MEDTECH & PHARMA
PLATFORM

Directorate-General for Communications Networks, Content and Technology
Artificial Intelligence and Digital Industry (Directorate A)
European Commission
1049 Bruxelles/Brussels
Belgium

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MPP input to the European Commission public consultation on the proposed Regulation laying down harmonized rules on artificial intelligence (AI Act)

To whom it may concern,

The not-for-profit Medtech & Pharma Platform Association (MPP) welcomes the European Commission proposal for a Regulation laying down rules on AI. MPP supports efforts to optimize the regulatory framework to create the right conditions for healthcare innovation. MPP welcomes the possibility to comment on the proposed Regulation and would like to seize this opportunity to share some reflections and suggestions.

We are the opinion that risk categories for AI provide a useful base for the regulation of AI. In this area, we would welcome clarifications on the determination of the high-risk category in the proposed Regulation and how such category correlates to existing legal frameworks, especially with the Medical Devices and *In Vitro* Diagnostics Regulations (MDR and IVDR). Notably, there is a concern that the existence of different risk assessments under the AI and medical device legislations might create confusion. Under a risk-based regulatory system and in consideration of the scope of use, some AI-driven software may be categorized as low or intermediate risk under the MDR and IVDR, whereas the proposed Regulation may classify such products as high-risk. In this regard, it could be beneficial to consider aligning the risk levels described in the proposed Regulation with risk levels outlined in the MDR and IVDR for consistency. The recently entered into force MDR and upcoming IVDR provide an adequate framework for the regulation of Medical Device Software (MDSW) and it is important to make sure that the proposed Regulation is fully compatible with them.

In addition, MPP would like to share the following comments and questions:

- Recital 60: Does this imply that a pre-trained model cannot be used in an AI high-risk system as a software of unknown (or uncertain) pedigree (or provenance) (SOUP) or off-the-shelf (OTS), for which the collaboration of the supplier is not necessarily needed?
- Article 43 section 4: How does the process for pre-determined changes for MDSW work? Are the rules mentioned in this article supposed to come from the regulators or does the paragraph mean that the manufacturer can specify in the instructions the modification (e.g. in accuracy) that can occur without implying a "substantial modification"?
- Annex II: Companies may develop internal products in the areas of high-risk AI systems. How does the EU intend to monitor the internal usage of AI systems that do not reach the market?
- Annex IV: Is the pre-specification in this Annex comparable to (SPS) Software as Medical Device (SaMD) pre-Specifications, Algorithm Change Protocol (ACP) from the US Food and Drug Administration (FDA) AI Discussion Paper on the regulatory framework for modification

to AI /machine learning (AI/ML) based SaMD? Is there any possibility to harmonize those two approaches with the current proposed Regulation?
- Annex IV, 2(e): More clarification is needed on how human oversight is defined and applicable, examples from medical device software would be appreciated.
- The proposal states that it will consider harmonized technical requirements. Will standards such as IEC 62304, ISO13485, ISO14971 be integrated?
- How does the Commission plan to build the regulatory sandboxes to facilitate products following regulations MDR and IVDR? More specifically, can certain activities, like data collection with the purpose of building a model or tests for clinical evaluation, be performed in the context of these sandboxes? And what would be the regulatory steps to move from a sandbox to the market for such a product?
- How is the expansion of the AI system (e.g. scaling up to different devices, from Android to iDevice) organized in terms of submission?

The proposed penalties in case of infringement may impact the commitment of manufacturers in ensuring deep and intensive monitoring of their own AI systems in the post-market surveillance phase. To promote a shared culture of rigorous monitoring, incentives to the manufacturers that find incidents in their own AI system could be put in place. Such incentives could, for instance, materialize via decreased fines when infringements are found and addressed by manufacturers themselves.

MPP continuously seeks dialogue with relevant stakeholders to create an appropriate framework for combined products (covering combined use of medicinal products, medical devices, MDSW, AI, and IVDs) that fosters innovation, reduces time to market, and addresses patients' needs. We thank you for considering our position and the proposals outlined above.

MPP remains at the European Commission's disposal for further dialogue and collaboration.

Yours sincerely,

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About the Medtech & Pharma Platform Association

The not-for-profit Medtech & Pharma Platform Association (MPP) draws together companies from the pharmaceutical, medtech and ICT sectors and provides opportunities to exchange knowledge and to collaborate in technology and regulatory areas related to combined products.

MPP's objectives are:

- To enhance synergies between the pharma, medtech and ICT industries,
- To establish new collaboration models to ensure and accelerate market access for safe and innovative treatment options,
  To contribute to the development of a balanced and proportionate regulatory and policy framework for combined products including connected combined products.