

Philips feedback to EC Proposal for AI Act

Philips welcomes the opportunity to provide feedback on the proposed AI Act.

In healthcare, AI is already a reality. It can help to address healthcare's most pressing challenges and enable people to live healthier lives. The opportunities for AI across the health continuum, from prevention, through diagnosis and treatment, to home care, lie in its potential to help make sense of data, turning these data into actionable insights for better health and better care. AI has also proven useful in the fight against the COVID-19 pandemic. It adapts to patient-specific contexts and can be embedded into workflows of healthcare providers or people's daily environment. At Philips, we believe AI can augment healthcare providers to deliver high-quality care to patients and increase operational efficiency.

While a robust regulatory framework providing certainty to all stakeholders involved is crucial as new technologies are being developed and brought to the market, medical device sector has been highly regulated for a long time already to make sure that safe and performant devices are placed on the EU market. The Medical Devices Regulation (EU MDR), combined with the GDPR, already offers detailed and extensive requirements covering various aspects of the proposed AI Act¹.

The following elements should be considered in the upcoming legislative process:

- **Scope and definitions:** The proposed AI Act defines high-risk AI system so widely that almost all medical device software may fall in its scope and be considered a high-risk system. Several other proposed definitions and requirements are not aligned (e.g. 'provider', 'user', 'importer', 'putting into service'), missing (e.g. definition of 'risk' which is the core concept for conformity assessment) or conflicting with safety and performance requirements of the EU MDR/IVDR. Different definitions and conflicting requirements will lead to an incoherent framework, possibly requiring two sets of technical documentation (instead of one), inefficient information flows with parallel incident reporting channels and overlapping technical standards. As medical device software has specific needs, contradictory technical requirements resulting from different definitions or conflicting requirements between the AI Act and EU MDR must be avoided to ensure legal certainty and consistency. **AI-based medical devices should be regulated by the applicable sectorial legislation, accompanied by detailed guidance developed by the Medical Device Coordination Group to support new requirements, and address any remaining gaps.**
- **Requirements for high-risk AI systems:** Although most of the proposed requirements seem appropriate to make sure that only safe and performant AI systems are placed on the market, some of them should be aligned with the state-of-the-art software development practices without creating barriers for innovative medical software. For instance:
 - o **Data and data governance (Article 10):** The proposed requirement for error-free and complete data for training, validation and testing is impracticable, especially when testing in real-world conditions. Datasets are often inaccurate to a certain extent. Accuracy is about the measurement results being as close as possible to the true value while precision

¹ For a detailed analysis of AI under EU MDR and examples please consult the paper developed by COCIR : <https://www.cocir.org/media-centre/publications/article/cocir-analysis-on-ai-in-medical-device-legislation-may-2021.html>

means repeatability/reproducibility of the measurement. For example, in medical imaging, the image data comes from the values measured by the system's detectors, and the measurement itself is done based on a system setting that is neither fully right nor wrong but developed by trained professionals. The resulting measurements can vary 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 also fear that the proposed wording would completely prevent the use of Real-World Data, an area representing huge potential for healthcare. Instead of 'completely error-free', **datasets should be sufficiently accurate and complete to meet the intended purpose.**

- **Human oversight (Article 14):** The proposed concept of human oversight may lead to very strict interpretation triggering undesirable harmful consequences. AI can help clinicians make sense of large amounts of data about individual patients, in a quicker and more integrated way. It can also provide insights that may not be visible to the human eye, enabling first-time right diagnosis and personalized treatment, with better patient outcomes. High performance computing allows systems to monitor hundreds of data points simultaneously. The system is able to act much faster than the human brain reacts. Any device relying solely or primarily on human attention and oversight cannot possibly keep up with the volume and speed of algorithmic decision-making or will be overwhelmed 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 or after the use of the device through retrospective periodic performance review for individual patients or patient cohorts. There are already applications where human intervention should be avoided for better patient outcomes (e.g. qPCR curve reading, segmenting of brain tumors). A restrictive interpretation may also prevent certain applications of AI in healthcare, e.g. AI-enabled eye surgery robot. Consequently, **human oversight should be guaranteed where necessary to reduce risks as much as possible, taking into account state-of-the-art technological and scientific progress. Users should be able to intervene while the AI system is operational or interrupt it unless human intervention puts patient at risk or hampers patient outcome. Users of AI systems should have a sufficient understanding of the AI systems to ensure their intended use and proper functioning.**
- **Access to training data (Article 64 & Annex VII):** Full access to training datasets for market surveillance authorities and notified bodies may be limited in situations where: providers/manufacturers have no direct access to training data due to security and privacy safeguards (cf. federated learning), IPR or privacy requirements not allowing providers/manufacturers to store training data (cf. personalized medicine), or where the quantity of training data is so big that storing it will have a disproportionate cost and impact on the environment. **Requirement to provide access to training data should therefore be removed and replaced with sufficient access to testing datasets which cover more sources of bias than only those in training datasets.**

- **Transitional provisions/Entry into force and application (Article 85):** Experience with the transition from the Medical Device Directives to the EU MDR showed that sufficient transition time is crucial not only for medical device manufacturers but for the entire regulatory system. Putting the necessary infrastructure in place, ensuring compliance with the requirements and guidance documents, as well as adequate notified body capacity needs sufficient time. **The transitional period should be therefore extended by at least two years, i.e. to 48 months to allow for all necessary elements to be in place in time before the date of application.**

If the abovementioned misalignments are not properly addressed, there is a definite risk of duplications and additional unnecessary administrative burden resulting in increased complexity, legal uncertainty, and higher implementation costs not only for the manufacturers but the entire healthcare system, including patients. We are concerned that the increased complexity will accelerate the already existing trend of privileging other geographies for first placing of innovative medical software on the market. This in turn will have a huge impact on the EU's competitiveness and innovation resulting in delayed patient access to innovative digital health products and solutions.

We look forward to further engaging with the EU institutions in the legislative process.

About Royal Philips

Royal Philips (NYSE: PHG, AEX: PHIA) is a leading health technology company focused on improving people's health and well-being, and enabling better outcomes across the health continuum – from healthy living and prevention, to diagnosis, treatment and home care. Philips leverages advanced technology and deep clinical and consumer insights to deliver integrated solutions. Headquartered in the Netherlands, the company is a leader in diagnostic imaging, image-guided therapy, patient monitoring and health informatics, as well as in consumer health and home care. Philips generated 2020 sales of EUR 17.3 billion and employs approximately 77,000 employees with sales and services in more than 100 countries.
