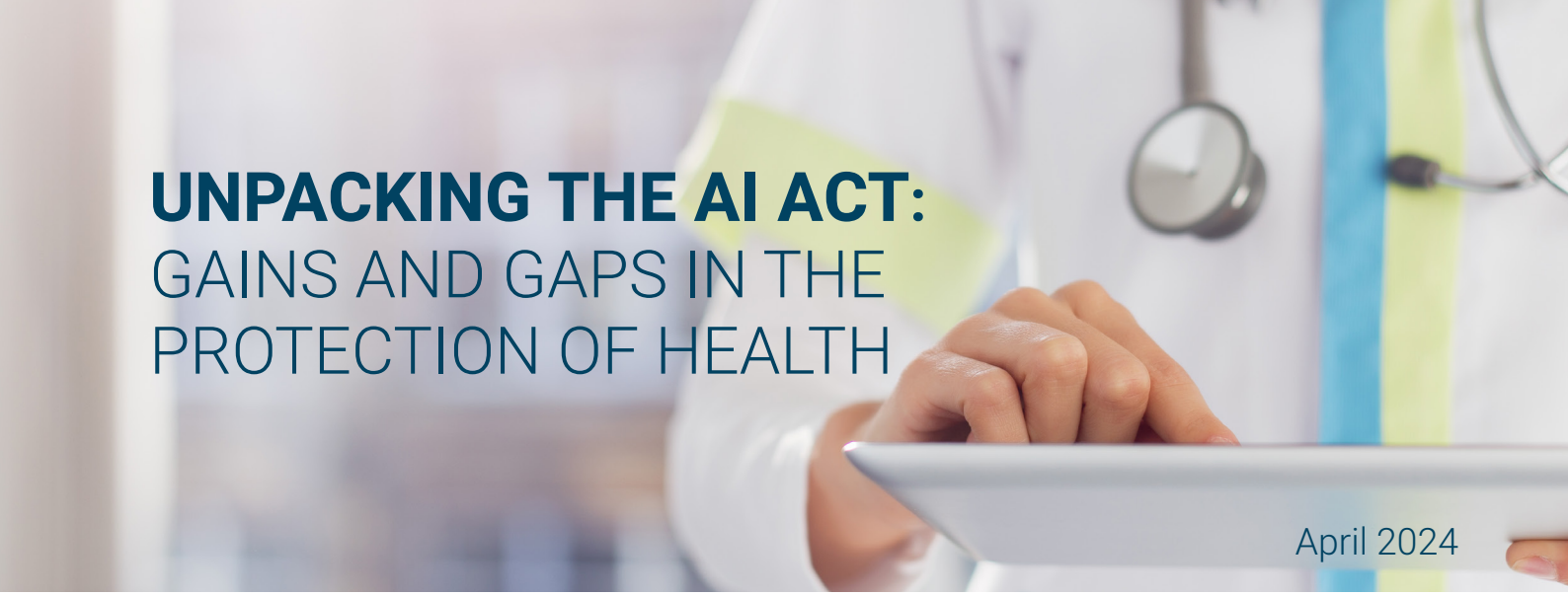

UNPACKING THE AI ACT: GAINS AND GAPS IN THE PROTECTION OF HEALTH

April 2024

The Artificial Intelligence (AI) Act is a much-discussed piece of innovative European Union (EU) legislation that is generating global interest. The law was adopted by the European Parliament in March 2024 and, at the time of writing, only subject to linguistic changes. The AI Act will have major implications for healthcare, making it essential to understand what it means for the sector. This fact sheet lists some of the protections that the Act will bring to health AI, as well as gaps that still remain.

STRENGTHS	WEAKNESSES
Risk Classification	
All AI-based medical devices will be high-risk. They will need to meet specific requirements in terms of the data used, performance for different target groups and risk management, and undergo a conformity assessment by a third party. This is of great importance for good quality of care.	Many AI systems used in healthcare are not medical devices, but can pose risks. For example, AI in surveillance systems and assistive technology in elderly care, a variety of health apps, including for women's health and mental health, chatbots for triaging and systems for public health surveillance, all of which represent booming markets. The quality and trustworthiness of these systems will not be secured under this Act.
High Risk Requirements	
Providers of high-risk AI must comply with requirements on risk management, data governance, provision of instructions, human oversight, accuracy and robustness. Conformity will be externally assessed: The notified bodies that assess conformity with EU medical devices regulation will also assess conformity with the AI Act. This will improve safety and quality of AI-based medical devices.	The devil is in the detail. The Act is currently broadly phrased and the exact scope and meaning of many requirements will have to be delineated in further European Commission guidance, delegating Acts, and standards. For example, what constitutes vulnerable groups, 'appropriate level of accuracy', and risks that must be assessed, should be comprehensively defined.
Fundamental Rights	
Public deployers of high-risk AI systems, such as municipalities and the Ministry of Health (or private operators providing public services), need to conduct a fundamental rights impact assessment before they start using the system, and submit the results.	In many European health systems, the majority of deployers of high-risk AI are private entities (e.g., privatised hospitals or insurance companies), and therefore will not have to conduct this assessment, despite providing essential services to people.

STRENGTHS	WEAKNESSES
Public Oversight	
Providers of some high-risk AI systems (those listed in Annex III, not medical devices) must register the AI system in a public database. Public deployers of some high risk AI systems (those listed in Annex III, not medical devices) must register their use in a public database.	These transparency obligations only apply to the high-risk AI systems listed in Annex III. Medical devices are not included. Furthermore, again, many deployers of AI in healthcare are private entities, so will also not have to register their uses of high-risk AI. These are major shortcomings. Mandatory registration of all high-risk AI systems in healthcare, including medical devices, by providers and public and private deployers, would improve oversight and assist in assessing the scope, implementation and potential gaps of the AI Act.
Informing People About AI Use	
If a person is subject to a decision that is made or assisted by some high-risk AI systems (those listed in Annex III, not medical devices), the deployer of the system must inform the person about it.	These transparency obligations only apply to the high-risk AI systems listed in Annex III. Medical devices are again not included. For AI-assisted medical devices, it is especially important that people who are subject to them are well-informed, in order to protect medical ethical principles of informed consent.
Health Specificity	
The Act aims to protect the health, safety and fundamental rights of individuals.	The AI Act does not define health or health protection. The Act is a horizontal legislation, therefore, some of its implications on healthcare still need clarification.

This overview shows that unfortunately, AI in healthcare is left out of protections on multiple fronts, which will compromise patient's rights and leaves serious gaps in oversight and accountability for the sector. Despite this, it is a step forward for protecting patients against the harmful effects of AI while reaping the benefits of trustworthy technologies that can advance healthcare. We will continue to encourage policymakers to centralise health when developing their plans for the Act's implementation.

Janneke van Oirschot
Research Officer and AI and Health Project Coordinator, Health Action International

Contact: janneke@haiweb.org

Hannah van Kolfschooten
Researcher and Lecturer at the Law Centre for Health and Life, University of Amsterdam

WWW.HAIWEB.ORG

European Artificial Intelligence & Society Fund

This project has been supported by the European Artificial Intelligence & Society Fund (EAISF), a collaborative initiative of the Network of European Foundations (NEF). The sole responsibility for the project lies with the organiser(s) and the content may not necessarily reflect the positions of EAISF, NEF or European AI Fund's Partner Foundations.

Funded by the European Union

Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency (HADEA). Neither the European Union nor the granting authority can be held responsible for them.