MEDTECH & PHARMA
PLATFORM

MPP Association statement on the AI ACT

March 2024

The MPP Association welcomes the adoption of the EU artificial intelligence (AI) Act by the European Parliament on 13 March 2024. The MPP Association supports the principles and objectives of the AI Act to ensure that safe and properly performing AI products are placed on the European market. However, many of the regulatory requirements of the AI Act are common to other existing legal frameworks in place for drugs, devices, diagnostics, and combined products, such as establishing a quality management system and drafting technical documentation that authorities can assess for compliance.

The MPP Association invites legislators to ensure that the implementation of the AI Act guarantees a seamless harmonization with the Medical Devices Regulation (MDR), *in Vitro* Diagnostics Regulation (IVDR) and EU pharmaceutical legislation with a view to avoid any duplication, overlap, or conflict with application and approval processes required for the AI incorporated into drugs, devices, diagnostics, or combined products. The existing legal frameworks for medical devices, *in vitro* diagnostics, and medicinal products should accommodate AI in the same way as they do for the Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), the Directive on Restriction of Hazardous Substances in Electrical and Electronic Equipment (RoHS), and the Directive on Waste Electrical and Electronic Equipment (WEEE).

The MPP Association continuously seeks dialogue with relevant stakeholders to create an appropriate framework for medical technology that fosters innovation, reduces time to market, and addresses patient needs.