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Input to the European Commission public consultation on the proposed 'Regulation laying down harmonized rules on artificial intelligence (AI Act)' by the Johner Institute

1. Preliminary remarks

First of all, we would like to thank the EU Commission for the opportunity to discuss and comment on this important proposal. The Johner Institute's mission is to help companies to develop safe medical devices and enable IT for better healthcare.

In our statement we not only included our experience, but also the feedback of 47 medtech companies from Germany and Austria. The entire feedback is tailored to medical devices only.

We welcome the EU Commission's undertaking to provide a harmonized AI regulation, as AI already is and will be even more in the future the technological basis for innovation and progression. However, in order to foster advancements, regulations need to be lean and precise as well as prevent over-regulation.

2. Feedback

Proposal AI-Act	**Comment**	**Recommendation**
The proposal not only includes machine learning as methods of artificial intelligence, but also: • Logic and knowledge-based concepts, including knowledge representation, inductive (logic) programming, knowledge bases, inference and	As a result of this broad definition many medical devices which contain software, could fall under the scope of the AI act, because every software-based decision tree would be considered an AI system.	The regulation should be restricted to machine learning methods only. Classic rule-based software, e.g. decision trees, should not fall under the scope of the regulation.

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deduction engines, (symbolic) reasoning and expert systems • Statistical approaches, Bayesian estimation, search and optimization methods		
The AI act requires cybersecurity, risk management, post-market-surveillance, a vigilance system, technical documentation, a QM system, etc. And the regulation addresses explicitly also medical and in-vitro devices.	This results in duplication of requirements. MDR and IVDR already demand cybersecurity, risk management, post-market-surveillance, a vigilance system, technical documentation, a QM system, etc. Manufacturers will have to prove compliance with two regulations. In addition, it should not be expected of manufacturers to check for any discrepancies, redundancies as well as tightening within the two regulations.	The regulation should either clarify that there are no additional requirements to MDR / IVDR related to risk management, cybersecurity usability engineering, vigilance and post-market surveillance or it should explicitly list these additional requirements. Terminology like "serious incident" should be synchronized with other regulations. The AI act could for example describe in an annex, which specific demands need to be fulfilled in addition to the MDR/IVDR.
The regulation applies regardless of what the AI is used for in the medical device.	Even an AI with which a low-wear operation of an engine is to be realized, would fall within the scope of the AI regulation. As a consequence, manufacturers will ponder if they will use the AI. This could have a negative impact on innovation but also on security and performance. As manufacturers usually implement AI to improve the security, performance and/or efficiency of their products.	Software as a medical device (class I* and higher) should not be considered a high-risk product per se. Rather, the AI act should follow its own reasoning and base this decision on the risk, specifically based on the AI and not based on the medical device which contains the AI. This decision should also be based on the actual risk and not only on the severity of potential harm. The EU has already made this mistake with the MDR rule 11

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	Otherwise they would not be allowed to apply the AI.	and has only inadequately addressed it with the MDCG document 2019-11.
Article 14 of the AI act states: High-risk AI systems shall be designed and developed in such a way, including with appropriate human-machine interface tools, that they can be effectively overseen by natural persons during the period in which the AI system is in use.	This requirement rules out the use of AI in situations in which humans can no longer react quickly enough. Yet it is precisely in these situations that the use of AI could be particularly helpful. If we have to put a person next to each device to "effectively supervise" the use of AI, that will mean the end of most AI-based products. It is possible that the regulation meant something else. But at least there is a risk of misinterpretation	A precise definition of the term "human oversight" has to be added. The AI regulation should not require that a natural person can intervene at any time and during any application. In addition, the duty to supervise should be risk-based. The requirement could be that the manufacturer needs to assess during the risk management if interference or oversight by a person is a suitable measure for risk control.
In article 3 (14) the regulation defines 'safety component' by using the not defined term 'safety function': 'safety component of a product or system' means a component of a product or of a system which fulfils a safety function for that product or system or the failure or malfunctioning of which endangers the health and safety of persons or property; Also, other terms' definitions are not in accordance with the MDR, e.g. "post-market	This will cause controversy about what is a safety function. It could be for example a feature that risks patients' safety, when it does not behave according to specifications. But it could also mean a feature that implements a risk reducing measure. Non-aligned definitions increase the effort required by manufacturers to understand and align the various concepts and associated requirements	The terms "function" and "safety functions" should be defined. In the process the definitions in the IEC 60601-1 and the ISO 14971 should be considered.

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monitoring" or "serious incident		
A device is considered a high-risk AI system, if the following two conditions are met (article 6): (a) the AI system is intended to be used as a safety component of a product, or is itself a product, covered by the Union harmonization legislation listed in Annex II; (b) the product whose safety component is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment with a view to the placing on the market or putting into service of that product pursuant to the Union harmonization legislation listed in Annex II.	Medical devices are covered by the regulations listed in Annex II, because the MDR and IVDR are mentioned. To fulfill the MDR, medical devices class IIa and higher must undergo a conformity assessment procedure. Does this mean all software as medical device using AI is considered to be a high-risk product? MDR rule 11 classifies software, independent of risk, in most cases in class IIa or higher. Thus, the extensive requirements for high-risk products would apply for medical devices. The negative effects of rule 11 would be amplified by the AI act.	Recital (31) states: The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the criteria established in the relevant Union harmonization legislation that applies to the product. This is notably the case for Regulation (EU) 2017/745 of the European Parliament and of the Council47 and Regulation (EU) 2017/746 of the European Parliament and of the Council48, where a third-party conformity assessment is provided for medium-risk and high-risk products. → This should be considered in the AI act
In article 10 the AI act requires „training, validation, and testing data sets shall be relevant, representative, free of errors and complete. "	Real-world data is rarely "free of error" and "complete". It is also unclear what "complete" means. Do all datasets need to be available (whatever this means) or is the complete data of one dataset required?	This requirement should be annulled. More suitable seems the requirement, that manufactures must define quality standards and verify their compliance. Another possible requirement could be the claim that the definition of the quality standards has to be risk-based. Further, definitions i.a. "correct" are needed.

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Article 64 (1) demands "Access to data and documentation in the context of their activities, the market surveillance authorities shall be granted full access to the training, validation and testing datasets used by the provider, including through application programming interfaces ('API') or other appropriate technical means and tools enabling remote access."	Making confidential patient data accessible via remote access conflicts with the legal requirement of data protection by design. Health data belongs to the particularly sensitive category of personal data. To develop and provide an external API in addition to the training data means high additional effort for the manufacturer. It is unrealistic that authorities will be able to download, analyze and assess the data or the AI respectively with reasonable effort and in a reasonable amount of time. For other, often even more critical, data and information related to the design and production of products (e.g., source code or CAD drawings), no one would seriously require manufacturers to give authorities remote access.	This requirement should be deleted without replacement. Access to data on site is already part of the conformity assessment procedures.
The regulation regularly mentions "validation", but means as a rule only the model validation of AI systems. This terminology appears multiple times in context with "training, validation and test data". Sometimes also "training, testing and validation processes" (recital 46), examination, test and	The manufacturers will have difficulties to differentiate between the different types of "validation". There is a validation in the context of testing the Ai model. There is the validation of medical devices and there is software validation. By not addressing product validation, the AI Regulation risks losing focus	The AI regulation should define the term "validation" and delimit this from the product validation. In addition, the AI act shall require that the target metrics (e.g. sensitivity) and their target values (e.g. 85%) are

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validation procedures (article 17) or development, testing and validation (article 53). In addition, article 9(6) states that "Testing procedures shall be suitable to achieve the intended purpose of the AI system and do not need to go beyond what is necessary to achieve that purpose." In article 9(5) it is mentioned that "High-risk AI systems shall be tested for the purposes of identifying the most appropriate risk management measures. Testing shall ensure that high-risk AI systems perform consistently for their intended purpose and they are in compliance with the requirements set out in this Chapter." And according to article 9(7) "Testing shall be made against preliminarily defined metrics and probabilistic thresholds that are appropriate to the intended purpose of the high-risk AI system." Article 17 (1b) requires "techniques, procedures and systematic actions to be used for the design, design control and design verification of the high-risk AI system;"	on the actual intended purpose and creating the misconception that validation of the AI system is sufficient.	comprehensively derived from the intended purpose.
The introduction talks about measures that, for AI systems, "adequately address both the	The unilateral focus on risk independent of the benefit will result in fewer products	The AI regulation should require that, like the MDR / IVDR in Annex I(1), "provided

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benefits and risks of AI at the Union level." Further, a well-balanced risk-benefit ratio plays an important role in the "HLEG AI" whitepaper. The AI regulation itself only considers the risk-side and does not allow any considerations towards the potential benefit of a system. Article 9(4a) requires a "elimination or reduction of risks as far as possible through adequate design and development;"	reaching the EU market, because the lowest risk is ostensibly achieved when there are no products. The statement "as far as possible" will lead to discussion, because an auditor could always require additional measures. This would increase the effort, without improving the risk-benefit-ratio.	that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient" The AI Regulation should also require that, like the MDR / IVDR (Annex I (2)) "The requirement (in this Annex) to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio."
Article 13 (3e) requires a description of "the expected lifetime of the high-risk AI system and any necessary maintenance and care measures to ensure the proper functioning of that AI system, including as regards software updates."	It is not clear how "lifetime" is defined. Software applications undergo regular modifications, if only to minimize cybersecurity risks. A continuous update of the model rather increases the security and performance.	The AI regulation should define the lifespan for software and data.
Article 28 (1) states that i.e. user "shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Article 16" if "(c) they make a substantial modification to the high-risk AI system."	The term "substantial modification" is not defined and thus probably not harmonized with the definition used in the MDCG documents. This will lead to uncertainties and more effort for users and manufacturers.	The AI act should define the term "substantial modification". Within the scope of intended use, "modifications" (e.g. further training) must be permitted by the users.

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3. Summary

a) EU's general approach

Additional regulation

While Dr. Jeff Shuren, director of FDA's Center for Devices and Radiological Health, fears that overregulation will cause the US to lose against China in the domain of digital health, the EU plans an additional extensive regulation.

Additional versus existing regulatory framework

The Johner Institute acknowledges the need for more specific guidance for manufacturers of AI based medical devices. Using the existing framework of EU medical device regulations, harmonized standards, common specifications and guidance documents such as by MDCG most probably would have been a less burdensome approach for medical device manufacturers.

Evidence and risk-based regulation

The proposed draft reveals the general considerations. But an evidence-based approach is not made obvious.

While the EU requires medical device manufacturers to provide evidence for risk and for benefits and to make sure that the benefits outweigh the risk, the EU does not provide this transparency.

The new regulation rather seems to follow — such as the MDR and IVDR — a notion that stronger regulation will lead to less risks. This, however, is not proven and this is only correct if one does not take into account

- the risks of lacking products (e.g. ignoring the benefits of these products) and
- the consequences for the European market such as the
    - competitiveness of European manufacturers,
    - innovative power in particular of smaller medical device manufacturers such as digital health startups,
    - dependency on Chinese imports (to cite Dr. Shuren).

It is a misapprehension to believe that the playing field already is leveled as manufacturers outside the EU have to stick to EU regulations for imported devices:

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The development of medical devices in Europe is so expensive (also due to existing regulations) that manufacturers have to market their products world-wide. Like in automotive industry, European manufacturers are rather dependent on their competitiveness in the Chinese market, than Chinese manufacturers are on the European market. If EU regulations are too restrictive, innovation and competitiveness of European manufacturers is constrained.

Target of the regulation

The AI regulation in particular targets manufacturers of AI based products such as medical devices. Any regulation is only as effective as its enforcement. Already previous and existing medical device regulations (MDD, IVDD, AIMD, MDR, IVDR) have proven that there is a lack of enforcement.

Many European authorities are unable to cope with the regulations due to a lack of resources, in particular highly trained experts and information technologies. Also notified bodies suffer from a lack of personnel and declare already now to be unable to deal with the demand for re-certifications due to the shift to MDR and IVDR.

As a result, additional regulation leads to additional bureaucracy, but not necessarily to devices that are superior with respect to safety, performance and clinical benefits.

b) Summary specific feedback

Scope

The scope of the KI regulation has to be narrowed down to

- algorithms that are not(!) hard coded by humans, in particular to machine learning methods,
- to medical devices with an AI that can harm patients (and not just to any device embedding AI).

On the other hand, the regulation should target the products and not just the KI components. Decisive for the safety, performance and clinical benefit of medical devices for patients are the devices, not just KI components that work as specified. Therefore, KI requirements have to be derived from the intended purpose, and the validation of products has to proof, that the intended purpose actually is achieved.

Classification

The classification into high-risk products, in particular for Software as a Medical Device (SaMD), should not be based on the MDR/IVDR classification (only), as this classification is not risk based.

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MDR's rule 11 only takes the severity of harm into account, not the probability. Hence, it is not a risk-based, as risk is defined as the combination of severity and probability of harm.

An approach aligned with IMDRF's concept for risk classification of SaMD seems to be more appropriate.

Conciseness and alignment

There is a lack of definitions as partially described in the table above such as:

- validation (several definitions required)
- safety function
- oversight by natural person
- data free of error
- complete data

Existing definitions and concepts (e.g. post-market surveillance, risk management, cybersecurity) are not aligned with relevant medical device regulations. This should be changed and complemented.

Least burdensome approach and power of Notified Bodies

The draft claims „to reduce the regulatory burden and to support Small and Medium-Sized Enterprises ('SMEs') and start-ups." It is unclear how the regulation lives up to this claim.

The medical device regulations (MDR and IVDR) allow manufacturers to assess the conformity itself (e.g. under the umbrella of a certified quality management system). Notified bodies „only" sample devices that are developed and produced within the scope of the respective certificate dependent on the class of these devices. Is the involvement of a Notified Body required for every medical device that contains AI? This would substantially increase the burden — also for SMEs.

It is also unclear how the requirement to develop and provide a remote API-access to training, validation and test data jars with GDPR's requirement of IT security by design and with a least burdensome approach.

c) Closing remarks

Next steps

The Johner Institute is dedicated to contribute to a next version of this AI regulation e.g. by

- Providing definitions

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- Proposing specific changes
- Aligning concepts (as described above)
- Compiling additional guidance such as gap analysis between medical device regulations and AI regulation

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About Johner Institute

The Johner Institute already supported several thousand medical device manufacturers, in particular manufacturers of devices that are or that contain software.

It compiled an AI checklist, that has been adapted and is applied by the German Notified Bodies. The Johner Institute drives the further development of this guideline at the WHO.

Notified Bodies, state and federal ministries as well as national authorities make use of Johner Institute's support. Its research team collects evidence for a more specific, efficient and effective regulation.

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