COMMENTS ON THE WHITE PAPER ON AI (EC)[1]

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Focus: A REGULATORY FRAMEWORK FOR HIGH-RISK HEALTHCARE AI APPLICATIONS

Key takeaways:

- EXTERNAL EX-ANTE CONFORMITY ASSESSMENT SHALL BE COMBINED WITH EX-POST CONTROL MECHANISMS

  Reasoning: in healthcare, the human stakes are particularly high. Controlling the performance and safety of relevant tools *by regulatory bodies before placing the tools in the market* prevents or at least minimizes the risks to the health and life of people concerned. *Ex-post control* is necessary because AI algorithms are not locked and constantly learn from real-world data.

- MEDICAL DEVICES FRAMEWORK SHALL BE APPLIED TO HEALTHCARE AI-APPLICATIONS SUBJECT TO SOME ADJUSTMENTS[3]

  Reasoning: the Medical Devices Framework[4] already includes general rules and procedures ensuring safety and performance of applied tools through prior conformity assessment by notified bodies and post-market surveillance.

- ADJUSTMENTS SHALL BE MADE TO ENSURE TRANSPARENCY OF AI HEALTHCARE APPLICATIONS

  Reasoning: the scope of the Medical Devices Framework is to ensure the safety and performance of medical devices rather than their transparency.

- TRANSPARENCY OF AI APPLICATIONS IS NOT THE SAME AS ITS EXPLAINABILITY

  Reasoning: explanations of algorithms and their outcomes are not always necessary and efficient. AI's opacity prevents a full explanation of its decisions in the way perceivable by users. **Transparency is a broad term and shall be viewed as access to information provided in a comprehensive manner that enables AI's users (such as healthcare providers) and beneficiaries (such as patients) to justify their actions and make decisions**.[5]

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[1] European Commission. WHITE PAPER On Artificial Intelligence - A European approach to excellence and trust. Brussels, 19.2.2020 COM(2020) 65 final. < https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf> accessed 13 June, 2020.

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The position expressed here is the individual position of Anastasiya Kiseleva and does not present the official position of affiliated organizations.

[3] For more details, see also section 'General remarks on the current regulatory framework applicable to AI-based healthcare applications'**.**

[4] In this paper the Medical Devices Framework includes the Medical Devices Regulation (EU) 2017/745 (MDR) and the In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

[5] A.Kiseleva, 'AI as a Medical Device: is it Enough to Ensure Performance Transparency and Accountability in Healthcare' (2020) European Pharmaceutical Law Review 1.

The analogy with prescribing medicines works well here. Physicians are not required to explain the chemical processes laid down in the production of medicines that they prescribe to patients. Instead, physicians are aware that the medicines were duly tested and certified. Also, doctors are provided with guidelines on when and how to prescribe the specific medicines. Based on that, they can make treatment decisions. In turn, patients are informed about the risks and consequences of taking prescribed medicines. *Thus, requirements for transparent AI shall be developed in the context of the current situation in a specific sector.*

- ONE OF THE MEASURES TO ACHIEVE AI'S TRANSPARENCY IS TO IMPROVE COOPERATION BETWEEN MANUFACTURERS AND USERS OF AI'S APPLICATIONS

  Reasoning: manufacturers of AI applications develop algorithms and choose data to train and validate them. Thus, they have all the information about the functioning of AI applications. It includes information about the development process, algorithmic parameters, training and validating datasets, level of accuracy achieved by AI. They also have an understanding of how developed applications shall be used in a real-world environment. In contrast, AI's users and beneficiaries do not always have the full picture.

  To make justified decisions AI's users and beneficiaries shall be provided with the necessary information. In a medical context, healthcare providers make decisions about using AI's outcomes for the medical treatment of a specific patient. They are also responsible for informing patients about the chosen treatment and its risks. It is necessary for respecting the patients' right to self-determination and be compliant with the requirement of informed consent. Although the AI-related information is in the hands of its manufacturers, there is no requirement to provide it to decision-makers – AI's users – who are also responsible for providing the information to patients.[6] The informational chain is broken. The relevant rules requiring manufacturers to provide information about AI applications to its users shall be developed. Following the suggested definition of AI's transparency, the information shall be provided to AI users in an accessible manner and in the scope necessary for them to make treatment decisions, justify their actions and provide information to patients.

- BETTER COOPERATION BETWEEN MANUFACTURERS AND USERS OF AI IS NEEDED FOR ITS SAFE USE AND EFFECTIVE POST-MARKET SURVEILLANCE

  Reasoning: while AI applications might change after its approval, cooperation between AI's manufacturers and its users is needed for safety. New data might change AI algorithms due to self-learning. After training AI application by the manufacture and placing it on the market, AI's users are the subjects that choose the data provided to AI. Thus, they influence on decisions made by AI and the outcomes of algorithms. Based on that, two adjustments to the current regulatory framework are suggested. First, *AI's users shall be provided with clear instructions on types, amount, quality, and other characteristics of data that is acceptable for a certified AI-based application*. Ultimately, this information should be provided by a manufacturer of a device as part of technical documentation at the stage of the market approval and/or by other means (training sessions, users' support). Second, the rights and obligations of AI's users for the post-market surveillance shall be established. Although the Medical Devices Framework sets the rules on providing periodic safety update reports by manufacturers to notified bodies[7] and establishes the regular audits of manufactures, the role of AI's users shall be reassessed. The rules for healthcare professionals' discovering and

[6] Although the Medical Devices Framework includes rules on public databases with the information about certified medical devices, the scope of this information is limited and does not enable healthcare providers to make informed decisions and justify their actions to patients.

[7] MDR, art 86.

reporting the issues of AI's use, as well as updating other related information, shall be specified. Possibly, the role of data specialists in healthcare organizations shall be intensified.

However, improving cooperation between manufacturers and users of AI-based medical devices does not mean allocation responsibility to users (healthcare providers) for non-conformity of the device with the Medical Devices Framework. Healthcare providers are responsible for their treatment decisions under medical malpractice regulations. While they do not control the process of a device's production, it is deemed unreasonable to make them accountable for errors in devices. Self-learning and the autonomy of algorithms also make it challenging. However, it does not exclude the accountability of healthcare providers for non-compliance with the rules on the use of AI devices (subject to providing them with these rules and with relevant information).

- PRIOR QUALITY AND SAFETY CERTIFICATION OF AI-APPLICATIONS IS ONE OF THE TOOLS TO INCREASE TRANSPARENCY

  Reasoning: when users of AI applications are guaranteed that the device went through authorization procedures, ensuring its safety and performance, they can partly justify their decisions based on that.

  The example of prescribing medicines explains this argument. Based on the information that medicine was duly tested and certified by competent authorities, physicians can make treatment decisions and justify their actions.

- BIASED AI'S DECISIONS ALERT ON INACCURACY OF ALGORITHMS

  Reasoning: AI can make unfair decisions caused by biases represented in data or algorithms. Whatever the reasons for a biased outcome, it always deviates from the expected and correct one concerning some groups of people. Thus, AI's unfairness always signals the possible inaccuracy of its decisions. While discrimination and stigmatization are difficult to identify and prove, especially for AI and especially for healthcare, the examination of AI's accuracy is an efficient tool to prevent and mitigate biases in AI systems. In turn, it can be achieved through controlling if the training of AI's device considers all the characteristics of its intended real-world use.

General remarks on the current regulatory framework for AI healthcare applications

Both the Medical Devices Regulation (EU) 2017/745 (MDR) and the In-vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR) are generally applicable to AI tools.[8] But, these Regulations do not cover all the AI applications used in the healthcare sector. For example, the AI system to make and manage appointments is outside of their scope. The intended purpose of the AI-based device determines the applicable legal regime. For example, if an AI-based device is intended to be used for medical purposes such as diagnosis or prediction of disease,[9] then the MDR is applicable.[10] The IVDR is applicable when an AI tool is planned to be used for genetic testing or other in vitro diagnosis.[11]

[8] This is true if AI is software. Although the White Paper on AI implies that (see p. 14 of the White Paper) it is recommended to explicitly state that in the general regulatory framework.

[9] For the full definition of medical device and what is deemed as medical purpose see the MDR, art 2(1).

[10] In fact, some AI-based devices have are already been authorized to be placed on the EU market as a medical devices. On October 28, 2019, the German start-up 'Merantix Healthare released the news that its AI-based application 'Vara' was certified to be placed on the EU market as a medical device. See here: 'Berliner Start-Up Erhдlt Zulassung zur Digitalen Auswertung von

The rules and procedures established in the Regulations are similar but not identical. This shall be taken into consideration while defining and improving the framework for AI healthcare applications. Between two Regulations, I argue that the IVDR is more tailored to AI characteristics and shall be taken as an initial framework. The reasoning is as follows:

1) The IVDR is more detailed concerning the control of software elements. It requires providing information about databases used as a basis for software decision-making, about software algorithms, and about evidence of the validation of the software, as it is used in the finished device.[12]
2) The IVDR is also more specified in demonstrating the analytical performance of the device, requiring to establish *trueness (bias), precision (repeatability and reproducibility), and accuracy (resulting from trueness and precision) of the IVD medical device*.[13] The Regulation is more detailed in demonstrating the clinical performance of devices requiring to show devices' 'diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.'[14]
3) The IVDR realizes the importance of the representability and reliability of clinical study data toward the circumstances of the normal use of the device.[15] Specifically, it requires providing 'information on the performance study population: specifications of the subjects, selection criteria, size of a performance study population, representability of a target population.'[16] All this is efficient to prevent and mitigate bias in data and thus to avoid unfair and inaccurate decisions made by an in-vitro diagnostic medical device. While AI is all about data, these rules are highly relevant to AI-based healthcare applications.

In summary, the IVDR is more detailed and more focused on data quality and relevance. Thus, the IVDR rules can be used as a good starting point for clarifying and implementing a regulatory framework for high-risk AI healthcare applications.

More information:

These comments are based on the author's article 'AI as a Medical Device: is it Enough to Ensure Performance Transparency and Accountability in Healthcare' published in the European Pharmaceutical Law Review, issue 1/2020 (the pre-published version is available at SSRN) and the article in progress on legal implications of biases in AI's clinical genetics. It is recommended to read the published article for more detailed explanations of the main points provided herein.

Mammografie-Bildern' (Aerzteblatt.de, 28 October, 2019)<https://www.aerzteblatt.de/nachrichten/107003/Berliner-Start-Up-erhaelt-Zulassung-zur-digitalen-Auswertung-von-Mammografie-Bildern>

[11] For the full definition of in vitro diagnosis medical device see the IVDR, art 2(2)

[12] See the IVDR, annex XIII, part A 1.1; annex II art 6.4

[13] IVDR, annex I chapter II art 9.1(a)

[14] IVDR, annex I chapter II art 9.1(b)

[15] IVDR, art 57(2)

[16] IVDR, annex XIII art 2.3.2(m)