MedTech Europe response to the inception impact assessment on the Proposal for a legal act with requirements for Artificial Intelligence

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Preface

This document is in response to the public consultation on the roadmap for artificial intelligence ("AI") by DG CNECT, Unit A2, and addresses directly the Inception impact assessment document Ares(2020)3896535 for the Proposal for a legal act of the European Parliament and the Council laying down requirements for Artificial Intelligence. MedTech Europe recently provided input to the public consultation on the White paper on AI and we have been following with keen interest the developments in the area of Sectoral Considerations for AI by the HLEG AI (we participated as an expert in the Healthcare focused workshops, organised by the group), as well as the work on the Liability implications of AI). We appreciate the opportunity to provide input to this conversation as well, bringing our specific healthcare expertise and perspective, and are open to answer any questions.

In this document we:

1) Outline the specificities of AI in medical technologies & relevant existing sectoral legislation;
2) Give some background on the risk management in medtech;
3) Discuss the possible scope of the legal initiative;
4) Provide our opinion on the pros and cons of the different policy options suggested in the impact assessment from a medical technology perspective;
5) Offer a conclusion.

1. Introduction & setting the scene

We understand that through the above-mentioned legislative initiative, the European Commission will aim to address a number of ethical and legal issues raised by AI, with the objective to foster the development and uptake of safe and lawful AI and to avoid fragmented regulations in the Member States. MedTech Europe greatly supports and welcomes these goals, which are essential in the healthcare area and more specifically in medical technologies.

The medical technology (medtech) industry is fully supportive of the need for its medical technologies utilising AI to be subject to an appropriate level of supervision, oversight and regulation. We agree that European citizens need to be confident that their medical technologies, with or without an AI component, provide a high level of safety and quality for patients. It is precisely for this reason that the Medical Device Regulation (EU) 2017/745 ("MDR") and In vitro diagnostics Regulation (EU) 2017/746 ("IVDR") provide a high level of protection of health for patients and users, whilst considering the small- and medium-sized enterprises that represent most part of the industry. At the same time, the regulations set high standards of quality and safety

for medical technologies in order to meet common safety requirements for such products. Both objectives are being pursued simultaneously and are inseparably linked, with one not being secondary to the other.

AI in medical technologies

Medical technologies ("medtech") cover any products, services or solutions used to save and improve people's lives and which can be used in a care setting, ranging from disposables, diagnostics, capital equipment and surgical innovations, to implant technology, biomaterials, sensors, 3D printing, regenerative medicine and connected health IT such as eHealth, mHealth, human genome decoding, disease prediction, biobanks, biomarkers, and many more.

The medtech industry has long-standing experience with operating in a highly regulated environment, including stringent self-regulation, in a field dealing with safety- and quality-critical application domains and with exposure to highly sensitive data. The core goal of AI technology in medtech is to save and improve people's lives. Therefore, safety, quality and ethical requirements (for example, as prescribed by the HLEG AI) are addressed throughout the development, deployment and life cycle of AI-supported medical technologies.

For more details on how the medtech sector addresses those requirements (privacy and data governance, diversity, societal well-being, accountability, human oversight, transparency, technical robustness and safety), please refer to our detailed response of November 2019 to the pilot on the Trustworthy AI assessment list, "Trustworthy Artificial Intelligence (AI) in healthcare".

Software as a medical device

In most cases in healthcare, AI is a tool and methodology used in the development and functioning of other healthcare products, and not a separate entity of its own. As such, several policies, principles and regulatory frameworks currently applying for medical device software also apply for AI (with an intended medical purpose).

Software with an intended medical purpose is already subject to strict existing regulations. Whether an artificial intelligence (AI) solution is embedded in a medical device or is a self-standing medical device software, it would be covered by the medtech sectoral regulations, i.e. MDR and IVDR. These regulations trigger considerably stricter legal requirements and liabilities than software without a medical purpose, as the manufacturer must thoroughly substantiate that the software is safe, performs as intended, and delivers a clinical benefit.

Safety & performance certification of medical devices (CE marking)

The principle behind MDR and IVDR is to ensure device performance and patient and user safety, by requiring that the manufacturer demonstrates this to regulatory authorities through the EU CE marking process. Therefore, all software with an intended medical purpose will have already gone through a rigorous

certification system before being placed on the EU market (regardless of whether it includes AI or not), which includes addressing safety and reliability as part of the design. Monitoring of safety and quality continue when a product is on the market, through broad post market surveillance and vigilance obligations.

As such and as previously explained, we believe that, for our specific sector, existing laws and regulations sufficiently cover the identified risks of AI with an intended medical purpose. Therefore, we support the suggested approach to exclude specifically regulated sectors from the scope of a new AI-specific legislation, in particular in view of avoiding conflicts between the various AI-relevant regulations as well as excessive barriers for the development of AI-supported medical technologies.

Managing risks and addressing liability in AI in medtech

The medtech sector is already regulated through a system which has its foundations in the identification of risk profiles and the management of risk, and which also builds on the Product Liability Directive's liability regime (Art 10.16). Many requirements that the EU Commission has rightfully identified as being relevant for AI are already included in the MDR/IVDR (such as ensuring the safety and the performance of AI that constitutes a medical device or IVD), and as such these requirements are already taken into account in the development and design of the product, via defined requirements regarding processes, evidence collection, and risk/benefit assessment and security assessments. In any case, the manufacturer will need to comply with a proper risk management framework, which includes striking a balance between benefit and risk.

It is also important that any new proposal takes in due consideration existing liability rules applicable for medtech manufacturers (i.e. manufacturing defects; design defects; warning defects). In case of any material gaps identified, any "new" AI-related liability risks (including liability of healthcare professionals) need to consider and build on existing rules.

Additional elements to consider when drafting the future policy approach towards AI in medtech:

- **Legal certainty for businesses**: it is essential to consider existing sectoral legislation, in order to avoid creating legal uncertainty for businesses resulting from incoherence and overlaps, which would impede the development and adoption of AI solutions in healthcare.
- **Engagement with relevant sectoral authorities:** when it comes to governance, it will be essential that the guidance and enforcement of MDR/IVDR on AI systems, which comprise medical devices or IVDs, rely on sectoral regulatory authorities and bodies (i.e. MDCG, Notified Bodies) which are best positioned to assess risk and potential management strategies, based on their expertise in the healthcare sector.
- **Alignment with international instruments**: there are various relevant standards, principles & codes of conduct at international level (EU & non-EU). It will be important to map and align with those to decrease international fragmentation, to support the goal of the EU Digital Single Market harmonisation and to advance EU competitiveness on the global scene.

2. Considerations on risk management in medtech

In addition to the above, given the risks identified by the European Commission in the inception impact assessment, the medtech industry would like to comment on how these risks are managed under applicable regulations in the medtech sector.

- **Safety:** Medical device software, including AI with an intended medical purpose, must fulfil the General Safety and Performance Requirements (Annex I) of the MDR and IVDR, which means implementing a design only after the risks have been reduced as far as possible.

- **Traceability, documentation and transparency**: In the medtech sector, traceability and transparency are assured through detailed technical documentation and retention obligations, and through labelling obligations. Device design and manufacturing processes are each subject to detailed technical documentation requirements under quality management systems which allow the design stages applied to an individual device to be understood and all sites and suppliers or subcontractors to be identified. This detailed documentation, which must be retained for a specified time after the lifetime of the device model, must include the manufacturer's risk management plan to reduce risks as far as possible; a benefit-risk analysis for the product; the risk management solutions adopted to design, manufacture, monitor and manage risk throughout the Total Product's Lifecycle (TPLC); the validation and verification testing conducted and the pre-clinical and clinical trial data including in particular data for any software verification and validation as well as data on performance and safety in clinical use. Over time the post-market clinical-follow-up, safety and performance data (including periodic safety update reports) for the device are added to the technical documentation so safety and performance of the device are monitored over the lifetime of the device. In addition, transparency and documentation is also ensured by manufacturers via compliance with the GDPR and in particular the accountability principle laid out in Article 5.2 of GDPR, providing that a data controller "must be able to demonstrate compliance with paragraph 1 [the other data protection principles]. This includes the principle that personal data are processed in a transparent manner in relation to the data subject."

- **Usability:** The inception impact assessment references the black box nature of AI and suggests potential risks related to interpretability. All medical devices and IVDs, including medical device software leveraging AI, must undergo usability/human factors testing, and IEC 62366 is the reference standard that addresses usability testing in medtech. Such usability assessments directly address the challenges of interpretability with respect to device risk and overall safety.

  The mandatory processes of clinical or performance evaluation and risk management require that the performance of the AI is understood and validated, in order for the AI to be approved for use as a medical device, which limits black box risks.

- **Risk Management:** A key consideration for any AI-based product is appropriate risk management both before and after product launch. For AI solutions with an intended medical purpose, the MDR

and IVDR regulate the AI solution, mandating both pre-market and post-market risk management requirements, and ISO 14971 is the reference standard that developers typically follow for risk management. In addition, specific standards for risk management in the design process apply, such as IEC 62304.

- **Post-market Surveillance:** The inception impact assessment specifically calls out risks related to post-market surveillance, but the MDR/IVDR already include specific and quite far reaching obligations in that regard, such as developing a post-market surveillance plan appropriate for the type of device, which includes post-market clinical evaluation reports, periodic safety update reports, and post-market surveillance reports.

- **Privacy:** Medical device software must conform to GDPR requirements, and these requirements are equally applicable to AI-based medical device software. Medtech companies should consider including a GDPR Data Protection Impact Assessment as part of both the design iteration and risk management-driven (re)design cycles. In addition, the GDPR prescribes implementation of privacy and security by design.

- **Cybersecurity:** The MDR and IVDR General Safety and Performance Requirements include medical device software security requirements, and EU guidance related to medical device cybersecurity already exists (for example, MDCG 2019-16 - Guidance on Cybersecurity for medical devices). Data protection-driven security is part of quality management software (QMS) processes. These requirements, guidances, and frameworks are equally applicable to AI-based medical device software, and there is no need to create specific frameworks for AI-based medical device software.

- **Change Management:** The inception impact assessment states as a risk that "…such legislation focuses on safety risks present at the time of placing the product on the market and presupposes 'static' products, while AI systems can evolve." Medical technologies, including medical device software and "AI with an intended medical purpose", are subject to change management requirements, as described, for example, in MDR/IVDR Annex VII.4.9. Therefore, manufacturers of such products are already required to assess the impact that changes can have on device safety and effectiveness, and they must have the related processes in place. This also applies to continuous learning AI-based medical device software products. Manufacturers must work with their Notified Bodies to develop processes related to change initiation, assessment, and commercialisation. While we believe guidance related to approaches to change management of AI-based medical device software would be beneficial to industry and regulators alike, this should be managed under existing regulatory frameworks, specifically, the MDR and IVDR.

3. Scope of the European Commission's legislative initiative on AI

As suggested above and in previous consultations, MedTech Europe supports the idea that, while assessing the need for new legislation specific to AI, the application of existing regulations on AI should be taken into

account to understand whether any gaps exist, to avoid overlap and conflicting regulations that could cause issues when AI is introduced.

As explained above, in the medtech sector, the safety and effectiveness of medical device software, including "AI with an intended medical purpose", is already addressed through existing, recently reinforced, regulations, i.e. MDR and IVDR. Further, data protection, security and privacy considerations related to such software are already addressed through GDPR. We believe these laws and regulations provide adequate requirements, and therefore the scope of any proposed AI legislative initiative should not include safety, effectiveness, nor privacy considerations related to AI-based medical device software.

Similarly, we would advise caution when considering introducing new generally applicable AI-specific legislation, in particular in view of the risk of creating conflicts between the various AI-relevant regulations, and of the need to avoid creating additional barriers for the development of AI-supported medical technologies. In addition, any such legislation should focus on providing definitions and guidance criteria for risk assessment on AI, and, where necessary, could be further developed and adapted per sector or area of application. Should such legislation be considered necessary in view of identified gaps, MedTech Europe suggests an approach to any new regulation to be based on the intended use of the technologies and not on the technology that drives them.

In the highly regulated medtech sector, guidance that provides interpretation and describes novel approaches to (existing) requirements fulfilment may promote more development efforts and enable developers to more readily navigate the challenging EU regulatory environment for medtech. An example of additional guidance in the medtech sector which may be helpful is in the field of documentation. While the performance of healthcare products incorporating AI can often be described with traditional indicators, and existing guidance comprehensively assesses the safety and performance of AI systems, further guidance governing the validation and/or approval of such products may be helpful to support authorities' assessment and harmonising requirements for manufacturers, particularly with unique AI features such as continuous learning. Such guidance would further the common understanding, transparency and trust of all stakeholders.

Finally, for any legislative initiative on AI to be effective, we believe that the term 'high risk AI' should be defined as narrowly as possible in view of the risk of overlap and incoherence with existing regulatory frameworks that also include risk classification (Annex VIII of MDR, Annex VIII of IVDR).

4. Policy options

The medical technology industry would like to re-iterate its support for EC's efforts to promote and drive the adoption of driving AI in Europe. More widespread deployment of AI in particular in healthcare will benefit European citizens, patients, and healthcare professionals, and advance the sustainability of Europe's healthcare systems. It will also further the competitiveness of EU industry by requiring AI design and deployment against state of the art standards.

In this section, we would like to outline further our views about the different policy options listed in the Inception Impact Assessment. Considerations are focused on our specific sector even though any additional legislation should only be considered if there is a clear gap, in which case, such gaps should be addressed as much as possible as part of existing regulations to ensure consistency (e.g. General Product Safety Directive (GPSD)).

Option 0 (baseline scenario)

Generally speaking, given the existing regulatory framework for "AI with an intended medical purpose" under the EU MDR and IVDR, there may be no need for any specific AI legislative initiative unless the sector-specific gap assessment would reveal a material risk or gap that is not sufficiently addressed by the current (and upcoming) MDR and IVDR frameworks.

Option 1

MedTech Europe supports many of the principles described in Option 1. Specifically, we support industry-led coordination of AI principles specific to medtech and propose that such principles are described within guidance rather than “soft law.”

As outlined earlier, the medtech sector is already heavily regulated, and this sector includes AI with an intended medical purpose. Where appropriate, guidance can be used to further common understanding of these requirements in the context of AI with an intended medical purpose and/or develop approaches applicable to AI-based medical device technologies under the existing regulatory frameworks.

As a ‘hybrid approach’, option 1 can be used to address part of the need for a ‘legislative initiative’. As an example, “soft law”, such as guidance or industry-led guidelines, may be useful to streamline the regulatory processes (especially when technology is fast moving). Another area where MedTech Europe sees value in developing guidance is on liability. While we believe that the Product Liability Directive (PLD) provides the right liability framework for medical technologies, developing guidance – in relation to specific deployment scenarios, AI technology concerned (e.g. self-learning and self-adapting) and applications – could clarify certain issues under the Directive such as the roles and responsibilities of parties in an AI value chain including user and end-user, e.g. by developing case studies. This could include e.g. whether the producer of a product will typically be the same entity as the one that is responsible for the safety of the product under other legislation (e.g. Medical Device Regulation (MDR) or in vitro diagnostic medical devices regulation (IVDR)); whether the producer of a product can be held liable where that product is defective (i.e. does not present the level of safety which consumers are entitled to expect) as a result of a failure in its software, including in respect of cyber-risks; etc.

This option may not, at first sight, be considered by some stakeholders as sufficient to ensure citizens’ trust. However, to the extent that AI in medtech is strictly regulated under the MDR and IVDR in terms of safety and the CE-mark is the European symbol of safe and high-quality products, this strengthens patients’ trust in the digital development while at the same time enabling innovative and competitive businesses in Europe.

Option 2

The medtech industry advises caution towards an approach as per Option 2, which may lead to confusion and incoherence in those sectors, such as ours, where there are already compulsory labelling requirements, such as MDR and IVDR's CE marking. Such labelling demonstrate conformity with a number of key requirements which are essential for the safe and proper use of the device, including those related to safety, performance, security, etc. Moreover, it is important to underline that labelling can be a significant cost for companies, especially for items that need frequent/regular labelling changes.

Option 3

As indicated above, in sectors where, as opposed to medtech, comprehensive sectoral regulation does not exist and therefore cannot mitigate material AI related risks, it may be appropriate for the European Commission to consider AI regulation for (to be defined) high risk AI applications.

That said, as noted previously, the medtech industry is already sufficiently regulated and governed by mandatory requirements, and MDR/IVDR address the need to safeguard patient safety in view of technological progress. Both regulations address risk classes and as such an AI solution in the scope of these regulations may in principle fall in any of the risk categories (low to high).

It is important that any new horizontal AI regulation explicitly excludes medical technologies regulated by MDR or IVDR, to avoid overlap or otherwise conflict with existing rules designed to evaluate the safety and effectiveness of life saving technology in a timely manner. We expect that if such explicit exclusion is not made, horizontal regulation could slow down patient access to AI technology with a medical purpose, as existing design and approval processes may be negatively impacted (also due to potential conflicts with medtech regulation), and/or sector-specific issues that are not appropriately regulated by the medtech regulation remain unaddressed as they will not have been individually identified and commented on by affected stakeholders.

Our concern is that while the EC recognised that EU legislation may class "risks" differently, it is unclear how to reconcile these classifications and thus, any additional legislation based on risk could duplicate or conflict with existing vertical regulatory requirements. In addition, should such new legislation include medtech, it may impact business decisions to invest in AI with an intended medical purpose.

Option 4

Option 4 was described to a lesser extent in the Inception Impact Assessment document. As such, this option may have strong benefits, if explained to mean that any legislative initiative on AI fully takes into account the

specialised strengths and knowledge of the sector-specific regulators for the medtech and IVD industry, and therefore:

- Focusing on Options 0 and 1 to further address AI 'with an intended medical purpose' under the MDR/IVDR frameworks;
- As appropriate, consider also options 2 and 3 for high risk AI that is not covered by MDR/IVDR.

5. Conclusion

In order to take full advantage of the impact and benefits of AI in the healthcare sector for patients, healthcare professionals and healthcare systems, policies need to remain flexible and follow the evolution of technological development, allowing space for innovation both within big and smaller companies.

With the MDR and IVDR we already have a strict regulatory framework in place. Industry believes that guidance that would provide interpretation and describe novel approaches to meet the requirements fulfilment may promote innovation and competitiveness, and enable developers to more readily navigate the challenging European medical technology regulatory environment.

Citizen's trust would help increase the adoption and use of these technologies in healthcare. There will be many factors driving that trust, one of them being the transparency and explainability of the purpose, use, benefits and limitations of AI systems. For example, a well-trained healthcare workforce on AI would help increase that understanding and build trust, in particular in the medtech field where the primary user is the healthcare professional.

We look forward to the impact assessment, which will follow after the inception impact assessment.

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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