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

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MedTech Europe recognises the amendments made by the Council of the EU aimed at clarifying the responsibilities under the draft legislation, such as the definition of AI systems and Chapter II requirements. **However, 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 a high level of protection afforded to 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 contradictory 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 and additional issues brought to the proposed legislation by the Council of the EU. 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

1.1. Natural or legal persons considered as a provider of new high-risk AI systems - Recital 54a

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.

MedTech Europe recommends, to reflect changes made by Recital 54a, analysing the alignment with sectoral legislation and explicitly refer to the provisions in which particular legislation (either MDR/IVDR or AI Act) takes priority over the other.

1.2. Notifying authorities - Article 30 (1)

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.

MedTech Europe recommends the addition of "where no such notifying authority exists or where sufficient competence to carry out the requirements of this Regulation cannot be met by existing notifying authorities." in the end of Article 30 (1).

1.3. Requirements relating to notified bodies - Article 33 (9)

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.

MedTech Europe recommends the addition of "For notified bodies designated under and carrying out tasks under Union harmonisation legislation listed in Annex II, Section A, of this Regulation, a specific code shall be designated for the evaluation of AI and specific criteria should be given to evaluate their competence to assess adherence to the requirements of this Act." in the end of Article 33 (9)

1.4. Conformity assessment – Article 43 (3) and Article 33a

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 recommends that the split for AI part evaluated by an AI notified body and the medical device part by an MDR/IVDR notified body should be avoided. This is to ensure that the special characteristic of medical devices and the general safety and performance requirements of a medical device are considered during the AI assessment, for which the non-MDR/IVDR-accredited notified body does not have the respective expertise. This is also in line with Team NBs latest position on the AI Act.

1.5. Designation of national competent authorities – Article 59 (1) and (7)

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.

MedTech Europe recommends that National competent authorities shall be established or designated by each Member State for the purpose of ensuring the application and implementation of this Regulation. For the purpose of establishing a central point of communication for incident reporting, market surveillance authorities shall be those designated under sectoral legislation listed in Annex II. National competent authorities shall be organised so as to safeguard the objectivity and impartiality of their activities and tasks.

1.6. Post-market monitoring by providers and post-market monitoring plan for high-risk AI systems - Article 61 (3) and (4)

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.

Additionally, the sectoral legislation contains detailed post-market surveillance requirements, which will, most likely not be met by this template. Therefore, the co-legislators should leave it up to companies' discretion to decide how to organise documentation to ensure it can meet the requirements of overlapping legislations.

MedTech Europe recommends the replacement of

- "a template for the post-market monitoring plan" with "[...] provisions establishing the list of elements to be included in the post-market monitoring plan in Article 61 (3).
- "Provided that the template referred to in paragraph 3 is used" with "provided that the list of elements is included in the plan referred to in paragraph 3" in Article 61 (4)

II. Definitions and scope

2.1. AI systems and removal of Annex I – Article 3 (1) and Article 4

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.

MedTech Europe recommends the deletion of Annex I and the last sentence of recital 6a and 6b as all the examples often use rules defined solely by natural persons to automatically execute operations;

2.2. Missing definition of risk and harm

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.

MedTech Europe recommends the insertion of a definition for risk and harm, whereby 'risk' refers to 'the combination of the probability of occurrence of a harm and the severity of that harm' and 'harms' refers to (a) the death of a person or serious damage to a person's health (b) a serious and irreversible disruption of the management and operation of critical infrastructure (c) serious damage to property or the environment.

2.3. Definition of provider – Article 3 (2)

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 recommends that the AI Act were to align with terminology used in the New Legislative Framework by using the term 'manufacturer'.

2.4. Inconsistent use of the concept of life cycle and lifetime – Recital 1a, Article 61 (2) and Article 12 (1)

While the General Approach introduces a definition on 'life cycle of an AI system' (Article 3 (1a)) MedTech Europe observed that this term is being used interchangeably with 'lifetime'. The differentiation of these two concepts is important as lifetime could refer to only a product post-market, whereas life cycle refers to its entirety, including design and development. The change can be observed in Article 61(2) and Article 12 (1).

MedTech Europe recommends that legislators to take mindful consideration for the two different concepts. As both terms are currently used within the AI Act, to avoid ambiguity, both should be clearly defined.

2.5. Scope – Article 2 (3)

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 recommends that the scope of the AI Act should:

- be more explicit, particularly as to what activities fall outside the Union law which they are referring to.
- address the interplay with New Legislative Framework legislation covered under Annex II, Section A, to avoid any duplication of requirements and obligations.

III. Chapter II requirements for high-risk AI

3.1. Compliance with the requirements – Article 8 (1) and Recital 63

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.

MedTech Europe recommends aligning the language of Article 8 (1) to reflect the commitment made in Recital 63. Therefore, the following sentence should be added at the end of Article 8 (1): "With regard to high-risk AI systems related to products covered by Regulations 745/2017 and 746/2017 on medical devices, the applicability of the requirements should be without prejudice and take into account the risk management logic and benefit-risk assessment performed under the medical device framework."

3.2. Risk management system – Article 9 (2) and (4c)

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.

The case of reducing the risk of a heart defibrillator to not cause burn wounds would require the voltage to be reduced to such an extent that the device becomes ineffective for its intended purpose.

MedTech Europe recommends replacing:

- "Requiring regular systematic updating" with "requiring the review of the suitability of the risk management process at planned intervals to ensure continuing effectiveness of the risk management process".
- "Technical information" with "information to users" (see Article 13).

MedTech Europe recommends adding:

- new paragraph to Article 9 (4) "For medical devices in scope of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 the requirement to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio."

3.3. Data and data governance – Article 10 (2 - 4)

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 recommends amending:

- Article 10 (2) as followed: **Data collection**, training, **development** ~~validation~~ and testing shall be subject to appropriate data governance and management practices. Those practices shall concern in particular **and if applicable:**
- Article 10 (3) as followed: training, **development** ~~validation~~ and testing data sets shall be **sufficiently** relevant, […]
- Article 10 (4) as followed: "and to the best extent possible free of errors and complete **in line with the intended purpose of the AI system**."

3.4. Technical documentation - Annex IV

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 recommends:

- refining the requirements that do not or are unlikely to serve that goal as it risks creating excessive bureaucracy, and consider what might be overlooked, but is still necessary to assess safety/performance/compliance.
- ensuring that concepts and terms are correctly used and match software practices. The way some terms are alien to software development or the way they are organised will force administrative practices that are not logical for software developers.

3.5. Human oversight – Article 14 (1)

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.

Consider an AI-based robot for eye surgery. The doctor and patient will have the ability to decide whether or not to use the robot for eye surgery, but once the robot is in use, it may be extremely hard or impossible to have effective human oversight during the actual use of the robot. The doctor may need to be taken out of the loop because of the doctor' limited decision-making capacity, limited situational awareness and sensing uncertainties (for a discussion on the role and limitations of AI in eye surgery[1].

MedTech Europe recommends the deletion of "during the period in which the AI system is in use" to avoid misinterpretation which consequently could result in withholding medical technologies from the EU market solely since no natural person can effectively oversee for example, robotic surgery, while the robot is in use.

IV. Additional issues

4.1. Prohibited artificial intelligence practices – Article 5 (1a and 1b)

MedTech Europe notes that while an exemption is made for medical applications through Recital 16, but this is not reflected in Article 5.

An exception for manipulative techniques if used for specific medical purposes needs to be ensured, such as cognitive behavioural restructuring to treat people with post-traumatic stress disorder (PTSD), sleep disorders and other diseases and conditions, as those are likely to cause harm due to withdrawal symptoms.

MedTech Europe recommends including a new subparagraph (Article 5 (1a)) that explicitly refers to the AI systems for specific medical purpose: "By way of derogation from Article 5 (1a and 1b), said prohibitions do not apply to AI systems for specific medical purposes as defined in Article 2 (1) of Regulation (EU) 2017/745 or AI systems solely or principally for the purpose of providing information as defined in Article 2(2) of Regulation (EC) 2017/746."

[1] Urias, M.G., Patel, N., He, C. et al. Artificial intelligence, robotics and eye surgery: are we overfitted? Int J Retin Vitr 5, 52 (2019))

4.2. Cooperation with competent authorities – Article 23

Providers of high-risk AI systems shall provide a national competent authority with all the information and documentation necessary to demonstrate conformity of the AI-system 'in a language which can be easily understood by the authority of the Member State concerned'. This is a very burdensome requirements as this is not limited to official community languages.

MedTech Europe recommends limiting this to 'in an official community language which can be easily understood by the authority of the Member State concerned'.

4.3. Market surveillance and control of AI systems in the Union market - Article 63 (8)

MedTech Europe believes that testing data sets should be sufficient to test for bias, especially as testing data sets cover more sources of bias than only those caused by training data. As it is currently written in Article 63 (8) the requirements will force providers to put contracts in place with their data custodians when the provider does not have the data in its possession. Giving full access to training sets used by providers is problematic as it would force providers to store training / validation data where they may not have direct access to that training / validation data or where there is no good reason for them to store the data other than to meet this requirement.

MedTech Europe recommends the addition of "Providers must provide access to training and validation datasets to the extent that the datasets are in their possession, and it is permitted under copyright provisions and third country legislation"

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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