Communication of the President of the Office of 19 July 2023 regarding the EMA's statement on a draft document on the use of artificial intelligence (AI) to support the development, and use of human and veterinary medicines.

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EMA has published a draft reflection paper outlining the current thinking on the use of artificial intelligence (AI) to support the safe and effective development, regulation and use of human and veterinary medicines. This paper, which is now open for public consultation, reflects on principles relevant to the application of AI and machine learning (ML) at any step of a medicines' lifecycle, from drug discovery to the post-authorisation setting.

The reflection paper is part of the joint HMA-EMA Big Data Steering Group (BDSG) [1] initiatives to develop the European Medicines Regulatory Network's capability in data-driven regulation. It has been developed in liaison between the BDSG, EMA's Committee for Medicinal Products for Human Use (CHMP) and its Committee for Veterinary Medicinal Products (CVMP).

"The use of artificial intelligence is rapidly developing in society and as regulators we see more and more applications in the field of medicines. AI brings exciting opportunities to generate new insights and improve processes. To embrace them fully, we will need to be prepared for the regulatory challenges presented by this quickly evolving ecosystem" said Jesper Kjær, Director of the Data Analytics Centre at the Danish Medicines Agency and co-chair of the BDSG. "With this paper, we are opening a dialogue with developers, academics, and other regulators, to discuss ways forward, ensuring that the full potential of these innovations can be realised for the benefit of patients' and animal health" said Peter Arlett, EMA's Head of Data Analytics and Methods, co-chair of the BDSG.

AI and ML tools have the potential to effectively support the acquisition, transformation, analysis, and interpretation of data across the medicinal product lifecycle. Their application can include, for example, AI/ML modelling approaches to replace, reduce, and refine the use of animal models during the preclinical development. In clinical trials, AI/ML systems may support the selection of patients based on certain disease characteristics or other clinical parameters; AI/ML tools can also support data recording and analyses which will in turn be submitted to regulators in marketing-authorisation procedures.

At the marketing-authorisation stage, AI applications include tools to draft, compile, translate, or review data to be included in the product information of a medicine. In the post-authorisation phase, such tools can effectively support, for example, pharmacovigilance activities including adverse event report management and signal detection.

This range of applications brings with it challenges such as the understanding of the algorithms, notably their design and possible biases, as well as the risks of technical failures and the wider impact these would have on AI uptake in medicine development and health.

The reflection paper highlights that a human-centric approach should guide all development and deployment of AI and ML. The use of AI in the medicinal product lifecycle should always occur in compliance with the existing legal requirements, consider ethics and ensure due respect of fundamental rights.

If an AI/ML system is used in the context of medicines' development, evaluation, or monitoring, and is expected to impact on the benefit-risk balance of a medicine, EMA advises developers to seek early regulatory support, e.g. through qualification of innovative development methods (for human medicines) or scientific advice.

All interested stakeholders are invited to comment on the draft reflection paper and to identify opportunities and risks of AI in the field of medicines. The public consultation is open until 31 December 2023 and the topic will be further discussed during a joint HMA/EMA workshop scheduled for 20-21 November 2023. The feedback from stakeholders will be analysed and considered for the finalisation of the reflection paper and future development of guidance as relevant.

More information available on the website: https://www.ema.europa.eu/en/news/reflection-paper-use-artificial-intelligence-lifecycle-medicines [2]

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Źródłowy URL: https://archiwum.urpl.gov.pl/pl/node/7734

Odnośniki
[1] https://www.ema.europa.eu/en/documents/work-programme/workplan-2022-2025-hma/ema-joint-big-data-steering-group_en.pdf
[2] https://www.ema.europa.eu/en/news/reflection-paper-use-artificial-intelligence-lifecycle-medicines