The European Association
Medical Devices - Notified Bodies

Team-NB Position Paper

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European Artificial Intelligence Regulation

Background

The European Commission has published their proposal for a regulation that covers many aspects of AI (Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL LAYING DOWN HARMONISED RULES ON ARTIFICIAL INTELLIGENCE (ARTIFICIAL INTELLIGENCE ACT) AND AMENDING CERTAIN UNION LEGISLATIVE ACTS COM/2021/206 final) in April 2021. The draft Artificial Intelligence Act (AIA) is a horizontal regulation implementing a risk-based approach to identify the level of control on AI Systems being placed on the European market. The members of the Team NB, the EU association for Notified Bodies for medical devices and IVDs publish this position-paper with the intention to express their opinion and concerns regarding the upcoming regulations, with a focus on the interface and overlap between the upcoming regulations and the Medical Device Regulation (MDR) and IVD Regulation (IVDR).

Definitions

Article 3(1): 'artificial intelligence system' (AI system) means software that is developed with one or more of the techniques and approaches listed in Annex I and can, for a given set of human-defined objectives, generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with

Annex I:

(a) Machine learning approaches, including supervised, unsupervised and reinforcement learning, using a wide variety of methods including deep learning;
(b) Logic- and knowledge-based approaches, including knowledge representation, inductive (logic) programming, knowledge bases, inference and deductive engines, (symbolic) reasoning and expert systems;
(c) Statistical approaches, Bayesian estimation, search and optimization methods.

Team NB Opinion:

The definition used includes terms related to logic and knowledge-based systems. This is an overly broad definition such that it could potentially include non-AI systems leading to confusion for the regulators, manufacturers and notified bodies. Since the goal of standardization is to provide harmonized definitions of technologies for the purpose of exchanges between relevant stakeholders, we recommend to use the definition found in the international standard "*ISO/IEC 2382:2015, Information technology – Vocabulary*".

Medical devices under Artificial Intelligence Act

A medical device, including *Software As a Medical Device* or *software embedded in a medical device*, that incorporates AI is considered to be a high-risk AI system and falls under the scope of the AI regulation. To ensure the safety and security of a medical device incorporating AI a

robust regulatory framework considering the special characteristics of AI and state of the art is essential.

Team NB Opinion:

1. The current safety requirements are covered under the New Legislative Framework, addressing sector specific requirements. For instance, the medical device requirements are covered under MDR. In regard to the AI regulation, it is important to address the enforcement under the existing NLF Framework to first avoid *de-fragmentation* and secondly to avoid *work duplication*, both of which serve to increase the costs, and impair the implementation efficiency.
2. During the transition to the day of publication in the official journal notified bodies will conduct assessment of high-risk products considering the state of the art. We recommend to adapt harmonized standards or common specifications to ensure that the notified bodies are able to implement a fair and a transparent conformity assessment process.
3. We recommend developing Industry specific guidance for implementation of the AI regulation together with existing NLF framework addressing risk category, state of the art, testing & assessment requirements
4. Under Article 10 "Data and data governance" the use of *error-free* and complete data for the training, validation and testing is required. It is recommended to use "sufficiently justified accurate complete data", as real-world data-sets are in most cases intrinsically of limited precision and not error free.

Reporting and Vigilance

The AIA requires the implementation of a vigilance reporting procedure to ensure timely communication of incidents to regulators.

Team NB Opinion:

Multiple reporting channels and lines of communication to authorities should be avoided. The current, well established vigilance reporting mechanisms prescribed in the MDR[1] and IVDR, which is now incorporated into the enacting provisions, should be used instead of developing a parallel approach

Conformity Assessment procedure

The AIA specifies a Notified Body conformity assessment procedure for AI Systems, that is similar to the e.g. Medical Device Regulation conformity assessment procedure but having some additional requirements relating to quality management system and technical documentation assessments.

Team NB Opinion:

1. Avoiding parallel documentation requirement is encouraged for the technical documentation, by providing a single set of technical documentation that covers both regulations MDR/IVDR and the AI regulations, as defined Tittle III, Chap. 2 Article 11 Paragraph 2.

[1] (Article 10, 33 and Chapter VII)

2. Attracting *technical experts (AI experts)* to build up the expertise necessary for the conformity assessment procedure is the *major challenge* for all stakeholders. This challenge applies on the same level to manufacturers, regulatory bodies as well as notified bodies. A strenuous effort necessary to build and attract those experts would need regulatory involvement. We recommend a European AI Initiative, as this challenge cannot be handled only on regional or organization level.

Accreditation

The notified bodies are required to be involved in the conformity assessment procedure according to the AIA. The current draft regulation leaves the question on the accreditation of the notified bodies being part of the procedure open.

Team NB Opinion:

1. A high level of technical and regulatory expertise is necessary for the notified bodies to be able to assess the technical documentation content of a medical AI system. This authorization requirement was already requested by regulators for notified bodies for medical devices and IVDs and implemented comprehensively for many different aspects of medical devices, such as software life cycle, single fault safety, biological safety and chemical safety. The notified bodies for medical devices and IVDs have already implemented an authorization procedure for the different aspects of a *medical device technical file assessment*. Additional accreditation of notified bodies against AIA would not bring more expertise, but just increase the administrative burden and by this reduce the already limited number of notified bodies and their capacity.
2. We suggest using the *existing authorization framework* for notified bodies to expand the designation scope covering AI related aspects under relevant NLF regulations. A notified body with a designation under MDR/IVDR, would in this case need to show competency for assessing AI related aspects.
3. A possibility to split the Medical AI System by having the *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-accredited notified body does not have the respective expertise.
4. Under Annex VII clause 4.4 and 4.5 include requirements for the notified body to perform additional testing to verify that the system is performing according to its intended purpose. Without a sufficient understanding of how a model works and generates predictions, it becomes very difficult to detect errors in a model's performance, to debug the cause of an error and to *test* its performance. For this reason, we recommend to ensure sufficient explainability for AI system that are intended for high-risk applications.