COCIR Feedback

Commission proposal for a European Artificial Intelligence Act

Executive summary

The proposed Artificial Intelligence Act defines high-risk AI systems so broadly that almost all medical device software may be considered a high-risk AI system. The Medical Device Regulations, especially in combination with the GDPR, already include an extensive, often more detailed, set of requirements related to various aspects of the new Act. However, the Act's definitions and requirements are not aligned, and the Act refers to risk and harm in complex and inconsistent ways. For specific devices, the Act's requirements conflict with the safety and performance requirements of the Medical Device Regulations. These misalignments increase complexity, legal uncertainty, and implementation costs, ultimately paid for not only by the manufacturers but also healthcare systems and patients. Certain requirements may even prevent European patients and citizens' access to specific state-of-the-art digital health innovations.

Instead, COCIR strongly supports a targeted, sector-specific, and risk-based approach to the regulation of artificial intelligence.

Introduction

Artificial Intelligence (AI) in healthcare is already a reality. Healthcare providers have embedded the technology into their workflows and decision-making processes[1]. The introduction of AI in healthcare has brought improvements for patients, providers, payers, other healthcare stakeholders, and society at large, also in the fight against the COVID-19 pandemic[2].

It is essential to have a robust regulatory framework that provides certainty to all actors as new technologies are being developed and introduced into the market[3]. Medical Device manufacturers have long-standing experience of operating in a highly regulated sector. COCIR members take the responsibility towards end-users, especially patients, very seriously, to place safe and performing products on the European market.

The following sections contain our detailed feedback to the Commission proposal for an Artificial Intelligence (AI) Act[4]. We are looking forward to engaging with the EU institutions in the upcoming legislative process, together with our technical experts.

Detailed feedback

1. Scope & definitions

The proposed risk classification and broad definition of AI system means that any software that qualifies as a medical device and that is placed on the market or put into service in its

[1] *COCIR collection of Artificial Intelligence Use Cases*
[2] *The vital role of Artificial Intelligence in a time of COVID-19*
[3] *COCIR Analysis on AI in Medical Device Legislation*
[4] *Artificial intelligence – ethical and legal requirements (europa.eu)*

own right or as a component of a hardware medical device falls under the scope of the Artificial Intelligence Act. As most medical device software requires notified body involvement during the conformity assessment, almost all medical device software would be considered a high-risk AI system. The definition includes logic and knowledge-based approaches which can be interpreted so broadly that essentially any basic software is included. Examples of medical software falling in the scope of the proposal range from medical device software embedded in electronic thermometers to alert the user when the temperature corresponds to fever, blood glucose meters and patient ventilators, migraine or asthma episode prediction apps, to medical image analysis software for tumour detection.

COCIR is a strong advocate of a targeted, sector-specific, and risk-based approach to the regulation of Artificial Intelligence. The Medical Device Regulations, especially in combination with GDPR, already have an extensive, often more detailed, set of requirements related to various aspects of the new Act (e.g., risk management, Quality Management System, transparency and user information or cybersecurity).

The proposed Act is largely based on the New Legislative Framework (NLF) and product legislation derived from the NLF, including the MDR and IVDR. While we believe that using the NLF is appropriate, the AI Act modifies many of the concepts and definitions in ways that are contradictory and confusing for manufacturers placing devices on the market that will need to comply with several regulations. Examples include the concepts of 'importer', 'putting into service', 'provider' or 'user'.

In addition, the proposed Act does not define risk – a fundamental concept for conformity assessment. Instead, its provisions include the term 'risk' and the related 'harm' in various meanings. This causes interpretation issues within the proposed Act and across its referenced legislations (see Figure 1), increases the Act's complexity and implementation cost and results in legal uncertainty.

We see a definite risk of duplications and additional unnecessary administrative burden on AI-based medical device software manufacturers. The different definitions and, for some applications, conflicting requirements create an incoherent framework, possibly requiring two sets of technical documentation rather than one. Furthermore, parallel incident reporting channels and communication with different authorities will create inefficient information flows. We expect that different technical standards will be harmonised under the two legislations and fear that they will likely overlap. Medical device software has specific needs. We need to avoid contradictory technical requirements resulting from e.g., potentially different risk definitions or conflicts between MDR safety and performance requirements and the AI Act's human oversight requirements. The European Union needs to ensure legal certainty and consistency.

Despite the enormous capacity for healthcare innovation in Europe, we have already noted over the last years that other jurisdictions like the United States have become the preferred location to first place innovative medical software on the market. We are concerned that the additional complexity introduced by the AI Act will accelerate this development. This in turn will reduce the European Union's competitiveness and innovation potential at a global level. Ultimately, European patients will then have later access to digital health innovation.

Recommendation: The Medical Device Regulations should be removed from Annex II Section A. In addition, the Act should include a provision to amend the General Safety & Performance Requirements (Annex I) of the existing Medical Device Legislations. The

Medical Device Coordination Group should develop detailed guidance for AI-based medical devices to support these new requirements and address any last gaps.

2. Requirements for high-risk AI systems

Most of the proposed requirements are appropriate to ensure that only safe and performing AI systems are placed on the market. However, some of the requirements require further discussion to align with state-of-the-art software development practices and ensure that no barriers are created for highly innovative medical software. Some examples of these requirements are provided here below.

Data and data governance (Article 10)

A clear data governance framework is crucial. However, the requirement 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 somewhat inaccurate. Accuracy consists of trueness (proximity of measurement results to the true value) and precision (repeatability or reproducibility of the measurement). Trueness and precision represent a certain margin of error. In medical imaging, the image data is reconstructed from the values measured by the system's detectors, and the measurement itself is done based on a system setting that is neither 100% right nor wrong but developed by trained professionals. The resulting measurements can differ for the same patient at the same stage depending on the model of imaging system and the chosen parameters – one can never ensure that the data (i.e. the images) is "completely error-free". We are also highly concerned that the proposed wording would completely prevent the use of Real-World Data, an area with huge potential for healthcare.

Recommendation: Article 10 (3) should require that datasets are sufficiently accurate and complete to meet the intended purpose rather than 'error-free and complete'.

Human oversight (Article 14)

The concept of human oversight proposed in the AI Act could be interpreted so restrictively that there are undesirable ethical consequences. In practice, human oversight could be continuous or intermittent or retrospective. High-throughput computing allows systems to monitor hundreds of data points simultaneously. The system can act much faster than the human brain can let a signal pass from eye to brain to hands. Any device that ultimately relies solely or primarily on human attention and oversight cannot possibly keep up with the volume and velocity of algorithmic decision-making or will necessarily be outmatched by the scale of the problem and hence be insufficient and potentially harmful to patients. In some cases, the only effective oversight possible will be before using the device or after the use through retrospective periodic performance review for individual patients or patient cohorts. A restrictive interpretation could prevent certain applications of Artificial Intelligence in healthcare (e.g., AI enabled eye surgery robot[5]).

Recommendation: Article 14 (1) should be modified to ensure that human oversight is guaranteed where necessary to reduce risks as far as possible and achieve performance in

[5] *Urias MG, et al. Artificial intelligence, robotics, and eye surgery: Are we overfitted? Int J Retin Vitr. 2019;5;52.*

consideration of generally acknowledged state-of-the-art and technological/scientific progress.

In addition, 'full' understanding would be very difficult to define and implement. As part of a risk-based approach, it is important that the software provider makes available information that is actionable to the user, as required to ensure the safe and effective use of the device.

Recommendation: Article 14 (4) should require that information be made available, so the user sufficiently understands the AI system to ensure intended functioning.

Medical device manufacturers generally place the human 'in' or 'on the loop.' However, in specific applications, limited in number today but expected to grow in the future, the variability and limitations introduced by human factors can result in the safety and performance of autonomous AI outperforming that of the human-AI team. Several medical applications are known today where regulators require the human to be taken out of the loop to ensure clinical safety and performance peaks and to avoid user intervention does not harm patient outcome (e.g., AI to read certain qPCR curves, AI to segment brain tumours, AI-enabled eye surgery robot[5]). For such applications, a requirement for continuous human oversight conflicts with the Medical Device Regulation's requirements to reduce risks as far as possible and achieve performance considering generally acknowledged state-of-the-art and technological/scientific progress.

Recommendation: Art. 14.4(e) should be modified to ensure that users be able to intervene on the operation of the high-risk AI system or interrupt the system through a 'stop' button or similar procedure except if human interference increases patient risk and/or reduces patient outcome.

Access to training data (Article 64 & Annex VII Conformity based on assessment of quality management system and assessment of technical documentation)

Requiring that market surveillance authorities and notified bodies get full access to training data sets is problematic where (1) providers/manufacturers do not have direct access to the training data, i.e., where the training data remains behind security and privacy shields (cf. federated learning), (2) copyright or privacy reasons do not allow providers/manufacturers to store training data themselves (cf. personalized medicine) and (3) where the quantity of training data is so vast that storing it causes a disproportionate cost and impact on the environment (cf. GPT-3 which was trained on the entire internet).

Recommendation: Remove the requirement to provide access to training data. Access to testing data sets should be sufficient, especially as testing data sets cover more sources of bias than only those caused by training data.

3. Transitional provisions and period

Entry into force and application (Article 85)

As we have experienced in the transition from the Medical Device Directives to the Medical Device Regulation, sufficient transition time is crucial for the entire regulatory system, not only manufacturers. Putting the necessary infrastructure in place, ensuring compliance with the requirements and guidance documents, as well as adequate notified body capacity require sufficient time.

Recommendation: the transitional period should be extended by at least two years (to 48 months) to allow for all elements to be in place in time before the Date of Application.

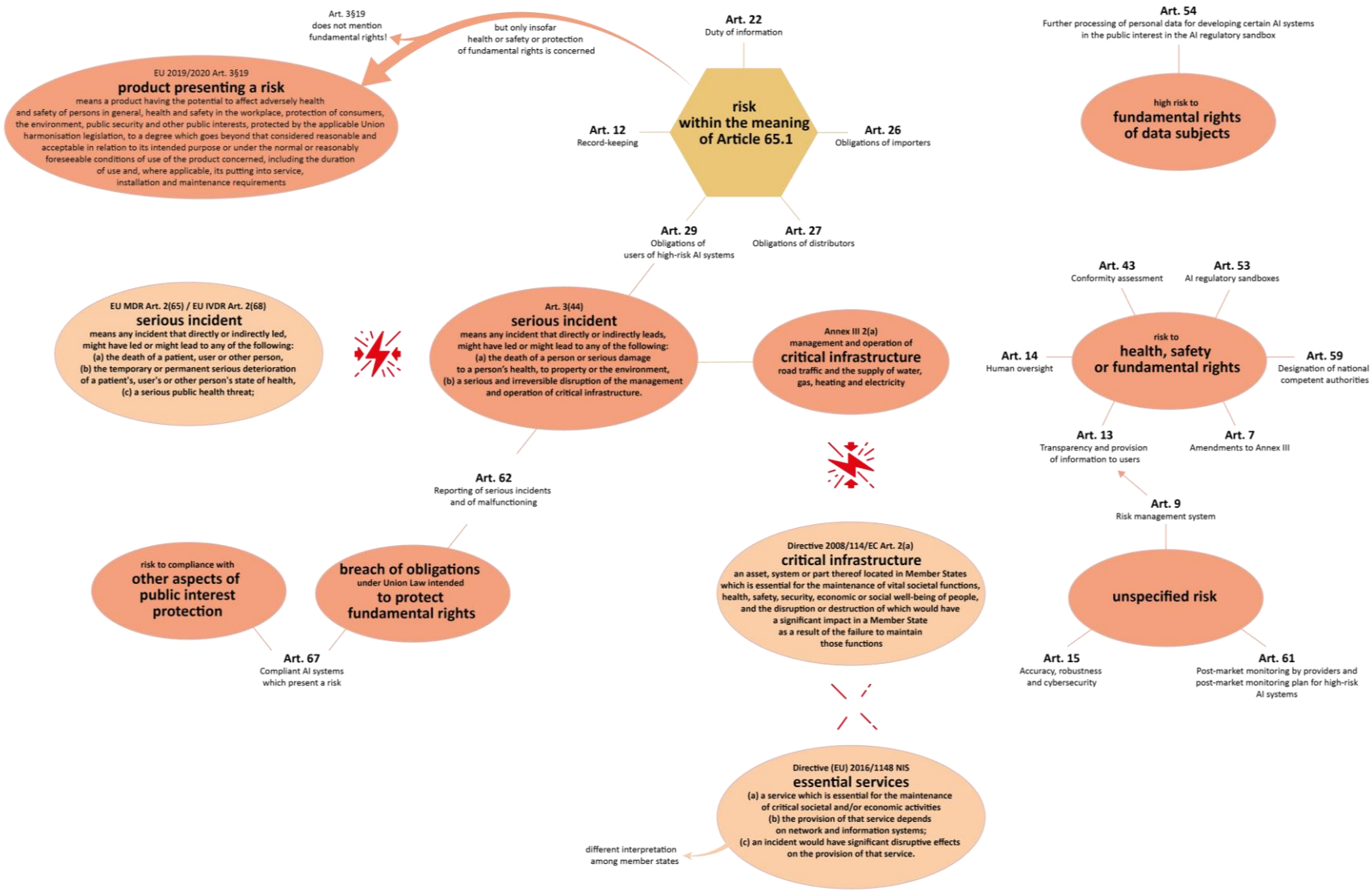

Figure 1 Illustration of risk and related discrepant meanings of harm in the AI Act and referenced legislation