MedTech Europe's reaction to the EU Council's General Approach on the AI Act

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MedTech Europe recognises the amendments made by the EU Council aimed at clarifying the responsibilities under the draft legislation, such as the definition of AI systems and Chapter II requirements. **Further steps are needed to ensure this regulation aligns well with sectoral requirements, such as the Medical Devices Regulation (MDR) and *In Vitro* Diagnostic Medical Devices Regulation (IVDR).**

The MDR and IVDR set out stringent requirements to ensure that actors in the healthcare ecosystem can benefit from technologies with high level of protection of health and safety before the technologies are placed on the market. By adding another regulatory layer, the AI Act **risks creating legal uncertainty and unnecessary regulatory burdens on providers of AI-enabled medical technologies** because of potential duplicate or contradicting requirements. Therefore, ensuring sectoral alignment is vital for European patients and healthcare professionals alike who either rely on AI-enabled medical technology now, or will do so in the future, as it will provide them with the opportunity to enjoy the fullest potential of healthcare they need and deserve. If the sectoral alignment remains unaddressed, resulting issues such as the fragmented conformity assessment procedures, risk creating new and unwarranted bottlenecks, adversely affecting the delivery of AI-enabled medical technologies to patients and healthcare professionals.

MedTech Europe would like to share its reaction on three key changes brought to the proposed legislation by the EU Council. We encourage the incoming Swedish Council Presidency to consider our recommendations on these amendments and maintain a flexible position with the regards the upcoming inter-institutional negotiations.

I. Sectoral alignment, scope and provisions pertaining Chapter 4 and 5

MedTech Europe welcomes the reference to the MDR and IVDR, in the recitals such as **Recital 54a**. However, the revised statement may be interpreted in a way that it alludes to the *lex specialis* principle. It is unclear in this case, whether either a) sectoral legislation would take precedence because it applies to a specific product, e.g., a medical device; or b) the AI Act would take precedence over sectoral legislation, because it applies specifically to products that either contain or that are an AI system; or c) sectoral legislation or the AI Act would take priority, depending on which legislation contains a requirement that is more detailed.

In regard to **Article 2 (3) on Scope**, MedTech Europe highlights that by including "the purpose of activities which fall outside the Union law", the text may be misinterpreted to the extent that AI systems for healthcare be excluded from the scope as the activities can be attributed to Member States' national competence, according to Article 168 (7) TFEU. The scope of the AI Act should address the interplay with Union Harmonisation Legislation to reduce misalignment, by noting that to the extent that the requirements of Title III, Chapters 2 and 3 or Title VIII, Chapters 1, 2 and 3 for high-risk AI systems are addressed by Union

Harmonisation Legislation listed in Annex II, Section A, the requirements or obligations of those Chapters of this Regulation shall be deemed to be fulfilled.

MedTech Europe would welcome further changes to **Article 30 regarding notifying authorities**. Fragmentation and additional burden for notifying authorities which are already designated under sectoral legislation (specifically MDR (Article 35) and IVDR (Article 31)) should be avoided. This would ensure that in the event such authorities are already in place and have the capacity to carry out the relevant functions laid down in the AI Act Regulation, such notifying authorities can be designated to perform such functions. When referring to provisions and **requirements relating to notified bodies (Article 33 (9))**, MedTech Europe believes that, where notified bodies designated under MDR and IVDR can demonstrate the appropriate levels of resources and expertise to carry out conformity assessment under the AI Act, those MDR/IVDR-designated notified bodies can be designated to carry out conformity assessment under this regulation. This would reduce the risk of having two parallel conformity assessment procedures, one for the AI component of a device, and the other for the MD or IVD component of a device.

In view of **Article 43 (3) on conformity assessment,** MedTech Europe is concerned that with the wording proposed, notified bodies might have to require a new assessment and notification under the AI Act, with again a review of their competence. MedTech Europe further highlights that the General Approach is not clear on the **designation of national competent authorities (Article 59 (7))**, in particular whether one central contact point for all sectors or per sector is meant. In regards to the **Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems - Article 61 (3) and (4)**, MedTech Europe notes that by providing the Commission with implementing powers to lay down provisions to establish a post-market monitoring plan template and to provide a list of elements to be included in the plan, such powers might ultimately lead to medical technology manufacturers being mandated to adopt a separate template for a 'post-market monitoring plan', which risks diverging from the post-market surveillance framework established under MDR/IVDR.

II. Definitions on AI systems, providers and lack of definition on risk and harm

The Council has narrowed the definition of 'AI system' in **Article 3 (1) and deleted Annex I.** While the definition particularly refers to 'systems developed through machine learning approaches' it also refers to 'logic- and knowledge-based approaches'. Thus, it is still unclear how this definition distinguishes AI from traditional software. The recital 6a and 6b reference these concepts, and contradiction to recital 6 as to certain examples use often rules that are defined solely by natural persons to automatically execute tasks. As to **Article 4,** MedTech Europe is concerned that by giving the Commission implementing power, they can include techniques which, consequently, change the scope after the adoption, without sufficient levels of input with relevant stakeholders.

By referring to a '**provider'** according to **Article 3 (2)** as 'a natural or legal person, public authority, agency or other body that develops an AI system or that has an AI system developed and places that system on the

market or puts it into service', the General Approach does not consider the possibility that an AI system could also be placed on the market by an importer, which is not considered a provider, and therefore is not subject to the respective requirements.

MedTech Europe highlights that the General Approach **continues to lack a definition of 'risk' and 'harm'**, whereby in particular 'risks' is used in different contexts throughout the document. The text continues to lack a determination of the severity of 'harm' that an AI system is capable of causing. In MedTech Europe's view, in order to achieve consistency throughout the proposed AI Act and with sectoral legislation, a definition of 'risk' and 'harm' is still needed.

III. Chapter II requirements for high-risk AI

MedTech Europe notes that the language used **in Article 8 (1)** is not aligned with **Recital 63**. To ensure consistency throughout the text, Article 8 (1) needs to include the reference to MDR and, additionally IVDR. In regard to **risk management systems (Article 9 (2)),** while it is vital to have up-to-date AI systems, the risk management system may be effective for a longer period without needing to be updated. The suggested wording however implies that updates are to be performed systematically, even if the process is deemed effective. In addition, the reference to 'technical information' is not adequately placed in the **second section of paragraph 2**, as this concept does not mitigate or eliminate risks, only safety notices for the users that have that capacity. As regards to **paragraph 4a,** MedTech Europe notes that reducing risks as far as possible for certain medical devices, would make the device no longer effective.

MedTech Europe notes inconsistencies in terminologies and tasks relating to **Data and data governance (Article 10 (2) and (3))**, as the bulleted lists suggests that data collection is part of training, validation and testing, which, in practice, is not the case. Collection of data takes place before training, validation and testing. In addition, the term 'if applicable' should be introduced because some of the bullet points apply only to some of these terms, such as (a) relevant design choices affect 'training' and 'validation', but not data collection or testing and (c) 'relevant data preparation processing operations' [...] only affects data collection. As to paragraph three, the wording is inconsistent with that of **Recital 44**. To test the robustness of an AI system, a provider needs to test using suboptimal data or deliberately introduce errors.

MedTech Europe believes that **technical documentation** should focus on aspects that are necessary for the assessor to understand what the AI system is about, what is its intended purpose, who are its users, how does it fit in the workflow or context in which it is used, and what could significantly impact the safety and performance or affect compliance with the AI Act. MedTech Europe believes that the suggested list **in Annex IV** may not meet that goal, because some information asked for is irrelevant for that purpose, or that important information is overlooked, or terminology is used that is unusual for the software environment.

MedTech Europe notes the General Approach did not address vital aspects on **human oversight (Article 14 (1)),** such as clarifications regarding the original Commission provision "during the period in which the AI system is in use". While this provision could be understood as 'during the lifetime of the device', it may also

be interpreted as ‘during actual use’, which for some medical technologies is problematic as manufacturers may not be able to provide effective oversight during use. Instead, human oversight should be allowed to be continuous or intermittent or retrospective, rather than "during the actual use". In addition, MedTech Europe notes that the General Approach failed to include that human intervention in the intended functioning of an AI system, should only be applicable where such intervention can be made safely, to ensure that an AI system is brought to a ‘safe stop’. Provisions on human oversight should reflect the varying characteristics that different AI systems, including AI-enabled medical technologies, are likely to have, and thus, regulatory requirements should reflect this diversity.

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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