CPME/AD/EC/06082021/085_Final/EN

On 6 August 2021, the CPME Executive Committee adopted the 'CPME Feedback on Commission Proposal for a Regulation on Artificial Intelligence' (CPME 2021/085 FINAL).

CPME Feedback on Commission Proposal for a Regulation on Artificial Intelligence

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.

General Comments

CPME commends the European Commission for developing a ground-breaking legislation laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) ('the Proposal').[1]

European doctors welcome the overall risk-based approach for artificial intelligence (AI), the creation of the *European Artificial Board*, the development of the *EU database for high-risk AI* and the proposed *risk management system*.

European doctors also welcome the proposed definition of the AI system and the possibility to update the list of AI techniques and approaches in accordance with market and technological developments. In healthcare, the proposed definition will ensure that where an AI system is a safety component of a medical device, or is by itself a medical device (software), subject to third-party conformity assessment under the medical devices framework, then the AI system is considered of high-risk for the purpose of the AI proposal. This high-risk classification is needed to guarantee patient utmost safety. To minimise additional burdens to providers, CPME further appreciates that the AI systems requirements set out in the AI proposal will be examined as part of the existing third-party conformity assessment procedures under the relevant medical device framework, ensuring alignment between both legal regimes.

Detailed Comments

1. Stand-alone high-risk AI listed in Annex III

CPME notes that the Annex III list of high-risk AI systems referred to in Article 6(2) should still include the use of AI i) for determining insurance premium, ii) for assessing medical treatments and iii) for health research. CPME advises that this list should be regularly updated in accordance with market and technological developments.

[1] COM(2021) 206 final.

Rue Guimard 15 (4th Floor) - 1040 Brussels - Belgium
Tel. : +32 (0)2 732 72 02 - Fax : +32 (0)2 732 73 44 - E-mail : secretariat@cpme.eu - Web : www.cpme.eu
Company registration number : 0462509658 - Transparency register number : 9276943405-41

2. Data and data governance - Article 10(6)

CPME recommends that it should be identified as an *appropriate data governance and management* practice the need to consult regularly, or conduct audits, by an AI external auditor. These audits by external auditors should be harmonized and standardized internationally or as minimum within the EU. The EU AI Board could be considered to serve as audit standardization and harmonization body. Similar to auditors for corporate governance, this new, complex and evolving environment calls for the establishment of independent external auditors who examine the processes and procedures put in place by the provider when developing the AI system. External auditors could provide an accurate and fair understanding of the technical documentation released by the provider, helping to generate trust among the public at large. A specific provision should be included in this regard.

3. Transparency and provision of information to users - Article 13

CPME fears that the information provided to users will not allow appropriate understanding of the AI system. Particularly in healthcare, transparency requires that the information provided to users is clear and understandable for non it-specialists. Moreover, an independent authority or third party should have access to the algorithm in case of complaints or questions, taking due account for copyright, privacy and commercial sensitivities. An open source should be allowed for certain AI systems, where specialist organisations can test the algorithm to ensure that there is no bias.

4. Human oversight – Article 14

CPME recommends that the *human oversight* is of 'high quality', meaning that the individual needs to have the necessary competences to guarantee an adequate oversight, and the provider is appropriately resourced for the effective performance of the task. Paragraph 3a: the function for the human oversight should be an integral part of the High Risk AI System which enables effective human oversight with high usability. The insertion "when technically feasible" should be deleted.

5. Quality management system – Article 17(1)(i) and Article 62

CPME supports a clear obligation to audit and to quality control with regularly statutory reporting obligation to the regulator. CPME further recommends full disclosure of serious incidents and malfunctions by providers/developers of AI systems to patients and users. In addition, medical obligations need to be supervised by medical regulators, such as the health inspectorate, to guarantee the quality of healthcare. Agreements and collaborations will be required on who ensures oversight over what.

6. Conformity assessment – Article 43

CPME supports the inclusion under Article 43 of the Proposal of an *ex-ante* third-party conformity assessment to be carried out for high-risk AI.2

7. CE marking of conformity – Article 49

CPME believes that the CE marking of conformity should only be given to those AI systems that comply with EU law, including the General Data Protection Regulation (GDPR). The compliance of the latter should be a requirement under Chapter II and audited by a third party before the CE marking is affixed.

[2] In this sense, please see point 37 of the EDPB-EDPS Joint Opinion 5/2021, 18 June 2021.

This would ensure alignment with the rules and principles of data protection, in particular the accountability principle pursuant to Article 5(2) of the GDPR.[3]

8. Transparency obligations for certain AI systems – Article 52 – & System of redress

CPME considers that the provider of the AI system needs to properly describe the AI-attributes in the instructions for use. For example, what aspects and how the AI provides for human oversight, what aspects and how the AI changes, providing a description of the changes and how humans could control the change. The provider should also inform the user how the system needs to be adjusted to ensure that fairness and accuracy are considered to be aligned, as well as the system precision, confidence and error percentages.

CPME supports the views of the European Data Protection Board and the European Data Protection Supervisor on the need for the Proposal to be fully aligned with the EU data protection framework.[4] In particular, the need for the AI system to provide from the very beginning the possibility for exercising data subject rights, such as deletion, correction, restriction, whatever the chosen approach for AI or the technical architecture. The individual should also be aware when his/her data are used for AI training and/or prediction, the legal basis for such processing, be given a general explanation of the logic (procedure) and the scope of the AI system, as well as a clarification on the rights and remedies available.

CPME also supports the development of a system of redress for the AI user. If a doctor uses an AI system according to the training provided and in adherence with the guidelines or instructions for use, he/she should be fully indemnified against adverse outcomes.

9. Designation of national competent authorities – Article 59

European doctors alert for the need to ensure that medical obligations resulting from the use of AI systems in healthcare are supervised by national medical regulators. This to guarantee the quality of healthcare and its effectiveness. Agreements and collaborations will be required to ascertain roles and responsibilities over healthcare oversight of the AI system.

10. AI systems already placed on the market or put into service – Article 83

CPME believes that after a certain transitional period, the AI systems already in operation should also comply with the requirements of the AI Regulation in order to ensure the same level of protection.

11. Specificities of AI use by healthcare professionals

Prior probability in AI for healthcare should not escape evidence-based science and fair treatment. A doctor when seeing a patient does not see the prior probability. He/she adapts the probability in accordance with the context and it will not be the same for every patient. In AI data sets, the prior probability needs to be properly assessed.

European doctors believe that the use of an AI system to infer emotions of a natural person is highly undesirable and should be prohibited except for health purposes (e.g. where emotion recognition is important for patients) or research purposes. In addition, even in healthcare, certain systems 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, among other related to emotions and behaviour).

---

[3] In this sense, please see point 23 of the EDPB-EDPS Joint Opinion 5/2021, 18 June 2021.

[4] Please refer to points 56-60, EDPB-EDPS Joint Opinion 5/2021, 18 June 2021.