Proposal for an Artificial Intelligence Act (COM/2021/206)

6 August 2021

MedTech Europe response to the open public consultation

MedTech Europe, the European trade association representing the medical technology industry including diagnostics, medical devices and digital health, would like to provide its response to the European Commission's adoption consultation on the proposed Artificial Intelligence Act (AIA). Artificial Intelligence (AI) technology is increasingly used in healthcare and in recent years has been greatly enhancing the workflows and decision-making processes of healthcare providers. New medical technologies employing AI are being developed and introduced on the market to bring improvements for citizens and patients, healthcare providers, payers, and society at large. One prominent example is the deployment of medical technologies using AI software to support in the fight against the COVID-19 pandemic.

The medical technology industry would like to stress the importance of a robust regulatory framework, which provides **legal coherence, certainty, and clarity** to all actors. In particular, **interpretation issues of the new rules for AI that comprises, or is incorporated in, a medical technology, should be addressed.** We call for particular attention to be paid to **misalignment between provisions in the AI Act and the Medical Device Regulation (MDR)[1] and In-Vitro Diagnostics Regulation (IVDR)[2]** as well as the **General Data Protection Regulation (GDPR)[3]**. Addressing this misalignment is essential to ensure the legal coherence, certainty and clarity needed to foster innovation, citizen access to quality care and competitiveness of industry.

1. Definition/Technical Scope

MedTech Europe would like to point out that the proposed broad definition of AI and risk classification will result in any medical device software (placed on the market or put into service as a stand-alone product or component of hardware medical device) falling in the scope of the AI Act and being considered a high-risk AI system, since most medical device software needs a conformity assessment by a Notified Body.

2. Misalignment between AIA and MDR/IVDR

Duplication and potential conflicts arising from **misalignment between the AIA and existing obligations under MDR/IVDR must be avoided** in order to ensure legal coherence, certainty and clarity. The sectoral regulations MDR/IVDR lay down some of the most stringent rules in the world on the safety and performance of medical technologies, including those medical technologies that comprise, or incorporate AI. These include, for instance, dedicated rules on risk management, quality management, technical documentation, and conformity assessment with Notified Bodies. Obligations in the AIA are thematically

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
[2] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
[3] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation).

similar to the requirements in MDR/IVDR but differ in terms of details, which may lead to complex interpretation issues. Although we acknowledge that duplication is not the Commission's intended vision, there are concerns that the AIA would in effect create the need for manufacturers to **undertake duplicative certification / conformity assessment, via two Notified Bodies, and maintain two sets of technical documentation, should misalignments between AIA and MDR/IVDR not be resolved.** Duplication of this kind would lead to unnecessary overlaps in the regulatory approval of AI as/in medical technology, which could have a negative effect on the timely access of citizens and patients to highly innovative and fairly priced AI medical technology in the EU.

Some examples of misalignment between the AIA and the MDR/IVDR include:

- **Risk Classification**: Medical technologies can be assigned to a range of risk classes under the MDR/IVDR. While the AIA is not meant to change sectoral classification, it would put most cases of AI in/as a medical technology in the highest risk class under the Act. This is a clear deviation from how medical technologies are regulated in Europe and around the world. It would drive confusion among regulators and manufacturers and would create additional, unnecessary complexity in the regulatory approval process that could hinder highly innovative technology to reach citizens in a timely manner.
- **Definitions**: Terms such as "provider", "importer", "serious incident", "putting into service" and "user" in the AIA do not match those under the MDR/IVDR. The definition of 'risk' which is the main concept of conformity assessment is missing in the proposal.
- **Certification**: The AI Act requirements for designation of Notified Bodies, conduct of conformity assessments, and issuance of certificates differ in substance from the corresponding requirements of the MDR/IVDR. In particular, MedTech Europe has concerns regarding the lack of clarity on the following matters, which collectively pose the risk of dual/duplicative certification of AI in/as medical technology:
- Designation of Notified Bodies for AI-specific competencies.
- Time and capacity required for the designation of Notified Bodies with AI and medical technology competencies to be ramped up.
- Roles and responsibilities for Notified Bodies conducting conformity assessments on AI as/in medical technology.
- The very possible scenario where an MDR/IVDR-designated Notified Body is not successfully designated for AI-specific competencies: should this occur, the risk of needing two separate technical documentation submissions, leading to two separate conformity assessments and certifications, must be avoided.
- **Vigilance and post-market surveillance reporting**: The future European Database for Medical Devices (EUDAMED) should remain the system used for these purposes to ensure aligned, streamlined, efficient non-duplicative market surveillance of AI in/as medical technologies.
- **Change control**: The question of what constitutes 'changes' in AI systems and the requirements for new submissions in case substantial changes are made is an area of considerable unclarity and urgently needs additional clarification in order to not hinder innovative AI medical technologies to enter the market.

Finally, an adequate transition period must be ensured: the 24 months foreseen would not be sufficient for the entire ecosystem to be ready and compliant with a new regulatory framework. The transition period should be at least 48 months.

3. Misalignment between AIA and GDPR

The AIA appears to provide a legal basis for processing certain categories of personal data. For instance, Article 10(5) states that providers of high-risk AI systems "may process special categories of personal data referred to in Article 9(1)" of the GDPR, where doing so is "strictly necessary for the purposes of ensuring bias monitoring, detection, and correction," subject to additional safeguards set out in that paragraph. While MedTech Europe supports this positive development **the AIA is nevertheless not sufficiently providing legal ground for processing personal data *in general* under the GDPR (as stated in Recital 41)**. As such, **providers of medical technology are likely to face numerous challenges in ensuring that the steps they take to comply with the AIA do not conflict with their obligations under the GDPR**. This is particularly relevant when it comes to the requirements set out in the following articles:

- **Article 10(3) of the AIA** requires providers of high-risk AI systems to ensure that training, validation, and testing datasets for such systems are "relevant, representative, free of errors, and complete." However, where providers cannot establish an independent legal basis under **Article 6 of the GDPR** to process certain sources of personal data for these purposes, they might find it difficult to ensure that their datasets are sufficiently "relevant" and "representative" to satisfy this requirement. In addition, Article 10(3) should be consistent with **Recital 44 of the AIA**, which adds the adverb "sufficiently" to the requirements for training, validation and testing data.
- **Article 12(1) of the AIA** requires providers of high-risk AI systems to ensure that these systems have the capability to generate automatic "logs" of events while the system is operating. **Article 16(d) of the AIA**, in turn, requires providers to retain copies of these logs when the system is "under their control," while **Article 23 of the AIA** requires providers to provide access to such logs to competent authorities "[u]pon a reasoned request." To the extent such logs include personal data, providers presumably will need to establish an independent legal basis for such processing under **Article 6 of the GDPR**, and will also need to establish that such activities comply with the data processing principles set out in **Article 5 of the GDPR**, in particular the principle of data minimisation. Without further clarity on how to fulfil these requirements in light of the GDPR, providers may not be able to achieve the necessary level of compliance.
- **Recital 60** states that, in light of the complexity of the AI value chain, parties "involved in the sale and the supply of software, software tools and components, [and] pre-trained models and data … should cooperate, as appropriate, with providers and users to enable their compliance with the obligations under this Regulation." If such cooperation requires the sharing of personal data with such providers or users, the entity sharing the data might need to establish an independent legal basis for such processing under the GDPR.

Given these compliance challenges, MedTech Europe considers clarifications urgently needed in order for the medical technology industry in Europe to be able to maintain and further foster the highest level of

innovation, ensure and increase timely citizen and patient access to quality care and retain global competitiveness of the industry.

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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