MERCK

Merck KGaA contribution to the Public Consultation on the European Commission's proposed regulation of Artificial Intelligence ("AI Act")

First of all, we would like to thank the EU Commission for the opportunity to participate and discuss this important act and commend the effort to draft regulation on such a complex and multi-faceted topic.

AI has a huge potential to solve today and future challenges. We welcome Europe taking this important step to develop regulatory certainty, which is essential to foster innovation and advance Europe's competitive position. In addition to managing the risks of AIs, the broader approach of the EU should also create a positive AI innovation ecosystem and contribute to public acceptance. It is an important signal if governments also adopt and employ AI systems, bringing real-world experience and allowing the exchange of best practices. Furthermore, governments should fund critical research and public-private partnerships, invest in workforce development and infrastructure.

Public acceptance requires trust in the technology, the producers, and the data. One can gain trust through proven ethical behavior based on ethical standards and proven adherence to them in a self-regulating approach. When Merck initiated AI projects, these ethical principles needed to be defined first, and we launched a scientific project which resulted in a set of principles for responsible use of data & algorithms/AI [1]. Based on our long experience in operationalizing bioethical standards, we set an early benchmark by implementing this in our development processes and have gained recognition by the public & private sectors.

Taking a risk-based approach to AI is indispensable, and we welcome that the EU Commission has embraced this concept. It is in line with our experiences of applying AI in areas subject to compliance and regulation [2,3,4,5]. We hope that the concept of self-governance and accountability will be further strengthened. The development of AI is a continuous process of piloting, reassessing, and improving. Constant self-assessment can govern the development very well, instead of a rigid ex-ante 3rd-party approval, which would come potentially in addition to existing ex-ante-assessments, such as software as a medical device. Self-assessment will also avoid additional competition on talents between developers and approval bodies, jeopardizing innovation power. To operationalize this approach, the regulator must proactively accompany standardization activities.

Ultimately, providers with proven best practices, such as companies with independent advisory panels, digital ethics codes, could have better ways to show compliance and get faster to market, reducing administrative burden.

We encourage the EU to consider alignment with key international partners. Regulatory cooperation can avoid unnecessary barriers to collaboration and innovation, e.g., around cross-border data exchange. An even regulatory playing field will prevent companies and start-ups from developing AI systems in more favorable markets and coming to Europe only in a second moment after customers validation.

Regulatory certainty is imperative for companies. While the draft AI Act sets the frame well, some aspects remain open to interpretation. Requirements and definitions need to avoid generalization,

abstract terms, or variables that depend on subjective interpretation. To name a few examples: the definition of AI in Annex I seems to be extremely broad. Restrictions such as "free of errors" in a dataset seem unnecessary and, in some cases, impossible to fulfill (Title III, Chapter 2, Article 10). The quality of the AI has to be assessed on the final outcome since even a perfect data set does not guarantee perfect algorithmic outcomes. In terms of logging, some aspects remain ambiguous and/or unclear on how to implement. For example, the term "Reference database" may not be applicable for many systems (Title III, Chapter 2, Article 12). Additionally, the attributes required for the log need careful consideration in order to follow the principle of data minimization and avoid records subject to data privacy regulation in the general log data. When considering high-risk, the act points towards the annex list, which brings additional uncertainty that the annex could change constantly. Predictability is crucial to direct medium and long-term investments.

Moreover, in regulated markets, it is essential to avoid uncertainty by duplicating the regulatory authority. Regulations for AI applications in the area of medical devices or in-vitro diagnostic tools, for example, should be integrated into those existing frameworks and rely on well-established authorities.

Lastly, since use cases are the basis of the risk assessment, strong AI may not fall under the regulation. Therefore, even though there is still a considerable way to reach strong AI, it would be relevant to have harmonized rules that are more futureproof and ready for the next pipeline of breakthroughs.

We are happy to exchange more deeply on the aspects outlined above and share our experiences on AI applications and compliance with ethical standards.

Sources

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