27 May 2022

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 proposed amendments to the IMCO-LIBE Draft Report on the Proposal laying down harmonised rules on artificial intelligence (Artificial Intelligence Act)

European Doctors support the draft report of the IMCO-LIBE Committees. The amendments proposed by the co-rapporteurs will increase the safeguards in relation to the protection of fundamental rights, in particular on personal data protection.

CPME believes that the draft report has a balanced and proportionate approach in terms of obligations between providers and users of high-risk AI systems, as well as on the requirement for the European Artificial Intelligence Board to consult with relevant stakeholders, in particular healthcare professionals and patient organisations.

CPME considers that AI systems that are a safety component of a medical device or are by themselves a medical device (software), should abide to the requirements for high-risk AI systems of the AI Act proposal.

Proposed amendments

Amendment 31, Recital 45 b (new)		
Text Proposed by the Commission	**IMCO-LIBE Amendment**	**CPME Proposed Amendment[1]**
-	***(45 b) Providers may not always be able to access the datasets needed to develop high-risk AI systems, such as when the datasets are in the exclusive possession of the user while the provider only provides the tools and the techniques to the user in order to develop the AI system. In such circumstances, the provider cannot objectively comply with the requirements and obligations on the quality of datasets laid down in this Regulation. Such obligations***	***(45 b) Providers may not always be able to access the datasets needed to develop high-risk AI systems, such as when the datasets are in the exclusive possession of the user while the provider only provides the tools and the techniques to the user in order to develop the AI system. In such circumstances, the provider cannot objectively comply with the requirements and obligations on the quality of datasets laid down in this Regulation. Such obligations***

[1] CPME proposed amendments are indicated in bold italics and underlined font.

	should therefore be fulfilled by the user, on the basis of an agreement between the provider and the user.	***should therefore be fulfilled by the user, on the basis of an agreement between the provider and the user. The Commission shall issue benchmarking guidelines on the content of these agreements, which should include rules for the provider to train users on the AI system prior to its use, on the instructions for use or on logging requirements by users.***
Justification		
Benchmarking guidelines on the content of the agreements between providers and users are needed as there could be enormous imbalances in terms of knowledge between parties leading to unfair practices in the market. Guidance on which obligations and how each party should comply with, in particular on offering adequate training on AI techniques and approaches to users of AI systems prior to their use in the healthcare environment, should be provided. These guidelines would support the development of digital skills and capacity building of users in relation to new technologies.		

Article 10, paragraph 6		
Data and data governance		
Text Proposed by the Commission	**IMCO-LIBE Draft Report**	**CPME Proposed Amendment[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.	-	(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		

[2] CPME proposed amendments are indicated in bold italics and underlined font.

it does now account auditors. The EU should not accept a system where companies act first and apologise later.

Amendment 137, Article 29, paragraph 1 point b (new)		
Obligations of users of high-risk AI systems		
Text Proposed by the Commission	**IMCO-LIBE Amendment**	**CPME Proposed Amendment[3]**
-	***1b. Users of high-risk AI systems shall ensure that natural persons assigned to ensure human oversight for high-risk AI systems are competent, properly qualified, and trained and have the necessary resource in order to ensure the effective supervision of the system in accordance with Article 14;***	***1b. Users of high-risk AI systems shall ensure that natural persons assigned to ensure human oversight for high-risk AI systems are competent, properly qualified, and trained and have the necessary resource in order to ensure the effective supervision of the system in accordance with Article 14. An appropriate degree of training and of technical documentation of the high-risk AI system shall be provided to users by providers in this regard.***
Justification		
Training as well as transparent and complete technical documentation on the functioning of the high-risk AI systems are required to be given by providers to users in order to ensure that the latter can properly train natural persons assigned to human oversight.		

Amendment 181, Article 56, paragraph 2 point c (new)		
Establishment of the European Artificial Intelligence Board		
Text Proposed by the Commission	**IMCO-LIBE Amendment**	**CPME Suggested Amendment**
-	-	*(c)* ***promote the exchange of knowledge and documentation, consulting with relevant stakeholders in relation to specific uses of AI in critical sectors, such as NGOs representing healthcare professionals and patients' organisations.***

[3] CPME proposed amendments are indicated in bold italics and underlined font.

Justification
Involve healthcare professionals in the formulation of digital policies related to Artificial Intelligence at local, national and European Level. This will be key to increase the potential of AI use in healthcare.

Article 83, paragraph 1		
AI systems already placed on the market or put into service		
Text Proposed by the Commission	**IMCO-LIBE Draft Report**	**CPME Proposed Amendment[4]**
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). Companies should comply with the AI Act.		

Article 83, paragraph 1		
AI systems already placed on the market or put into service		
Text Proposed by the	**IMCO-LIBE Draft Report**	**CPME Proposed Amendment**

[4] CPME proposed amendments are indicated in bold italics and underlined font.

Commission		
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 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). Companies should comply with the AI Act.		

Amendment 284, Article 84, paragraph 1		
Evaluation and review		
Text Proposed by the Commission	**IMCO-LIBE Amendment**	**CPME Proposed Amendment[5]**
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 ***and on a regular basis following a recommendation of the Board.***	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 ***and on a regular basis following a recommendation of the Board. Such assessments shall be made public and shall take into account the criteria outlined under 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.		

[5] CPME proposed amendments are indicated in bold italics and underlined font.