Johnson & Johnson's contribution to the public consultation on the Artificial Intelligence Act proposal

6 August 2021

AI Act: an opportunity to build trust and foster innovation

Johnson & Johnson welcomes the opportunity to build a trustworthy and innovative ecosystem for artificial intelligence (AI), where the AI Act (AIA) plays a critical role in combination with the existing regulatory framework. The AIA should have a **clear scope and framework, facilitating its implementation and avoiding complexity, in order to build trust** between citizens, developers, deployers and users and **create a favourable environment which fosters innovation**. The **international implications** of this regulation and cross-border regulatory cooperation are important to ensure EU citizens and businesses have access to beneficial AI solutions.

The AIA includes in its objectives addressing health-related AI systems, and aims to support parties in effectively managing risks and unlocking the potential benefits of using AI in healthcare. We support the current approach of focusing on healthcare applications that are covered under the Medical Devices Regulation (MDR) and In-Vitro Diagnostics Regulation (IVDR), such as Software as Medical Device (SaMD).

An efficient, harmonized and consistent regulatory framework working in conjunction with existing legislation on medical technologies and privacy

This proposal is joining a very robust regulatory framework which already addresses potential risks emerging from the development and use of AI in medical technologies. The **interplay of the new regulation with regulations such as the General Data Protection Regulation (GDPR), MDR and IVDR needs to be further clarified**.

Medical devices, including many aspects related to medical software, are comprehensively and clearly regulated under the EU MDR/IVDR, which pursue similar objectives as the AIA, i.e., ensuring a high level of protection of human health and avoiding a harmful impact on the health and safety of persons, and they already take into account the use of AI systems operating as "components of products". In order to achieve **legal certainty, we believe that those requirements (e.g., conformity assessment, database registration, Notified Bodies, etc.) already specified under the sectoral legislation, i.e., MDR/IVDR, should supersede AIA provisions**. Nevertheless, the AIA may help fill any potential gaps by giving a framework upon which the Medical Devices Coordination Group (MDCG) could develop further guidance for AI in medical technologies.

The scope of the regulation needs a clear definition of AI. As written, it could cover any software or statistical approach, leading to a lack of certainty regarding which products are within the scope of which obligations.

Taking into account the GDPR experience will be fundamental for a successful development of this regulation, as we observed how important objectives and well-intended architecture led to **fragmented interpretation and inconsistent implementation across Member States**. The role and flexibility given to Member States should not lead to divergence but rather to ensuring a more cohesive and harmonized interpretation, implementation and enforcement of the legislation. For

instance, we believe the deployment and outcomes of the regulatory sandboxes should also be aligned and leveraged at the EU level through the appropriate mechanisms (AI Board, MDCG) to avoid fragmentation across countries. Clarifying the role of the European Artificial Intelligence Board and empowering it compared to National Boards within the aligned regulations will help ensure consistent interpretation and implementation of the AIA. Sufficient expert and public oversight will be necessary, while protecting its independence to ensure and preserve public trust. Per the European Commission Proposal, Member States should be encouraged to set up a basic framework around complex liability cases such as injuries/accidents where it is challenging to track specific human decisions due to the gradually increasing autonomy of the AI technology.

The requirements in this regulation will demand considerable **effort and implementation time** by regulators and all relevant stakeholders, including multiple industries. Therefore, based on the experience of key pieces of the New Legislative Framework such as MDR/IVDR and the Machinery Directive, 24 months would not be enough for such implementation period and we urge consideration of a minimum of 36 months for implementation.

Finally, we also welcome the development of voluntary **codes of conduct for low-risk applications** where aspects such as transparency, explainability, human oversight, and monitoring could benefit from relevant guidance[1].

Striving for strong alignment with MDR/IVDR

Aligning the risk levels in the AIA proposal with those under MDR and IVDR will be fundamental to ensure legal certainty. While the AIA does not imply a change in classification under MDR/IVDR, the **denotation of AI systems as high-risk should not mislead or alter the original classification under MDR/IVDR**. There are also other important elements which require clarification or specification to **avoid a misalignment or duplication with MDR/IVDR**. We advocate for:

- **Alignment of submissions, assessments and CE markings,** particularly after the recent application of MDR/IVDR which establishes a rigorous framework on medical technologies.
- **Alignment of changes in AI systems and requirements for new submissions** with existing guidance for SaMD and internationally with other regulatory agencies, such as the United States Food and Drug Administration (FDA).
- **Consistent definitions with MDR/IVDR**. The definitions of safety and quality under MDR/IVDR take precedence, as they are intrinsically linked to the intended purpose and use. Definitions like "provider" (vs "manufacturer") or "serious incident" are also inconsistent with those under MDR/IVDR. The obligations for manufacturers and importers should also be clearly distinguished.
- **Clarify the role of Notified Bodies** regarding designation for AI competencies; time to designation and capacity; roles and responsibilities in conformity assessment; and implications for medical devices certified by them.
- **EUDAMED should be used as the database for medical devices and in vitro diagnostic devices**, without additional requirements. Unique Device Identification - device identifier (UDI-DI) (as required under MDR and IVDR) should be used as the system of traceability for issuing entities. Furthermore, the post market surveillance of these devices should be reported via EUDAMED, avoiding the addition of new reporting pathways or burden.

[1] For example, ALTAI (European Commission's High-Level Expert Group's Assessment List on Trustworthy Artificial Intelligence), OECD Principles on AI, and the WHO Guidance on *"Ethics and governance of artificial intelligence for health"*

AIA requirements: need for further guidance and legal certainty

Many aspects of the legislation, such as the requirements for good testing practices (Article 9), data governance (Article 10), technical solutions on cybersecurity (Article 15), criteria for non-confidentiality (Article 33), will require **further details addressed in guidance developed by relevant regulatory bodies, such as the Medical Devices Coordination Group.** This regulatory guidance will need cross-stakeholder input throughout and actual use cases and examples to bring more clarity and applicability to the guidance. For instance, data requirements seem to be developed for supervised models but unfit for unsupervised ones. Further clarity is also needed on how the statistical properties around bias shall be integrated, measured and monitored, how full transparency can be ensured, and which testing and security controls are to be implemented to address bias.

The **roles and responsibilities along the AI value chain**, including citizens, developers, manufacturers, deployers and users, must be clearly defined. The regulation can help ensure safety as a continuum by appropriately addressing the lifecycle management of AI systems, from development to deployment and use. However, the regulation does not specify proportionate and clear obligations for 3rd party providers, which would be needed in order to avoid placing unreasonable burden or unattainable obligations on AI providers.

Data Governance as core element to AI development

The establishment of clear standards of collection, storage, and handling of data will enable data to be shared, combined and used for the purposes of using AI applications safely for innovation. A balance between the **AIA requirement to use representative and relevant data for training and validation and the implications of GDPR for access to such data** is essential to ensure robust and representative AI solutions.

Implicit **links exist between privacy-by-design and security-by-design under the GDPR, and risk management under the MDR/IVDR**. The AI Act adds a new layer of regulation, which will make designing and deploying AI systems even more complex. A clear, transparent and efficient process for ensuring consistency and alignment across the overlapping remits of the MDR/IVDR, the AI Act, and GDPR requirements could position Europe in a leading role in fostering AI innovation.

We welcome the **proposal to address bias** (Article 10 (5)) by providing a legal basis under GDPR which would allow processing of certain types of personal data in high-risk applications. However, additional guidance will be needed on acceptable bias[2].

[2] Again see ALTAI (European Commission's High-Level Expert Group's Assessment List on Trustworthy Artificial Intelligence), OECD Principles on AI, and the WHO Guidance on *"Ethics and governance of artificial intelligence for health"*