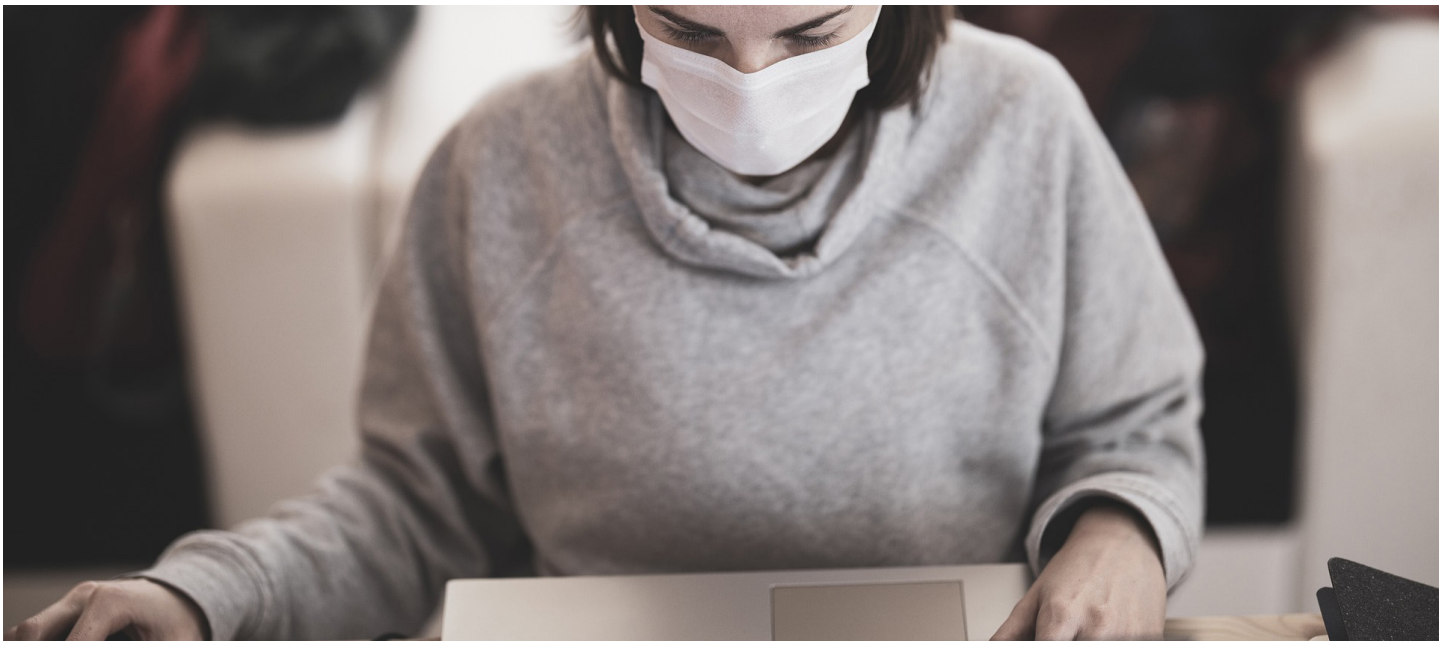
RECOMMENDATIONS

FEBRUARY 2022

ADDRESSING **RISKS AND HARMS** FROM **HEALTH-RELATED ARTIFICIAL INTELLIGENCE**



INTRODUCTION

It is essential to protect citizens from the potential harms of artificial intelligence (AI) technologies and realise their safety and accountability. That is why, in April 2021, the European Commission 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 the EU Artificial Intelligence Act (AIA) regulatory proposal would have on both the health sector and AI innovation itself.

The current design of the EU AIA regulatory proposal falls short on addressing risks and harms from health-related AI. The following list of specific concerns—and recommendations on how these may be mitigated—is explained with detail and analysis in the full report "Interpreting the EU Artificial Intelligence Act for the Health Sector" (Health Action International, February 2022).

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.

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 & 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

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.

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

The Act's enforcement is jeopardised because it does not provide adequate means to notified bodies. 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. While there are specific regulations concerning software as a medical device, currently no specific pathways or requirements exist for AI-based medical devices.

Recommendation:

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

D. EU PUBLIC DATABASE AND REGULATORY STATEMENT

Under EU 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 is too limited. 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.

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.

For more information: janneke@haiweb.org

www.haiweb.org