MedTech Europe welcomes the adoption of the opinion by the European Parliament's Legal Affairs Committee on the AI Act

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MedTech Europe welcomes the adoption of the opinion by the European Parliament's Legal Affairs Committee, which sends a strong message to the leading European Parliament Committees for Civil Liberties, Justice and Home Affairs (LIBE) as well as Internal Market and Consumer Protection (IMCO) on the need for context-based human oversight, which is particularly relevant in the healthcare sector.

MedTech Europe fully supports the adopted provisions by the European Parliament's Legal Affairs (JURI) Committee on human oversight. The amendments provide a right step toward **context-based human oversight**, with effective consideration regarding the particular risk of the AI system in question and its level of automation. For AI-embedded medical technologies, such AI systems traditionally provide assistance and support by for example by providing more accurate recommendations and leave the final say to the licenced healthcare professional, charged with the patient's care, before any action is taken. In addition, the JURI Committee has rightly recognised the nuanced nature of AI in the healthcare setting. In certain circumstances, human intervention can negatively impact the functioning of AI-embedded medical technology, affecting the patient's well-being.

Other points of progress

MedTech Europe recognizes further progress in the following areas:

European AI Board (EAIB): The proposed reinforced mandate and structure of the EAIB and its role in bringing together EU bodies (e.g., in standardisation) will ensure effective implementation of the AI Act at the EU Member State level. Another important step is JURI's view that external stakeholders, such as industry, should be provided with regular opportunities to participate in meetings with the Board and that the outcomes of such meetings be transparently published. This will ensure appropriate levels of accountability and provide for well-informed, context-based discussions on AI. At the same time, it needs to be highlighted that adequate resources will need to be allocated to match the Board's ambitious role and staff it with the relevant expertise.

AI literacy and user focus: The amendments relating to AI literacy are a key means for ensuring a baseline understanding of the specific AI technology by professional users. The changes relating to transparency will ensure that AI systems users sufficiently understand the workings and intended function of the AI system.

> ***"MedTech Europe would like to reiterate its concerns over the legal unclarity and regulatory overlap of the AI Act with the sectoral legislation of the Medical Devices Regulation and In Vitro Diagnostic Medical Devices Regulation (MDR/IVDR), "says Patrick Boisseau, Director General, Strategic Initiatives***

We call on policymakers to address these concerns to **provide a clear and consistent legal framework for AI-enabled medical technologies that ensure their continued availability for patients, healthcare professionals and healthcare systems.** MedTech Europe will continue following the ongoing technical meetings and negotiations between the European Parliament's IMCO-LIBE Committees and following the progress in the above areas.

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.

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