical System Still Compatible with the Constitution? J Eur CME. 2021 Nov 17;10(1):1989243. doi: 10.1080/21614083.2021.1989243. PMID: 34804636; PMCID: PMC8604483.