Stakeholder joint statement on access to innovative healthcare under the Artificial Intelligence Act (AI Act)

14 June 2023

As representatives of the healthcare sector, ranging from medical technology manufacturers to healthcare professionals and patient groups, we have a shared goal of **improving health outcomes and healthcare systems**. We welcome the intent of the proposed AI Act, which has the potential of giving individuals the confidence to embrace AI-based solutions, including AI-enabled digital health services and tools. These tools and services support the safe continuity of care and access to innovative, state-of-the-art healthcare across Europe.

Many existing AI solutions that are being used in national healthcare systems are integrated into medical technologies and regulated under the Medical Devices Regulation (MDR), and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR). As medical technologies constitute an integral component of healthcare systems, it is essential that the AI Act will facilitate the delivery of innovative healthcare.

We, therefore, urge all Member States and EU decision-makers to strongly consider the impact the proposal will have on the EU health ecosystem, act mindfully and engage with the broad range of stakeholders. The final Regulation should **optimise AI's potential for the benefit of individuals, patients, carers, families, healthcare managers, healthcare professionals and health systems**.

We would like to highlight four considerations that are pertinent to healthcare, such as those requiring alignment with existing and forthcoming legislation, definitions, data and data governance, human oversight and requirements for third-party-conformity assessment for high-risk AI systems. These elements need to apply to the particularities of the healthcare ecosystem and in no circumstances impact patient autonomy or the healthcare professional-patient relationship. The signatories see opportunities to further enhance and clarify the regulation, which should be taken into account during the trilogue negotiations:

1. **The AI Act must align with all relevant horizontal and sectoral European laws and concepts**

The regulatory framework should **be fit for purpose to enable innovation** and to deliver ethical, safe and effective care and diagnosis. The AI Act can achieve this by **providing consistency** with existing legislation, such as General Data Protection Regulation (GDPR), the Medical Devices Regulation (MDR), and the *In vitro* Diagnostic Medical Devices Regulation (IVDR) as well as forthcoming (digital) legislation including the AI Liability Directive, Cyber Resilience Act, Data Act, Data Governance Act, the European Health Data Space Regulation and the revised Product Liability Directive.

AI-enabled medical devices and *in vitro* diagnostic medical devices (MDs/IVDs) are already regulated under MDR/IVDR as Medical Device Software, while in many respects, AI goes unregulated elsewhere.

Hence, in this **specific case, conflicting requirements may be imposed if the AI Act were to come into force as proposed by the European Commission**. The European Parliament's position aims to remove these conflicting requirements by deeming obligations relating to high-risk AI systems as fulfilled if they are already addressed by sectoral legislation.

Signatories welcome the views of the European Parliament including on conformity assessment and note that additional reference to notified bodies should be made, as this would further integrate the requirements laid down by sectoral legislation. If not adequately addressed during the trilogue negotiation, the AI Act may risk creating two-track systems, one applicable to the AI component of a device, and the other to the MD or IVD component of a device. This could create legal uncertainty and obstacles in delivering the ethical, safe and effective devices that this Act intends to support. Besides, the AI Act must also align with fundamental rights and the rule of law enunciated in the Charter of Fundamental Rights of the EU.

The AI Act needs to align with all relevant provisions in the EHDS and related national legislation and regulations with regard to electronic health data as processed by medical devices, *in vitro* diagnostic medical devices, electronic health records systems and wellness applications, for primary and secondary use.

2. The AI Act needs to provide more clarity on the definitions

This alignment and clarification are needed at both the European and Member State level, including designated authorities and bodies.

Definition of 'user' (Article 3 (4))
It is crucial to distinguish professional users from the more general term 'user' to reflect laypersons, including individuals or patients, so that they get the same level of protection afforded by the AI Act as professional users, such as healthcare professionals. Therefore, the differentiation should be made accordingly throughout the Act. To that end, the European Parliament exchanged 'user' with 'deployer' and introduced a new definition of 'affected person', which refers to *"any natural person or group of persons who are subject to or otherwise affected by an AI system"* (Article 3(8a).

Definition of 'risk' (Article 3 (new))
While the proposed AI Act is a risk-based legislation, the term 'risk' currently lacks a dedicated definition in the European Commission proposal and the Council of the EU General Approach. The European Parliament introduced a definition of risk (Article 3(1a), which is an essential element for understanding and implementing the risk-based approach.

Definition of 'AI systems' (Article 3 (1))
Considering the proposed definition of the European Commission, the signatories would like to note that the definition is overly broad, potentially including all medical technologies with software components that are not necessarily considered artificial intelligence. The European Parliament's and

the Council of the EU's position towards an internationally aligned definition of that of the OECD is therefore welcome.

3. The AI Act must provide a clear data and data governance framework as data is indispensable for AI

The AI Act's requirement on data and data governance **(Article 10 (3))** to use error-free and complete data for training, validation and testing is neither practicable nor desirable if testing takes place under real-world conditions. Datasets are often incomplete or inaccurate. We are also concerned that the proposed wording would represent a hindrance to the use of Real-World Data, an area with enormous potential for healthcare. The AI Act must ensure balanced human oversight, including, where necessary, the conditions for human intervention as well as user literacy of the capacities and limitations of the high-risk AI system.

According to the MDR/IVDR, excessive human interference could negatively impact the benefit-risk ratio of medical devices, which in turn inhibits the uptake of innovative and potentially life-saving applications and limits learnings from them. The signatories, therefore, support the opinion of the European Parliament's Legal Committee and the support of the leading Committee on the Internal Market and Consumer Protection and the Committee on Civil Liberties, Justice and Home Affairs on Article 14, in particular, 14 (1) the need for "*natural persons in charge of ensuring oversight [to] have sufficient level of AI literacy […] and the necessary support and authority to exercise that function*" and 14 (4c) and (4e) for natural persons "*to be aware of and sufficiently* understand the relevant capacities and limitations of the high-risk AI system". This is imperative to ensure that patient safety will not be inhibited by the absolute requirement, such as prompting a stop button.

Signatories welcome the European Parliament's proposal on AI literacy (Article 4a) which requires Members States to "*promote measures for the development of a sufficient level of AI literacy, […] taking into account the different needs of groups of providers, deployers and affected persons concerned, including through education and training, skilling and reskilling programmes […]*." To that end, the value of AI in healthcare can only be properly exploited when the limits of AI are clearly defined, users have the necessary competence, training and authority to engage with these innovative technologies, and when the appropriate safeguards are in place.

4. The AI Act must ensure uniform application and implementation of its provisions across Member States with regard to its governance structure to avoid unnecessary fragmentation within the Single Market

The signatories welcome the proposal for the establishment of an AI Board (Council of the EU) and the AI Office (European Parliament) to provide support to the Member States in the implementation and enforcement of the AI Act. The composition of the AI Board / Office should be strengthened to involve stakeholders, who should participate regularly in meetings within the context of advisory groups or forums, and the outcomes of such meetings should be publicly available. This will ensure appropriate levels of accountability and provide a forum for well-informed and context-based discussions on AI. The

Board / Office must be allocated adequate resources to match its ambitious role, including staff with the necessary relevant expertise.

The signatory organisations[1] of this statement are actively engaged in European and Member State initiatives relating to AI. We have areas of expertise, together with established methods and tools, which could facilitate the **high-quality adoption** and **rapid benefits realisation** from the AI Act. Therefore, we would welcome the opportunity to contribute to its success and to discuss further with co-legislators how to achieve the **ultimate goal of improving health outcomes, health systems and enhancing access to innovative healthcare solutions**.

The signatories

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[1] Opinions expressed in this statement do not necessarily represent the views of the members of each signing organisations.

Annex – The benefits of AI in healthcare

Safe, high-quality and trustworthy AI in healthcare can improve the prevention, early detection and diagnosis as well as treatment and care management of people living with medical conditions, resulting in **better health outcomes for individuals /patients and more effective health systems.**

AI solutions currently serving in healthcare include, but are not limited to:

- **Preventing death from cardiovascular disease:** Indicators of heart failure can now be detected by a combination of smartwatches with electrocardiograms and AI algorithms[2], which has the potential to significantly reduce hospitalisations and save up to €36.9 billion. In turn, this could have the potential to contribute to the prevention of over 1.8 million cardiovascular disease-related deaths in the EU.[3]

- **Reducing radiation dose and shortening examination time in radiological examinations:** Deep learning image reconstruction can reduce radiation dose in Computed Tomography and shorten examination times in MRI. For example, a systemic review of AI for radiation dose optimization in paediatric radiology found that most studies demonstrated that AI could reduce radiation dose by 36–70% without losing diagnostic information.[4]

- **Reducing administrative burden for healthcare professionals and systems:** Virtual scribes linked to smart speaker devices and combined with an AI algorithm are able to transcribe clinical data recorded between people living with medical conditions and physicians. These voice-to-text applications can be used to take notes about symptoms, write prescriptions, order additional tests, arrange follow-up appointments, classify, and enter everything into the patient's electronic health record. This could reduce the burden on healthcare professionals by up to 507.2 million hours, translated into a yearly opportunity cost of about €7.9 billion, reallocating these savings back into the healthcare system.

- **Decreasing human error in surgeries:** AI-enabled robot hands can use data from past operations to perform new surgical techniques, reducing the risk of human error[5]. Such applications could potentially save up to 35.9 million days of hospital stay, leading up to €12.9 billion of savings per year. And post-surgery hospital stays could be reduced by up to 21%[6].

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[2] https://www.sciencedirect.com/science/article/pii/S1050173819301495
[3] https://ehnheart.org/cvd-statistics.html
[4] https://doi.org/10.3390/children9071044
[5] https://www.roboticsbusinessreview.com/health-medical/ai-assisted-surgery-improves-patient-outcomes/
[6] https://www.insightbrief.net/wp-content/uploads/AI-in-Healthcare-Benefits-Challenges-Risks-InsightBrief.pdf?tagged=true