Medical technology industry perspective on the final AI Act

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MedTech Europe
from diagnosis to cure

Introduction

In response to the European Parliament Plenary endorsement of the AI Act, MedTech Europe would like to present a medical technology industry perspective on the final agreed text of the AI Act.

We welcome the significant efforts made by the co-legislators to reduce unnecessary administrative complexities and legal uncertainties arising from the simultaneous application of multiple Union Harmonisation Legislation and encourage consistency across the relevant applicable rules for the medical technology sector. We appreciate the difficulty of the task presented to lawmakers to provide for horizontal regulation on an emerging and complex technology such as artificial intelligence while providing for its safe and effective integration across the EU market. Co-legislators have made great strides to increasing clarity and consistency within the AI Act, including on rules on data and data governance, which we agree are further reflective of the technological realities of training and validation, or the revised approach taken by co-legislators towards the exercise of human oversight, with requirements based on contextual realities rather than a one-size-fits-all requirement.

However, further clarity is still needed to ensure that the AI Act supports European technological innovation, and the wider integration of AI within and across European healthcare settings, ensuring timely delivery of trustworthy, safe and effective care and diagnosis, for the benefit of patients and healthcare systems.

Many existing AI solutions used today in national healthcare systems are integrated into medical technologies and regulated under the Medical Devices Regulation (MDR), and the *In Vitro* Diagnostic Medical Devices Regulation (IVDR) which each lay down comprehensive requirements for product design and development, as well as for clinical performance, patient safety and security protections. MDR/IVDR also regulate medical devices and *in vitro* diagnostic medical devices incorporating or qualifying as artificial intelligence-based software. Going forward, many such AI solutions will qualify as high-risk AI systems under the AI Act, and medical technology manufacturers will therefore need to ensure compliance with both the MDR/IVDR and the corresponding requirements under the AI Act.

In order to ensure a clear and practical applicability of the AI Act to the medical technology sector, MedTech Europe recommends that the following steps be considered:

- European Commission guidelines should be developed swiftly and well before the end of the transition period. They should be developed with active input by stakeholders, including the Medical Device Coordination Group (MDCG).
- Alignment of horizontal AI Act standards under development, with existing vertical standards, including with those for medical technologies.
- Further clarity underpinning a single conformity assessment procedure, let by sectoral processes.
- A clear pathway for clinical and performance evaluation of medical technologies

1. Need for further alignment between high-risk AI systems requirements under the AI Act and related standards, and MDR/IVDR requirements and related standards

The AI Act's recitals acknowledge the need for consistency, avoiding unnecessary additional burdens or costs, and allowing for flexibility for AI systems providers (manufacturers) to make operational decisions on how best to ensure compliance with the applicable requirements of Union Harmonisation Legislation when incorporating AI systems into their products. However, the final text in the AI Act only translates these recital principles into clear legal rules with regard to some obligations (e.g., the possibility to integrate testing and reporting processes, information and documentation into already existing documentation and procedures required under the existing Union Harmonisation Legislation). Importantly, the AI Act legal text does not address and provide clarity on many critical principles. MedTech Europe is concerned that the current wording of Article 8 (2a) leaves room for diverging interpretations among medical technology manufacturers and will lead to confusion, inconsistency, and ultimately delays to the delivery of safe and effective products to patients and healthcare systems. For example, clarity is needed to confirm that a 'substantial modification' within the AI Act, as it relates to transitional provisions and new conformity assessments, aligns with the definition/interpretation outlined in MDR/IVDR and relevant guidance for change control for medical technologies that are AI systems.

In order to avoid legal uncertainty, it is essential to provide further clarity as to what extent conformity with the MDR and IVDR and related harmonised standards are presumed to be in conformity with the requirements set out within the AI Act.

- The requirements for providers of high-risk AI systems under the AI Act should in no way contradict, misalign, or compromise the requirements for those medical technology manufacturers under MDR or IVDR, as unintended contradictions or duplications will delay the delivery of safe and effective medical technologies to patients and healthcare systems.
- Timely European Commission guidelines as well as MDCG Guidance clarifying the integration of the AI Act with the existing MDR/IVDR rules, including the application of key concepts and definitions will be of the utmost importance. This can be achieved through close collaboration with relevant sectoral expert groups and bodies, such as the MDCG.

MedTech Europe appreciates that the final text of article 40 explicitly states that the European Commission, when making a request for standardisation, must clearly specify that standards must be consistent with both current and future standards being developed across sectors for products covered by the existing Union safety legislation, including MDR/IVDR. Indeed, alignment of horizontal standards of the AI Act with sectoral standards under MDR/IVDR is key to the clear implementation of the AI Act's requirements into sectoral processes and to facilitate compliance. The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are tasked with the development of horizontal harmonised EU standards on AI which, if not appropriately considered, could duplicate or, worse, conflict with vertical standards in the medical technology space. As an example, CEN-CENELEC will develop a harmonised standard on risk management, which may need to be applied and aligned simultaneously with an existing vertical standard on risk management under MDR/IVDR. Vertical standards (such as those employed within the medical technology sector) should therefore be taken into account during the CEN-CENELEC harmonised standards development process to ensure that compliance with one set of standards does not result in a divergence from others. As such, MedTech Europe encourages CEN-CENELEC to consult with CEN sectoral groups for MDR/IVDR and industry stakeholders in order to ensure appropriate coherence between horizontal and sector standards pertaining to the same area. The complementary nature

between the AI Act and existing sectoral legislation should be taken into account in future standardisation activities or guidance adopted by the Commission.

- Consistency among horizontal and vertical standards is key, including with the existing and future standards developed in the medical technology sector, and aimed at ensuring that AI systems placed on the market or put into service in the EU meet the essential requirements laid down in the AI Act. Additionally, applicable international standards need to be preferred over local European standards.

2. Support for the single conformity assessment and technical documentation

As mentioned above, we appreciate the efforts of the co-legislators to ensure that high-risk AI systems related to products following the New Legislative Framework approach comply with the requirements of the AI Act. The assessment of such compliance should be carried out as part of the conformity assessment procedure already foreseen under that legislation. In addition, the application of the requirements of the AI Act should not affect the specific logic, methodology or general structure of conformity assessment under the relevant NLF legislation. MedTech Europe welcomes the envisioned single EU Declaration of Conformity which shall be drawn up in respect of all EU legislation applicable to the high-risk AI system, considering that the Declaration of Conformity of the AI Act will be integral to the Declaration of Conformity required under the MDR/IVDR.

- Legal certainty and the avoidance of obstacles in delivering the ethical, safe and effective devices that the AI Act intends to support can only be achieved if the conformity assessment processes and requirements are aligned with the MDR/IVDR. MDR/IVDR quality management certificates should be used to express that medical device manufacturers also meet respective requirements of the AI Act.

The availability of detailed technical documentation, containing information necessary to prove compliance of the high-risk AI system with the relevant requirements is an integral part of the medical technology industry to commit to continuous general safety and performance requirements (GSPR) for patients and healthcare professionals, as it is already regulated under MDR/IVDR. The sector-specific technical documentation covers the AI Act requirements, among others, the intended purpose, detailed description, instructions for use, design specifications, validation and testing and risk management system. Given the extensive overlap between the type of documentation and information required for conformity assessment under the MDR/IVDR and the AI Act, it should be made explicit that manufacturers can leverage a single set of technical documentation.

- European Commission guidelines should explicitly clarify that a single set of technical documentation can be developed to demonstrate compliance with the requirements in both the AI Act and the MDR/IVDR.

Since both the MDR/IVDR and the AI Act are risk-based regulations, they require third-party conformity assessment for products of a higher risk class, which is carried out by independent Notified Bodies. However, the AI Act does not provide sufficient clarity whether providers of AI-enabled medical technologies can continue to rely on the established MDR/IVDR processes with notified bodies used today for AI-enabled medical technologies. For a smooth functioning of the process for providers and notified bodies alike and to prevent unnecessary delay, it is essential to make use of the existing conformity assessment procedure to enhance notified bodies' designation scope under MDR/IVDR to cover AI-related aspects. In addition, it

should be clarified that the same notified body identification number used for MDR/IVDR conformity assessment can be used for conformity assessments undertaken for the AI Act.

- Notified bodies should be able to use existing technology codes for the assessment of AI-enabled medical technology, with the same notified body identification number maintained for both the AI Act and the MDR/IVDR.
- Under the AI Act, and specifically, to assess conformity of AI-enabled medical devices in accordance with the AI Act's "high risk" requirements, the notifying authorities that are responsible for notified bodies according to the MDR/IVDR shall also be responsible for notified bodies according to the AI Act.

3. A clear pathway for clinical and performance evaluation of medical technologies

In accordance with the MDR and IVDR, medical devices and *in vitro* diagnostic medical devices that require third-party conformity assessment by an MDR/IVDR-designated notified body must be supported by clinical evidence to demonstrate their safety, performance and clinical benefit.

As per the MDR and the IVDR, medical devices and *in vitro* diagnostic medical devices undergo a clinical investigation or performance study in order to gather sufficient clinical evidence to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer. In both cases, the devices, referred to as investigational devices under MDR and devices for a performance study under IVDR, are tested in real-world conditions to support them with the appropriate clinical evidence in view of the characteristics of the devices, their intended purpose and functioning.

It is crucial to note that at this investigational stage, these devices do not require a CE marking for the testing process/procedure, nor are they regarded as placed on the market or put into service in the sense of EU product legislation. This process ensures that these medical technologies are of high quality and meet the necessary requirements to be marketed in the EU including clinical output and therefore, it is an essential step in the medical device development process.

The AI Act however does not specifically address clinical investigations and performance studies. As such, MedTech Europe is concerned that investigational devices (per the MDR) and devices for performance study (per the IVDR) would require an AI Act CE mark before they undergo clinical and performance evaluation.

- Conducting clinical investigations/performance studies is critical to gather the necessary information for a medical device or an *in vitro* diagnostic medical device to ensure the safety and effectiveness of the device and complete its conformity assessment with a notified body, and by extension, receive its MDR/IVDR CE-marking. However, under the AI Act, there is a risk that these investigational devices and devices used for performance study may be deemed to be "put into service" or "placed on the market" and therefore may require an affixed CE-marking prior to their testing. MedTech Europe therefore recommends that investigational devices and devices for performance studies follow an MDR/IVDR logic and, as such, be exempted from the requirements of the AI Act, insofar as those processes respect patient safety and fundamental rights, such as those stipulated under GDPR.

Conclusion on AI Act implementation

For the seamless implementation of the AI Act alongside MDR/IVDR, MedTech Europe recommends that the European Commission work to deliver implementation guidelines in a timely manner to assist all stakeholders to adequately comply with the new regulatory requirements. Stakeholders, including the medical technology industry, should be consulted in the development of such guidelines.

In view of those European Commission guidelines, further attention should be given to the following areas in order to deliver on comprehensive regulatory interplay for the medical technology sector:

- Firstly, there is a need to build upon alignment of high-risk AI systems requirements and standards from the MDR/IVDR and the AI Act, insofar as they affect medical technologies.
- Furthermore, it is necessary to continue to operate through an MDR/IVDR approach to assess conformity of AI-enabled medical technologies, including all necessary processes and procedures to ensure the safety and performance of AI-enabled medical technologies.
- Finally, it is critical that the AI Act does not represent a regulatory barrier to the functioning of the MDR/IVDR-required clinical investigations and performance studies. Such processes are required to demonstrate that a medical technology performs safely in view of the device characteristics and as clinically intended.

MedTech Europe is committed to being a proactive partner throughout the AI Act implementation process and looks forward to supporting the work of the European Commission and the Medical Device Coordination Group in ensuring clear regulatory integration and alignment.

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. www.medtecheurope.org.

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