Response to EC roadmap: Artificial intelligence – ethical and legal requirements

Philips welcomes the opportunity to provide feedback on the roadmap for AI ethical and legal requirements.

As rightly pointed in the roadmap and the AI White Paper, AI is developing fast and has the potential to improve and reshape healthcare. Applying AI in healthcare can improve people's lives across the health continuum from personalized lifestyle support through targeted prevention of disease, earlier precision diagnosis and personalized therapy to monitoring patients proactively from the hospital to the home. At Philips, we embrace AI as a combination of data science technology with knowledge of the clinical, operational and personal context of a patient. As a result, AI adapts to patient-specific contexts and can be embedded into workflows or people's daily environment. It augments healthcare professionals, rather than replacing them.

- *Baseline (Option 0): no policy change*

As indicated in the roadmap, 'EU legislation on the protection of fundamental rights and consumer protection as well as on product safety and liability remains relevant and applicable to a large number of emerging AI applications'. For instance, the EU Medical Devices Regulation (EU MDR) in combination with the General Data Protection Regulation (GDPR) already contain requirements for AI in healthcare to be safe and performant. These requirements, both ex-ante and ex-post, ensure that medical devices based on AI are safe and performant throughout their entire lifecycle, including the management of changes in software. We therefore see no need for new regulatory frameworks for AI-based devices in healthcare. In order to facilitate the practical implementation of the existing legal requirements, we support the adoption of practical guidance, preferably accompanied by the development of international standards.

For a detailed analysis of AI in the EU Medical Device legislation, we refer to a recent paper developed by COCIR[1].

*Proposed alternative policy options*

- Option 1: EU soft law

Philips supports an 'ethics by design' approach to the development and use of AI systems. It is important for EU citizens to be able to trust AI, and that recommendations or decision-making support by AI is transparent to those relying on it for healthcare decisions. Technology should be inclusive and respectful of everyone. Ethics and principles should not come up after a crisis or breach of trust: they should be part of an organization's DNA.

We therefore support the EU Ethical Guidelines and sectoral recommendations developed by the AI High Level Expert Group (AI HLEG) and their voluntary adoption per industry sector. We also support the development of self-regulating codes of conduct for responsible application of AI. An EU ethical approach to AI is key to enabling responsible competitiveness, as it will generate societal and user trust, and facilitate broader uptake of AI.

[1] https://www.cocir.org/media-centre/publications/article/cocir-analysis-on-ai-in-medical-device-legislation-september-2020.html

- Option 2: EU legislative instrument setting up a voluntary labelling scheme

An EU legislative instrument establishing a voluntary labelling scheme could enable consumers and patients to identify AI applications that comply with certain requirements for trustworthy AI and serve as an indication to the market that the labelled AI application is trustworthy. However, when creating labeling schemes, care shall be taken that the rules and requirements for such schemes do not overlap with or duplicate already existing mandatory requirements, and such labels are clearly used as an additional sign indicating compliance with additional requirements. It should be clear whom would such schemes apply to. Furthermore, such legislative instrument shall also arrange for appropriate, fair and efficient standard setting process and enforcement infrastructure. However, in case the enforcement infrastructure is missing or insufficient, there is a risk of unfair use of labelling schemes.

- Option 3: EU legislative instrument establishing mandatory requirements for all or certain types of AI applications

AI applications will need to comply with various regulations as explained above in the Baseline scenario. This is particularly true for AI applications that qualify as a medical device, and which are regulated by and need to comply with the [strict] Medical Devices Regulation and CE marking framework. If AI applications process personal data, they also need to comply with the GDPR.

In the context of this proposed option, we would like to reiterate the points made above, as well as, in our feedback to the Commission's public consultation on the White Paper on Artificial Intelligence:

- Healthcare is a well-regulated industry. AI solutions may be separate products (e.g. stand-alone software) or be built in medical devices. When they constitute a medical device, Medical Device Regulation will apply.

- Regulatory approach in healthcare is already risk-based, particularly when it comes to the medical devices framework. Risk classification and ex-ante conformity assessment (also during the entire lifecycle of the device) are the fundamental principles and are even reinforced under the upcoming Medical Devices Regulation. These rules will apply to software (with embedded AI) as medical device. GDPR may also apply to AI (i.e. any processing of data through algorithms) and requires to ensure compliance with its principles.

- MDR is fully adequate for 'locked AI' applications that do not learn in the field and those AI applications which change within pre-defined boundaries, and for which a conformity assessment was carried out. However, the MDR does not allow manufacturers to place devices on the market comprising AI that changes outside of pre-defined boundaries, i.e. AI-based devices intended to change outside of the change envelope or to suggest claims, intended uses or use conditions to the device for which no conformity assessment was carried out[2].

[2] For a detailed analysis 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-september-2020.html

- With regard to sub-option 2 in option 3: when considering the use of categories like 'high-risk AI', there shall be clarity on the correlation (or lack of it) between the MDR risk classes and the definition of 'high-risk AI'. Under the MDR, the approach to software as medical device is risk-based according to the intended use of the device i.e. it already requires a risk assessment and identification of the device's risk level. When determining the risk level, it should therefore be taken into account if an assessment has already taken place as part of a conformity assessment under the MDR. For instance, a medical device, classified as an AI application as proposed in the Commission's AI White Paper, currently may possibly fall into the MDR class 1, 2a, 2b or 3. None of these classes shall render the medical device to be considered as a 'high-risk AI application', but the manufacturer should have the possibility to clarify as to whether such system is to be regarded as high-risk AI system or not. It is important to acknowledge that not every use of AI in healthcare necessarily involves significant risks.

- Principles of the Product Liability Directive have been proven in last decades and fit for use in diverse situations. Product liability is reinforced under the MDR (Article 10.16). There is therefore no need for specific AI-based product liability regime.

- Under the GDPR, the principle of accountability requires to ensure compliance and ability to demonstrate it. Already now, under current legislation, all potential risks that the use or creation of algorithms can pose to the rights and freedoms of persons must be considered and properly addressed.

In light of the above, the existing regulations generally cover AI in healthcare in an appropriate manner. In any event, in case of still introducing AI specific legislation, it should be done very carefully not to create conflicts or duplications between the various regulations and new barriers for the development of AI-supported medical devices. Therefore, any potential gaps should be clearly identified, assessed and, if needed, addressed, always taking into account the existing regulations to ensure legal consistency and certainty. Instead of a one-size-fits all, generic AI legislation with high level principles, sector-specific legislation would be preferred, ensuring that knowledgeable experts identify real gaps in their own field and address them in a way that corresponds to the specific industry's needs, way of working and base of standards. In this regard, it is welcome to combine this option with the conformity assessment process as opposed to a completely new set of standards and enforcement bodies. However, in such approach care shall be taken that all relevant sectors are addressed (e.g. software/applications, which are not medical devices, and not even subject to CE marking) and not unfairly only those being in the focus of attention.

- Option 4: combination of any of the options above

The preferred combination would include the existing legislative framework, i.e. EU MDR and GDPR accompanied with practical guidance, international standards and soft law, including self-regulating sectoral codes.

*Definition of AI*

We embrace the definition of AI as proposed by the AI HLEG[3]:

[3] file:///C:/Users/320076840/Downloads/AIDefinitionpdf%20(4).pdf

'Artificial intelligence (AI) systems are software (and possibly also hardware) systems designed by humans that, given a complex goal, act in the physical or digital dimension by perceiving their environment through data acquisition, interpreting the collected structured or unstructured data, reasoning on the knowledge, or processing the information, derived from this data and deciding the best action(s) to take to achieve the given goal. AI systems can either use symbolic rules or learn a numeric model, and they can also adapt their behaviour by analysing how the environment is affected by their previous actions. As a scientific discipline, AI includes several approaches and techniques, such as machine learning (of which deep learning and reinforcement learning are specific examples), machine reasoning (which includes planning, scheduling, knowledge representation and reasoning, search, and optimization), and robotics (which includes control, perception, sensors and actuators, as well as the integration of all other techniques into cyber-physical systems).'

Philips offers its support to the European Commission in further refining of the AI policy options and achieving the EU's ambition to become a globally significant player in AI.

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*Royal Philips (NYSE: PHG, AEX: PHIA) is a leading health technology company focused on improving people's health 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 2019 sales of EUR 19.5 billion and employs approximately 80,000 employees with sales and services in more than 100 countries.*