



Interpreting the EU **Artificial Intelligence Act** for the Health Sector

FEBRUARY 2022

Interpreting the EU **Artificial Intelligence Act** for the Health Sector

Janneke van Oirschot

Research Officer, Health Action International

Gaby Ooms

Research Manager, Health Action International

For correspondence: janneke@haiweb.org

February 2022

Acknowledgements

We would like to thank Sarah Chander, Senior Policy Advisor at European Digital Rights (EDRI), for reviewing an earlier version of this report.

**Publisher**

Health Action International
Overtoom 60 (2) | 1054 HK Amsterdam
The Netherlands
+31 (0) 20 412 4523

Copyright

This report is licensed under a Creative Commons Attribution-NonCommercial 4.0 International Licence. View a copy of this licence at www.creativecommons.org/licenses/by-nc/4.0.

HAIWEB.ORG

CONTENTS

1. BACKGROUND	2
2. INTRODUCTION OF THE EU ARTIFICIAL INTELLIGENCE ACT (AIA) REGULATORY PROPOSAL	3
3. WHAT DOES THE EU AIA REGULATORY PROPOSAL MEAN FOR HEALTH-RELATED AI SYSTEMS? .	5
4. THE DEFINITION OF A MEDICAL DEVICE ACCORDING TO REGULATION (EU) 2017/745 ON MEDICAL DEVICES	6
5. WHICH MEDICAL DEVICES REQUIRE ‘THIRD PARTY CONFORMITY ASSESSMENT’ UNDER THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES?	7
6. HOW DOES THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES CLASSIFY MEDICAL SOFTWARE INTO RISK LEVELS?	8
7. HOW WILL HEALTH-RELATED AI SYSTEMS BE CLASSIFIED UNDER THE EU AIA REGULATORY PROPOSAL?	9
8. THE COMPLIANCE REQUIREMENTS UNDER THE EU AIA REGULATORY PROPOSAL.....	12
9. CONCERNS OF THE EU AIA REGULATORY PROPOSAL FOR HEALTH-RELATED AI SYSTEMS.....	14
A. Risk Categorisation	14
B. Regulatory Requirements	17
C. Third Party Assessment	18
D. EU Public Database and CE Marking	19
10. CONCLUSION.....	20
11. RESOURCES	21

ABBREVIATIONS

AI	Artificial Intelligence
AIA	Artificial Intelligence Act
ANEC	European Association for the Co-ordination of Consumer Representation in Standardisation AISBL (a.k.a. The European consumer voice in standardisation)
CE	Conformité Européenne
EC	European Commission
EMR	Electronic Medical Record
EU	European Union
EUDAMED	European Database on Medical Devices
HAI	Health Action International
IC	Intensive Care
MDR	Medical Devices Regulation
ML	Machine Learning
R&D	Research and Development

1. BACKGROUND

The incredible increase in digital data covering every aspect of our lives, both within and outside the health system, provides a myriad of new opportunities to monitor our health, learn about causes of disease, develop new therapies, and influence lifestyles. At the moment, artificial intelligence (AI) systems are penetrating the health sector and are increasingly successful at diagnosis using scans and images; repurposing or development of new therapies; patient triaging; care planning; and increasing administrative efficiency. However, its use in clinical practice remains limited to date, and the breakthrough developments that will revolutionise healthcare are yet to be seen.

Expanding boundaries of the type of data that can make inferences about an individual's health, and who has access to these data, raises concerns about our autonomy and privacy (Ada Lovelace Institute, 2020; IDB, 2020). An example of this is the use of our health data by pharmaceutical and tech companies for commercial purposes. On top of that, healthcare data is historically full of flaws and biases. When it is used to build AI systems, it can cause discrimination and perpetuate inequities (Leslie et al., 2021). Finally, an important concern is the question who benefits from technological advancements and how they impact on national and international systematic inequities.

It is essential to protect citizens from the potential harms of AI technologies and realise their safety and accountability. That is why, in April 2021, the European Commission (EC) presented a regulatory proposal for AI in the European Union (EU). Today, more than ever, individual health and public health systems are of paramount importance to EU Member States, so it is crucial to understand what impact any new AI regulation would have on both the health sector and AI innovation itself. In this report, we will dismantle and interpret the regulatory proposal to determine when a health-related AI system would be managed and controlled and what regulatory requirements it would be subject to, in order to identify the gaps and weaknesses of the EU AI Act (AIA) regulatory proposal.

Throughout this paper we use the terms **health-related AI** and **AI systems used in the health sector** interchangeably to mean a broad collection of all AI systems used within the formal healthcare sector and those used outside formal healthcare with the aim to influence people's health and wellbeing.

2. INTRODUCTION OF THE EU ARTIFICIAL INTELLIGENCE ACT (AIA) REGULATORY PROPOSAL

After repeated requests from the European Parliament and the European Council to adequately regulate AI systems at EU level, in April 2021, the EC came forward with a proposal for a ‘Regulation of the European Parliament and of the Council laying down harmonised rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative Acts’ (European Commission, 2021). This proposal for a supranational regulatory framework on AI is a first of its kind globally. Its stated objectives are to:

- Ensure that AI systems placed on the Union market and used are safe and respect existing law on fundamental rights and Union values;
- Ensure legal certainty to facilitate investment and innovation in AI;
- Enhance governance and effective enforcement of existing law on fundamental rights and safety requirements applicable to AI systems;
- Facilitate the development of a single market for lawful, safe and trustworthy AI applications and prevent market fragmentation (European Commission, 2021).

Over the coming months, the regulatory proposal will be scrutinised by the European Parliament and the EU Council. In the meantime, this report clarifies the consequences of the proposal for health-related AI systems.

The regulatory proposal uses a broad definition of AI: an “artificial intelligence system’ (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with”.

Annex I lists (a) machine learning approaches, (b) logic and knowledge-based approaches and (c) statistical approaches.

This means both techniques that **learn from data automatically** without explicit programming (machine learning), and those **that involve human programming** (logic, knowledge based & statistical approaches) are covered by the regulation.

The regulation subsequently uses a risk-based approach to classify AI systems into unacceptable risk, high risk, and low or minimal risk. Different requirements apply for every classification according to the risk level.

Unacceptable risk

Systems that fall under this category are prohibited and cannot be placed on the market, put into service or used. Examples are AI systems which “*deploy subliminal techniques beyond a person’s consciousness in order to distort a person’s behaviour in a manner that is likely to cause physical or psychological harm*”, which “*exploit the vulnerabilities of a specific group of persons due to their age, physical or mental disability, in order to distort the behaviour of a person in a manner that is likely to cause physical or psychological harm*”, and which “*use ‘real-time’ remote biometric identification systems in publicly accessible spaces for the purpose of law enforcement, except for in limited exceptional cases.*”

High risk

Systems which fall under this category are subject to “*compliance with certain mandatory requirements and an ex-ante conformity assessment*”.¹ The regulatory requirements are discussed in more detail in section 7 of this report. The regulation defines high-risk AI as following:

“An AI system shall be considered high-risk where both of the following conditions are fulfilled:

- *The AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonisation legislation listed in Annex II;*
- *The product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonisation legislation listed in Annex II.*

In addition, AI systems referred to in Annex III shall also be considered high-risk.”

In other words, all AI systems listed in Annex III of the proposal, plus all systems that fall under the regulations listed in Annex II that are required to undergo a third-party conformity assessment, would be classified as high-risk systems under the EU AIA.

Low or minimal risk

These AI systems are not specifically defined by the regulation but comprise all other AI systems. Producers of low-risk AI are encouraged, but not obligated to create behavioural codes of conduct to promote adherence to the legal requirements which apply to high-risk systems. They are solely subject to self-assessment. Further, some specific systems, including those intended to interact with people (e.g., chat bots), emotion recognition systems, biometric categorisation systems and those using content manipulating ‘deep fake’ technologies, need to meet transparency obligations and inform users that they are interacting with an AI system.

A crucial aspect of the risk categorisation is that it is based on the **intended purpose** of an AI system. This means, the purpose of the AI system as intended by the provider, as described in the instructions for use, promotional or sales materials and statements, and technical documentation. The classification as high-risk therefore depends on the function performed by the system and on the specific purpose for which that system is used. How users are likely to **actually** use the system, referred to by ANEC as “foreseeable use”, is not taken into account (ANEC, 2021).

¹ ‘Ex ante’ meaning before a product is placed on the market or put into service.

3. WHAT DOES THE EU AIA REGULATORY PROPOSAL MEAN FOR HEALTH-RELATED AI SYSTEMS?

Only a limited number of specific AI systems are designated as having ‘unacceptable risk’ and are therefore prohibited, and this category has limited relevance for AI systems deployed in the health sector.² For high-risk systems this is different. To recap: all systems listed in Annex III of the AIA regulatory proposal, plus all systems that fall under the regulations listed in Annex II which are required to undergo a third-party conformity assessment, would be classified as high-risk systems under the EU AIA.

The only legislations listed in Annex II that are relevant to health are the European regulations on medical devices:

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 **on Medical Devices**, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).
- Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 **on in vitro diagnostic medical devices** and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Further, in Annex III, only point five lists an AI system relevant to health. Namely 5(c): “AI systems intended to be used to dispatch, or to establish priority in the dispatching of emergency first response services, including by firefighters and medical aid.”

No other AI systems used in the health sector are marked as high-risk. What this means for health-related AI systems, is that all which fall under the EU Medical Devices regulation (EU 2017/745) **AND** require third-party conformity assessment under that regulation, are classified as high risk, together with systems focused on dispatching emergency first response services.

Hence, the next question is: which AI systems qualify as a medical device and require third-party conformity assessment under the EU Medical Devices regulation (MDR)? Those will automatically be classified as high-risk AI systems under the EU AIA regulatory proposal.

² Some prohibited systems may use health data or relate to the health sector in another way. Please see section 6, ‘unacceptable-risk medical device/software’.

4. THE DEFINITION OF A MEDICAL DEVICE ACCORDING TO REGULATION (EU) 2017/745 ON MEDICAL DEVICES

According to the MDR (EU) 2017/745, a medical device is defined as follows in Article 2 (1):

*“Medical device means any instrument, apparatus, appliance, **software**, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:*

- *Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease;*
- *Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;*
- *Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state;*
- *Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.*

And which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means” (the European Parliament and the Council of the European Union, 2017).

Further, devices for the control or support of conception, and products intended for the cleaning, disinfection or sterilisation of devices also classify as medical device.

This is a comprehensive definition, and many health-related AI systems can be classified as medical device. However, many are also left out. In section 6 of this report specific examples are provided to illustrate which systems would and would not qualify. AI systems which are classified as a medical device can be assumed to fall under the category of software.

Specifically for software, line 19 of the preamble of the MDR clarifies that:

“It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, qualifies as a medical device, while software for general purposes, even when used in a healthcare setting, or software intended for life-style and well-being purposes is not a medical device. The qualification of software, either as a device or an accessory, is independent of the software's location or the type of interconnection between the software and a device.”

As in the EU AIA, the classification of systems as medical device in the MDR is based on the intended purpose of the provider. The next section will provide insight into the risk categorisation.

5. WHICH MEDICAL DEVICES REQUIRE ‘THIRD PARTY CONFORMITY ASSESSMENT’ UNDER THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES?

Similar to the EU AIA regulatory proposal, the EU MDR uses a risk-based approach, classifying medical devices into four categories: from the lowest risk (Class I) to medium risk (Classes IIa and IIb), to highest risk (Class III). The conformity assessment procedure for Class I devices is the sole responsibility of manufacturers. Hence, these devices are not subject to ‘third party assessment’ and will not be classified as high risk under the EU AIA. The MDR states that “for Class IIa, Class IIb and Class III devices, an appropriate level of involvement of a notified body should be compulsory”.

Further down in the regulation it states that the notified body carries the responsibility to:

- *Verify, for Class IIb devices, the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to those devices,*
- *Confirm, for Class IIa devices, the conformity with the technical documentation referred to in Annexes II and III and with the requirements of this Regulation which apply to those devices.*

This would mean that all systems from IIa onward are subject to a level of ‘third-party conformity assessment’, which would imply that those systems are classified as high-risk under the EU AIA regulatory proposal.

The next section looks at how the MDR classifies software as a medical device in risk categories.

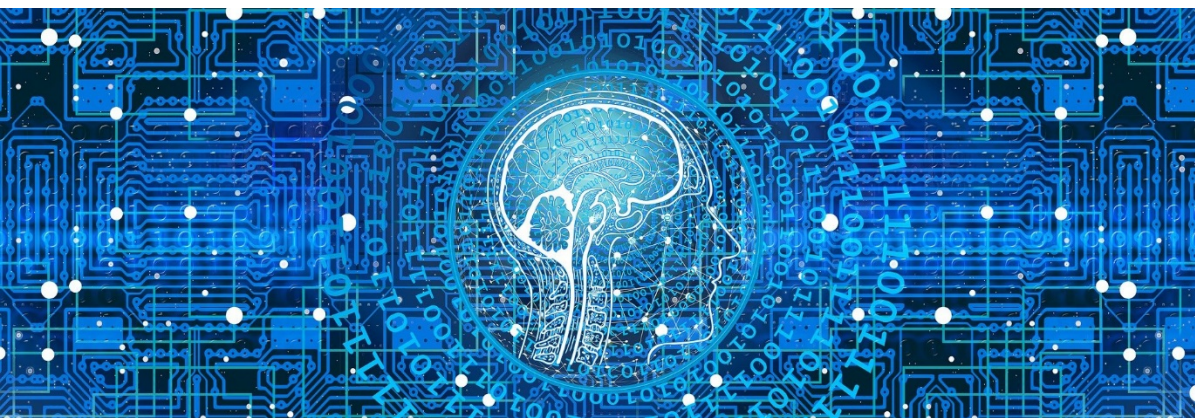


Image by Gert Altmann from Pixabay

6. HOW DOES THE REGULATION (EU) 2017/745 ON MEDICAL DEVICES CLASSIFY MEDICAL SOFTWARE INTO RISK LEVELS?

The final question to be answered before we can derive what health-related AI systems are assigned to which risk category in the EU AIA regulatory proposal, is how the MDR classifies health-related AI systems into risk categories. The regulation does not specifically define a risk categorisation for software that makes use of AI approaches. However, rule 11 of the regulation defines the classification of software in general, under which AI-based systems will likely fall. It states:

“Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause:

- *Death or an irreversible deterioration of a person's state of health, in which case it is in Class III; or*
- *A serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as Class IIb.*

Software intended to monitor physiological processes is classified as Class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as Class IIb. All other software is classified as Class I.”

Finally, under rule 15, software used for contraception will be classified as Class IIb. Hence, both the seriousness of the health condition as well as the significance of the systems' contribution to the decision weigh in on the risk categorisation.

7. HOW WILL HEALTH-RELATED AI SYSTEMS BE CLASSIFIED UNDER THE EU AIA REGULATORY PROPOSAL?

As stated previously, due to the broad definition in the EU MDR, many AI systems used in health could be classified as a medical device. Some of those will not be subject to external conformity assessment and will therefore not be regarded as ‘high-risk’ under the EU AIA regulatory proposal. Further, many AI systems used in health will, despite the broad definition, not be classified as medical device, and will therefore not be classified as ‘high-risk’ under the EU AIA either—for example, systems that influence health on population level, and systems which indirectly influence health, including those used in medical research and development (R&D) (see Figure 1). If we summarise this, it means that, **for health, only software which is used to diagnose patients, make therapeutic decisions, monitor physiological processes or which is used for contraceptive purposes, is classified as a IIa medical device or higher, and hence subject to third party conformity assessment and classified as a high-risk AI system in the EU Artificial Intelligence Act (AIA).**

This means health-related AI systems belong to one of three groups under the EU AIA:

1. Not a medical device or a low-risk medical device/software.

Systems that do not fall under the definition of the EU regulation on Medical Devices, as well as systems that do make the definition of a medical device but are not used to diagnose patients, make therapeutic decisions, monitor physiological processes or for contraceptive purposes, which are hence classified as a level I medical device. Both types of systems are not classified as high-risk AI so are not subject to third-party conformity assessment within the EU AIA regulatory proposal.

Examples of health-related AI systems not classified as a medical device

Fitness or nutritional apps

Specifically, those that provide tailored exercise or dietary advice based on personal characteristics including weight and age, intended to promote a healthy lifestyle. Based on line 19 of the preamble of the MDR, software intended for lifestyle and well-being purposes is not a medical device.

AI system that identifies patients likely to not attend a CT scan appointment

This system is not intended for one of the medical purposes set out in the definition of Article 2 (1) of the MDR.

Hospital Information System that uses an AI algorithm intended to help streamline insurance and billing procedures

Again, this system is not intended for one of the medical purposes set out in the definition of Article 2 (1) of the MDR.

Examples of low-risk medical devices

AI system that predicts 30-day hospital readmissions for patients with coronary heart disease based on Electronic Medical Record (EMR) data intended for hospital management to plan their intensive care (IC) capacity

This system would classify as a medical device as it is used for the prediction of disease (Article 2 (1) MDR). However, it is not used for the specific characteristics as outlined in rule 11 of the MDR, so will likely be defined as Class I under this regulation. Hence, it will be assigned a low-risk status within the EU AIA.

AI system that selects patients who meet specific medical and biomarker criteria from EMR data intended to recruit participants for participation in a clinical trial

This system would classify as a medical device as it investigates a physiological or pathological state (Article 2 (1) MDR). However, again it is not used for the specific characteristics as outlined in rule 11 of the MDR, so will likely be defined as a Class I under this regulation. Hence, it will be assigned a low-risk status within the EU AIA.

2. A high-risk medical device/software.

Systems that make the definition of medical devices and are used to diagnose patients, make therapeutic decisions, monitor physiological processes or for contraceptive purposes. These are classified as high-risk under the EU AIA regulatory proposal and are subject to third-party conformity assessment under this proposal.

Examples of high-risk medical devices

Application for consumers used to assess skin lesions intended to provide a risk estimate and medical advice

This system would classify as a medical device as it is used for the diagnosis and monitoring of disease (Article 2 (1) MDR). Automatically this means it is a system with diagnostic or therapeutic purposes, and therefore classified as a Class IIa medical device (Rule 11 MDR).

AI system which monitors patient side effects to selective serotonin reuptake inhibitors intended to make dose adaption recommendations to physicians

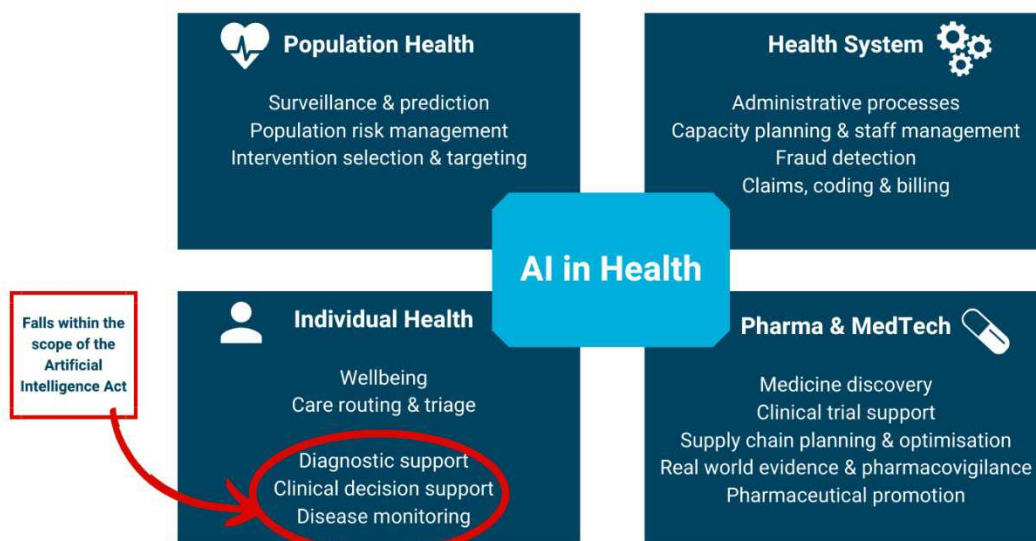
This system would classify as a medical device as it is used for the monitoring and treatment of disease (Article 2 (1) MDR). Again, this means it is a system with diagnostic or therapeutic purposes, and therefore classified as a Class IIa medical device (Rule 11 MDR).

3. An unacceptable-risk medical device/software.

Systems that deploy subliminal techniques beyond a person’s consciousness or that exploit the vulnerabilities of a specific group of persons due to their age, physical or mental disability in order to distort a person’s behaviour in a manner that is likely to cause physical or psychological harm. Some prohibited systems may use health data or relate to the health sector in another way.

Examples of unacceptable risk	
AI-based social scoring for general purposes done by public authorities	Health data can be used for social scoring, but often has consequences in areas other than health, such as social welfare.
‘Real-time’ remote biometric identification systems	Prohibited in publicly accessible spaces for the purpose of law enforcement. This means that such systems are still allowed to be used for other purposes. For example, in hospitals for access control. ³

Figure 1. Applications covered by the AIA vs. wider use of AI in health



Based on USAID & the Rockefeller Foundation (2019), IDB (2020)

³ Civil society would like to see all biometric identification in public spaces prohibited, including for example in hospitals. See [An EU Artificial Intelligence Act for Fundamental Rights: A Civil Society Statement](#). 30-11-2021 Page 3.

8. THE COMPLIANCE REQUIREMENTS UNDER THE EU AIA REGULATORY PROPOSAL

Low risk systems

There are no mandatory requirements to low- or minimal-risk AI systems, but development of codes of conduct are encouraged to foster the voluntary application of requirements to low-risk AI systems.

High risk systems

Title 3, Chapter 2, outlines the legal requirements for high-risk AI systems on data and data governance, documentation and record keeping, transparency, and provision of information to users, human oversight, robustness, accuracy and security.

Providers of high-risk AI systems must adhere to the following requirements:

- Establish, implement and maintain a risk management system.
- Establish and implement a quality management system in its organisation (as described in Article 17).
- Draw-up and keep up-to-date the technical documentation.
- If possible, save the automatically generated logs of the AI system.
- Undergo conformity assessment and potentially re-assessment of the system (in case of significant modifications) prior to its placing on the market or putting into service.
- Conduct post-market monitoring.
- Take corrective action if the system does not comply with requirements (set out in Chapter 2 of Title III) and inform the relevant national competent authorities/notified bodies of the non-compliance and corrective action taken.
- Upon request of a national competent authority, demonstrate the conformity of the high-risk AI system with the requirements (set out in Chapter 2 of Title III).
- Register AI system in EU database (As described in Article 51).
- Affix CE (Conformité Européenne) marking and sign declaration of conformity.
- Collaborate with market surveillance authorities.

Further, there are some (minimal) obligations on the users of high-risk AI systems, listed in Chapter 3, Article 29. Users are defined as “any natural or legal person, public authority, agency or other body using an AI system under its authority, except where the AI system is used in the course of a personal non-professional activity” (Title 1, Article 3). Users’ obligations come down to using high-risk AI systems in accordance with the instructions of use, monitoring of the functioning of the AI systems, reporting of malfunctioning to providers, and carrying out a data protection impact assessment where applicable.

To enforce the EU AIA, a cooperation mechanism at EU level called ‘the European Artificial Intelligence Board’ will be established. Further, existing structures at Member States level will be used for governance.

Paragraph 3 of Article 43 sets out that “For high-risk AI systems, to which legal acts listed in Annex II, section A, apply, the provider shall follow the relevant conformity assessment as required under those legal acts. The requirements set out in Chapter 2 of this Title shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6. of Annex VII shall also apply.

For the purpose of that assessment, notified bodies which have been notified under those legal acts shall be entitled to control the conformity of the high-risk AI systems with the requirements set out in Chapter 2 of this Title, provided that the compliance of those notified bodies with requirements laid down in Article 33(4), (9) and (10) has been assessed in the context of the notification procedure under those legal acts.”

This means that, in the case of medical devices, it is the notified bodies who are usually responsible for conformity assessments of medical devices that will also be responsible for assessing the additional requirements of the AIA, when faced with a medical device using AI classified as high-risk under the EU AIA (meaning Class IIa or above in the MDR).

EU versus National Competency?

The AIA will be a supranational legislation while the protection and improvement of human health is a national competency. Therefore, the EU has competence to carry out actions to support, coordinate or supplement the actions of the Member States, but “the EU may not adopt legally binding acts that require the Member States to harmonise their laws and regulations”. (European Union, 2016)

What will this mean for health-related AI?

9. CONCERNS OF THE EU AIA REGULATORY PROPOSAL FOR HEALTH-RELATED AI SYSTEMS

The current design of the EU AIA regulatory proposal falls short on addressing risks and harms from health-related AI. The following non-exhaustive list sets out specific concerns. Each of the issues is explained in more detail afterwards.

- A. Risk categorisation.** The EU AIA proposal's approach to risk categorisation results in an arbitrary distinction between low- and high-risk systems used in the health sector and leaves many systems unregulated. All AI systems used in the health sector should be subject to basic regulations and external audit to at least verify the accuracy of claims made and ensure the systems' safety and effectiveness.
- B. Regulatory requirements.** The regulatory requirements for high-risk systems set out in the proposal are too narrow to ensure trustworthy AI. The Act lacks specific explainability requirements of high-risk AI systems, which is especially important in the case of health-related AI. Further, conformity assessments should explicitly include an impact assessment on fundamental rights, public interest, health equity and accessibility. In addition, the obligations on users of AI systems are too limited, these should be expanded to assess the impact of AI systems in their context of use.
- C. Third party assessment.** The Act's enforcement is jeopardised because it does not provide adequate means to notified bodies. More investments are needed to ensure notified bodies responsible for third-party assessments have the expertise, capacity, and resources to conduct thorough assessments.
- D. EU public database and regulatory statement.** The public database in which high-risk AI systems will be listed should be expanded to include all AI systems used in the health sector and the institutions where they are used. For transparency's sake, all AI systems should indicate their risk level and whether they have undergone third-party conformity assessment.

A. Risk Categorisation

The regulation produces an arbitrary divide in low- and high-risk systems for the health sector, with major implications for oversight and regulatory requirements. The intended use of an AI system is currently leading in risk categorisation. This approach assumes that the risks of an AI system can be foreseen before it is implemented and can be established based on the systems' intended purpose. However, intended use does not fully expose a system's potential risks of harm to patients and society. It is not so much the purpose of the system, but the context in which it is deployed and its real-life application which determine risk.

As the distinction between low- and high-risk AI systems depends on its intended purpose, there will be cases in which the same system can be classified in either group. For example, an app which calculates the user's fertility status based on basal body temperature and menstruation days to track and predict ovulation (Medical Device Coordination Group, 2019). If this app is intended to support conception, it should be classified as 'low-risk medical software' Class I (rule 11c.). If, however, its intended purpose is contraception, then Rule 15 applies, and the app should be classified as 'medium-high-risk medical software' Class IIb. Further, there will be a fine line

between AI systems used for lifestyle and wellbeing purposes, and those used for disease prevention purposes, while this distinction has major implications on the risk categorisation and regulatory requirements of the system. It should be analysed whether there are discrepancies between intended use and actual use. However, this is not something on which providers or users of low-risk AI systems need to report. Only once an AI application is categorised as a high-risk system does the regulation require providers to provide “*estimation and evaluation of the risks that may emerge when the high-risk AI system is used in accordance with its intended purpose and **under conditions of reasonably foreseeable misuse***” (point 2b of article 9 in Chapter 2 of Title III).

The precautionary principle, which has common application in healthcare, is completely absent in the AIA regulatory proposal. According to this principle, innovations which have foreseeable harm should be restrained in absence of clear evidence on their impact (Hayes, 2005). As AI systems can have unpredictable negative impact on patients or societies, risk categorisation based on intended purpose instead of real-life evidence of actual usage and impact is a weakness of the Act. All types of AI systems in healthcare should be required to undergo comprehensive impact assessments before and after being authorised for the market, and any evidence, as well as reasonably foreseeable risks of misuse and harm, should be assessed and addressed. For more information on such an impact assessment, see section B. Regulatory Requirements.

The field of health-related AI is diverse and not comprehensively regulated. Under the current proposal, many health-related AI systems are not regulated or are in a grey area. To illustrate:

- A legion of health, fitness and wellbeing applications and wearables exist that keep track of one’s activities, vital signs, mental health, menstrual cycle, eyesight, pregnancy and even “resistance to stress”.⁴ These do not fall under the definition of a medical device and will be unregulated, despite the possibility that they could make unrealistic claims or harmful health strategies.
- Some products are right on the border of being a medical device. It is currently unclear whether the providers consider their product to be a medical device and whether they have a CE mark⁵, as this is not explicitly stated on their webpage or in the apps. For example, genetics-based services: an app which is available in the EU offers “gene testing to discover what your DNA has to say about lifestyle factors like diet, exercise, and sleep, health predispositions and carrier status”.⁶ The provider states that some of their tests have been reviewed by the United States Food and Drug Administration, and others have not. It is unclear whether their products have been reviewed by the European Medical Device Authorities or are CE marked. They do state that their tests are not intended to diagnose any disease, which might indicate they do not consider their product a medical device. Other examples are apps for diabetes blood glucose monitoring,⁷ and those which recommend treatment for common skin conditions based on pictures⁸.

⁴ <https://healthtechhub.net/10-best-mobile-health-apps>, <https://www.verywellfit.com/best-fitness-apps-4173707>, <https://www.healthline.com/health/mental-health/top-healthy-lifestyle-iphone-android-apps#health-and-nutrition-guide-fitness-calculators>, <https://bellabeat.com/leaf-chakra/>

⁵ The European conformity mark which signifies that products sold in the EU have been assessed to meet specific safety, health, and environmental protection requirements

⁶ Such as [23andMe](#)

⁷ Such as [Glucose tracker & Diabetic diary](#), [CONTOUR Diabetes App](#)

⁸ Such as [Aysa](#)

- Many systems that do not work as medical device on the individual level, but on health system or population level health will go unregulated, including systems used in the medicines development cycle. For example, most of the AI systems used in the discovery of medicines, in clinical trials and used by pharmaceutical companies to inform R&D investments and pharmaceutical promotion strategies. AI systems used in hospital settings, not for medical purposes but, for example, planning and staffing, will also go unregulated. However, they can have a major effect on population health if they are widely used because they influence the distribution of healthcare resources (IDB, 2020).

For health-related AI systems which will be classified as low risk under the current proposal, our main concerns are the complete lack of oversight on use of these systems and the absence of requirements to which manufacturers must adhere. This is specifically risky for the health sector as it is known to have ubiquitous data biases historically ingrained in all levels, from biomedical research to clinical trials, clinical guidelines and care provision (Cirillo et al., 2020; Fitzgerald and Hurst, 2017; Perez, 2019).

Further, Annex III, which lists high risk AI systems, does not include any health-related AI, except for systems that establish priority in the dispatching of emergency first response services for medical aid. While Annex III can be updated if deemed necessary, new areas cannot be added. This means that the headings of the annex cannot be changed, only the subheadings. Therefore, it is likely that a new category, such as health or healthcare, cannot be added as high-risk use.

For that reason, Annex III should be amended with a category “Healthcare”. A similar risk classification matrix as is used for classifying medical devices can also be helpful in classifying other health related AI. The matrix can consider the significance of the systems’ contribution to the decision, the impact of (faulty) recommendations on individuals and public health, the urgency of the decision and whether it can be reversed (IDB, 2020).

AI in the Medicine Development Cycle

The medicine development cycle has seen a recent surge of interest in AI technologies. In computer assisted medicine discovery, AI is starting to be used to predict a molecule’s properties and activity based on its structure, for the repurposing of existing medicines and design of new molecules from scratch, as well as for planning the synthesis of compounds (Jiménez-Luna et al., 2021). It is expected that the availability of data and AI technologies will enable a move to a precision model of medicine, where therapies are tailored to individuals’ characteristics.

The Slovenian Presidency of the Council of the EU published its proposed amendments to the AIA on 29 November 2021. They have added a provision saying that “the AIA should not apply to AI systems and their outputs used for the sole purpose of research and development” (Council of the European Union, 2021). This might imply that AI systems used in medical R&D will fall outside the scope of the AIA. Especially in the move to a precision model of medicine, it is essential that such technologies are assessed and regulated to ensure they do not leave out disadvantaged populations and reinforce health inequities.

Recommendations

- ➔ All AI systems used in the health sector should undergo an impact assessment and be subject to oversight, basic regulatory requirements, and external audit to verify whether claims made are accurate and to ensure the systems' safety and effectiveness.
- ➔ Further, as European Consumer Voice in Standardisation, ANEC, proposes in their report, the providers' formulated intended purpose should not be leading in classification, but externally determined foreseeable use should (ANEC, 2021).
- ➔ If the Act holds on to its approach of risk classification, it should broaden the scope of high-risk health-related AI to also include AI systems which work on health system or population level, and those used in Pharma and MedTech. Therefore, Annex 3 should be amended to include a category "Healthcare", and should include:
 - AI systems of which the output directly influences individuals' or population health outcomes.
 - AI systems whose (faulty) output would have potential serious negative influence on individuals' or population health outcomes, or on health equity, which can include those used for population risk management, capacity planning & staff management, care routing & triaging, medicine discovery and clinical trials, and pharmaceutical promotion, among others.

B. Regulatory Requirements

Regulatory requirements of high-risk AI systems are too narrow to assess their true impact and prevent from causing harm. In short, they do not ensure trustworthy AI. The Ethics Guidelines for Trustworthy Artificial Intelligence by the High-Level Expert Group on AI define requirements to ensure Trustworthy AI more broadly, and include essential components such as societal and environmental well-being, diversity, non-discrimination and fairness, and transparency and accountability (High-Level Expert Group on Artificial Intelligence, 2019). However, some of these are not adequately addressed in the current regulatory proposal. The proposal states that: *"providers should also be encouraged to apply on a voluntary basis additional requirements related, for example, to environmental sustainability, accessibility to persons with disability, stakeholders' participation in the design and development of AI systems, and diversity of the development teams."* In other words, these components are considered a 'nice to have' but are not required. We believe these are crucial components for trustworthy AI and that their consideration should be mandatory.

Societal and environmental wellbeing

According to the regulation, a risk management system should be in place for estimation of risks prior to and post-market, but the type of risks that should be assessed are not defined. Further, the conformity assessment of providers is formulated in general terms and focused largely on technical aspects. Therefore, it may miss the social consequences of the use of a system. Users of AI systems (institutions which use a particular system) have limited obligations and are neither required to conduct an impact assessment of a system on societal wellbeing. Specific requirements should be added for providers, as well as users, to assess the systems' impact on societal and environmental wellbeing, including fundamental rights, public interest, health equity and accessibility, pre- and post-market.

Transparency & explainability

Article 13 of Chapter 2 of the AIA proposal provides transparency requirements for the provision of information to users but does not include requirements on the explainability of the model, i.e., having insight into how it comes to a prediction (which features, parameters and weights are involved). Especially for health-related AI systems, explainability is of paramount importance, not only because their output can affect people's health, but also because, as mentioned before, healthcare is a field historically abundant with ingrained biases. Knowing how decisions are made, and which information is being used, allows physicians to make informed choices on the utility of the systems' recommendations and would help to find potential mistakes and biases (Panch et al., 2019). At the same time, it could yield new insights about legitimate differences across population groups, which might require a different therapeutic approach (Cirillo et al., 2020). Further, transparency obligations should be imposed on the users of AI systems to register high-risk uses, including information on the scope, affected populations, and the results of the broader impact assessment mentioned above to the EU Public database. For more on this database, please see section 4. **EU public database and CE marking.**

Model development

The requirements are largely focused on documentation and assessment of the AI system but contain little on the development process of the system, only around data management processes. However, AI development is not a neutral process, and algorithmic bias of health-related AI can be weaved into the design of the system (Panch et al., 2019). Therefore, responsible model development is of utmost importance and this process should be documented, including which actors were involved throughout the stages of model development and how developers ensured diversity and inclusion of the different stakeholder groups, including users and beneficiaries.

Recommendations

- ➔ Not only technical aspects of the system should be assessed, but also its impact on fundamental rights, health equity, public interest and accessibility, pre- and post-market. This requires additional obligations on the side of both providers and users.
- ➔ Health-related AI should have specific explainability requirements.
- ➔ As biases go beyond the use of appropriate, good quality data, providers of AI systems should be obliged to report on the steps taken in the model development process, including how stakeholders were involved at each stage.

C. Third Party Assessment

For AI systems in the health sector which will be classified as high risk (medical devices Class IIa and up) under the current proposal, concerns arise about the proper enforcement of the regulatory requirements. In recent years, the number of approved AI-based medical devices has surged in the EU, while the number of notified bodies available to review medical devices has been decreasing (Muehlematter et al., 2021).⁹ While there are specific guidelines and regulations concerning software as a medical device, there are currently no specific pathways or requirements for AI-based medical devices. Also, the EU MDR does not include any specific

⁹ <http://meddev.minerva-plm.com/blog/posts/2019/march/the-lack-of-notified-bodies-puts-medical-device-companies-at-risk-of-missing-compliance-deadline-with-eu-mdr/>

provisions on AI-based medical devices (Medical Device Coordination Group, 2020, 2019; Minssen et al., 2020; the European Parliament and the Council of the European Union, 2017). For these medical devices, the EU AI regulatory proposal is a welcome addition. However, it will only have a meaningful impact when notified bodies can adequately assess AI systems. Therefore, medical device notified bodies need technical experts who can comprehensively review all technical and social aspects and risks of the system throughout its life cycle (Minssen et al., 2020). It is unclear from the regulatory proposal how it will be ensured that notified bodies have the proper level of expertise, capacity, and resources at their disposal to thoroughly assess AI-based medical devices.

Recommendation

- ➔ Adequate investments should be directed towards notified bodies to ensure they have the expertise, capacity, and resources to conduct thorough assessments.

D. EU Public Database and CE Marking

Under the AIA proposal, an EU public database will be built containing information on all stand-alone high-risk AI systems. While we applaud this initiative, the information to be submitted to this database (which can be found in Annex VIII), is too limited. Alongside information on the status of the AI system and the Member States where it is on the market or in service, information on the users of the system (institutions which use a particular system e.g., a specific hospital) should also be included, as well as how they use it and any impact assessments carried out. This would provide a better oversight on deployment of AI systems.

Further, only information of high-risk AI systems is required to be submitted to the database. We propose to also include low-risk AI systems, because as mentioned before, this distinction is, in practice, arbitrary, and low-risk systems can just as well cause harm. [EUDAMED](#), the European Database on Medical Devices also lists all risk classes of medical devices, from I to III.

If the Regulation sticks to its proposed approach of risk classification, all AI systems should include a statement to indicate their risk level and whether they have undergone third-party conformity assessment, which is transparent and easy to find for people interacting with the system. Low-risk AI systems should explicitly contain a statement that the AI is classified as low-risk and therefore unregulated. Further, the compliance with the use of the CE marking to notify approval of high-risk systems to its users should be closely monitored. These provisions ensure users can easily find what type of system they are dealing with and whether it has been externally assessed.

Recommendations

- ➔ The EU public database should be extended in scope and content, and should:
 - Contain information on the users per AI system, and the results of an impact assessment for specific uses.
 - Include low-risk AI systems.
- ➔ All AI systems should include a statement to indicate their risk level and whether they have undergone third-party conformity assessment.

10. CONCLUSION

This report analysed how health-related AI systems will be regulated under the EU AIA regulatory proposal. It identified that for healthcare the AIA has a narrow definition of high-risk AI, limited to AI systems which classify as medical devices (level IIa and up). We believe AI systems that influence health on health system or population level can also impose risks on patients and societies. Therefore, we have proposed to broaden the scope of high-risk AI systems to include those with potentially high impact at individual, as well as population-level, health. We further recommended a change in approach to risk categorisation, with evaluations of risks and harms being leading instead of intended purpose, more comprehensive regulatory requirements including a societal impact assessment, and better provisions for thorough enforcement of the Act, as well as transparency on the uses of AI systems. These provisions will help to ensure the Act achieves its intended purpose of lawful, safe and trustworthy AI. The precautionary principle can be used in the reshaping of the AIA to ensure it protects EU patients and citizens. The reasoning is that we should not allow health-related AI systems to be used on us without proof of their value for health and an adequate assessment and addressing of risks for harm to fundamental rights, health equity and public interest.

11. RESOURCES

- Ada Lovelace Institute, 2020. The Data Will See You Now. Datafication and the boundaries of health.
- ANEC, 2021. POSITION PAPER: ANEC comments on the European Commission proposal for an Artificial Intelligence Act.
- Cirillo, D., Catuara-Solarz, S., Morey, C., Guney, E., Subirats, L., Mellino, S., Gigante, A., Valencia, A., Rementeria, M.J., Chadha, A.S., Mavridis, N., 2020. Sex and gender differences and biases in artificial intelligence for biomedicine and healthcare. *npj Digit. Med.* 3. <https://doi.org/10.1038/s41746-020-0288-5>
- Consolidated version of the Treaty on the Functioning of the European Union PART ONE - PRINCIPLES. TITLE I - CATEGORIES AND AREAS OF UNION COMPETENCE Article 6, 2016
- European Commission, 2021. REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS.
- Fitzgerald, C., Hurst, S., 2017. Implicit bias in healthcare professionals: A systematic review. *BMC Med. Ethics* 18. <https://doi.org/10.1186/s12910-017-0179-8>
- High-Level Expert Group on Artificial Intelligence, 2019. Ethics Guidelines for Trustworthy AI.
- IDB, 2020. Artificial Intelligence in Health Care, Promises and Challenges, Inter-American Development Bank.
- Leslie, D., Mazumder, A., Peppin, A., Wolters, M.K., Hagerty, A., 2021. Does “AI” stand for augmenting inequality in the era of covid-19 healthcare? *BMJ* 372, 1–5. <https://doi.org/10.1136/bmj.n304>
- Medical Device Coordination Group, 2020. MDCG 2020-1 Guidance on Clinical Evaluation (MDR)/ Performance Evaluation (IVDR) of Medical Device Software.
- Medical Device Coordination Group, 2019. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.
- Minssen, T., Gerke, S., Aboy, M., Price, N., Cohen, G., 2020. Regulatory responses to medical machine learning. *J. Law Biosci.* 7, 1–18. <https://doi.org/10.1093/jlb/ljaa002>
- Muehlematter, U.J., Daniore, P., Vokinger, K.N., 2021. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015–20): a comparative analysis. *Lancet Digit. Heal.* 3, e195–e203. [https://doi.org/10.1016/S2589-7500\(20\)30292-2](https://doi.org/10.1016/S2589-7500(20)30292-2)
- Panch, T., Mattie, H., Atun, R., 2019. Artificial intelligence and algorithmic bias: Implications for health systems. *J. Glob. Health* 9, 020318. <https://doi.org/10.7189/jogh.09.020318>
- Perez, C.C., 2019. Part IV. Going to the Doctor, in: *Invisible Women: Exposing Data Bias in a World Designed for Men*. Vintage, London, pp. 195–235.
- The European Parliament and the Council of the European Union, 2017. REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EE, Official Journal of the European Union.
- USAID and The Rockefeller Foundation, 2019. Artificial Intelligence in Global Health. Defining a Collective Path Forward. <https://www.usaid.gov/cii/ai-in-global-health>



Health Action International
Overtoom 60 (2) | 1054 HK Amsterdam
The Netherlands
+31 (0) 20 412 4523

HAIWEB.ORG

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