## **VOTING ADVICE**

## JUNE 2023



Compromise Amendment	Implication	Advice
CA1: Title III, Chapter 4 and recitals 65 and 65a	<b>Notified bodies</b> Additional criteria for notified bodies, including on conflict of interest, expertise, sufficient numbers of bodies, and cybersecurity. This is essential as the level of independence and expertise of notified bodies for medical devices is often disputed	SUPPORT
CA3: Articles 16 to 29a and associated recitals	Obligations of providers, deployers, distributors The deployer of high-risk AI systems should carry out a fundamental rights impact assessment prior to putting it into use. Elements of this assessment are detailed. Additional obligations for providers of high-risk systems, such as provision of specifications for input data, including limitations and assumptions, as well as conformation with accessibility requirements.	SUPPORT
CA5: Articles 8 to 12, Annex IV and recitals 42-46b	<b>Environmental provisions &amp; requirements high-risk Al</b> Includes additional specification on types of biases, provisions to detect and address biases, and cybersecurity provisions.	SUPPORT
CA9: Title VI, Chapter 2, Title VII, Title VIII and recitals 77- 80a and 82-82b	<b>Complaints &amp; explanation</b> The right to lodge a complaint and right to explanation are included. Right to explanation and to be informed when high risk AI is used to assist in decision making. This is an important prerequisite to enable people to exercise their right to informed consent in case of AI used in healthcare.	SUPPORT



CA10: Title III, Chapter 1, Annexes II and III and recitals 27 to 41a	<b>High risk Al</b> Healthcare is added as area which deserves specific consideration, and several uses of AI in healthcare are added to Annex III. Specifically, AI for public assistance benefits and services from public authorities, including healthcare services is now in Annex III, as well as systems which influence decisions on eligibility for health insurance, and emergency patient triage systems, as they could limit access to healthcare of perpetuate discrimination.	SUPPORT
CA11: Article 5(1)(a) to (c), (da) to (dc), Article 5(1a), recitals 14-17 and 26a-26d	<b>Prohibited uses</b> Additional prohibited uses, including purposefully manipulative or deceptive techniques, biometric categorisation, predicting or risk assessments for criminal or administrative offences, based on profiling, as well as emotion recognition in areas of workplace, education and border management.	SUPPORT

We further ask MEPs to include the following AI systems as high-risk in Annex III:

- AI systems which process sensitive health data, as defined by Article 9 of the General Data Protection Regulation (2016/679), irrespective of their intended use.
- Al systems intended to be used for monitoring or tracking of movement and activity for purposes of surveillance in home care and long-term care.

For more information email:

## Janneke van Oirschot

AI and Medicines Project Lead

janneke@haiweb.org

www.haiweb.org



