MEDTECH & PHARMA
PLATFORM

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European Commission
Directorate General Connect
Robotics and Artificial Intelligence (Unit A.1)
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European Commission consultation on the "White Paper on Artificial Intelligence – A European approach to excellence and trust"

Comments from the Medtech & Pharma Platform (MPP)

Dear Sir or Madam,

The Medtech & Pharma Platform welcomes the opportunity to comment on the proposals set out in the European Commission's "White Paper on Artificial Intelligence – A European approach to excellence and trust".

MPP supports the objectives of the European Commission to promote the adoption of appropriate and hence trustworthy Artificial Intelligence (AI), as well as the ambition to establish leadership where it has excellent capabilities.

We suggest to keep the following key points in the proposed regulatory framework:

- We are in favor of a risk-based approach. New pan-European regulation should be pursued only in cases in which procedural and control alignment, as well as common standards are essential, i.e. for high-risk pan-European markets. A regulation on high-risk AI applications may well be the fastest way to establish a common ecosystem for AI to foster. However, harmonization of existing sectorial regulation should be assessed carefully.
- We welcome the European Commission's parallel data strategy to enhance successful AI.
- AI regulation must be modest, pragmatic and proportionate to the risks involved.
- Harmonized applicability shall be adopted, irrespective of the location of the producer.
- A regulatory framework in lower-risk areas, which could be tailored to various application fields. Clarifying interpretation and practical applicability of the General Data Protection Regulation (GDPR) in this context would be helpful.

- When evaluating risks associated with new AI applications, the regulatory acceptance criteria should be based on the relative risk of the proposed new AI solution in comparison with current existing good practice as opposed to the residual absolute risk still inherent with the solution.

- Transparency requirements on AI like its intended use, information to explain what the output means in lay language and suitable form are appropriate. The protection of proprietary knowledge and Intellectual Property (IP) rights of the producer shall be guaranteed. Tools to support the explicability of decision are nascent and evolving. It is also essential to mandate regular review of AI performance, robustness/validation and potential bias, also post launch, in particular, but not limited to adaptive AI solutions. Audit trail and moderate documentation requirements could help to at least be able to inspect output creation ex-post. The policy should anticipate that explicability tools will improve over time and commensurate to this, consumers will be able to make more informed choices on the reliance they put on these tools. To the extent such tools are made available, the respective documentation and control procedures in the regulation can be waived.

- MPP favors a regulatory framework where the producer has obligation to comply by defined standards, certifies compliance and must be able to demonstrate compliance over an ex-ante approval by authorities. This approach will be much more dynamic and allows to avoid bureaucratic control overhead and delay. We also support a voluntary label, irrespective of high- or low-risk AI applications. Consumer protection can be assured by not diluting their accountability and effective liability system, as well as through inspections by authorities on a reasonable sample basis. We think there is an opportunity to learn from the Medical Device Regulation and seek a lighter approach where the overhead on manufacturers and notified bodies has been excessive. This is particularly important for small innovative companies. A new regulation should specifically also remove obstacles identified in some countries unreasonably hindering the uptake of AI.

- We think the liability system should not fundamentally be changed, but we agree that standalone software could be included in a product liability framework. Where AI sourced from a supplier is part and parcel of a product or service offered to consumers, the producer of the product or service should assume accountability of the product as a whole. The burden of proof for tort cases should still be on the claimant in principle. We acknowledge the difficulty for consumers to evidence malfunction. This should be addressed by an obligation of the producer to transparently inform the consumer, and any evidence requirements of the producer should be limited to product claims made, process and due diligence applied as outlined in the standards set forth in the regulations or if applicable the label under which the AI was produced. Additional standards which could be included in regulations and labels may include transparency requirements about the performance of a device and the circumstances under which they operate, as well as the risks if these conditions cannot be upheld (e.g. loss of connectivity or cyber risks). Waiving these risks as a producer should only be allowed to the extent that they cannot reasonably be expected to control them. AI systems should not be made a legal subject in their own right.

- An error reporting process for AI could be envisaged, similar to adverse event reporting of medicinal products or anonymous error reporting systems in clinical practice. This could help disclosing AI malfunctions and facilitate learning processes for the practice community (examples exist with pilots or physicians).

We thank the European Commission for the opportunity to provide our comments to this consultation. Please do not hesitate to contact the Medtech & Pharma Platform for further information.

Yours sincerely,

Shayesteh Fürst-Ladani
President

About the Medtech & Pharma Platform:

The Medtech & Pharma Platform (MPP) is a cross-sectoral not-for-profit industry association focusing on combined products. MPP is made up of Medtech, Pharma and Software companies dedicated to enhancing synergies between the sectors and to provide a cross-sectoral forum to exchange knowledge, collaborate in technology and regulatory areas as well as to promote product development and innovation. The association aims to further strengthen advocacy work for companies to reduce time to market for drugs, devices and combinations thereof, improve access to innovative products and better match patients' needs.