HMA/EMA Multi–stakeholder workshop on Artificial Intelligence (AI) - enabling the safe and responsible use of AI

Workshop Report

The HMA/EMA 2024 multi-stakeholder workshop on Artificial Intelligence follows on from AI workshops in 2021 and 2023 and was the first multi-stakeholder AI workshop under the new HMA/EMA multi-annual AI workplan.

The workshop objectives were to:

- Update on state-of-the-art of AI developments with keynote speakers.
- Update stakeholders on:
  - policy and legislative environment;
  - HMA/EMA activities on AI.
- Discuss with stakeholders and experts:
  - progress of the multi-annual AI workplan and possible updates;
  - AI use cases in the medicine lifecycle.

Opening and keynotes

The workshop was opened by Emer Cooke, Executive Director of the European Medicines Agency (EMA) and Karl Broich, President of Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM).

Emer Cooke emphasized how AI is transitioning from promise to practice, delivering tangible benefits for public and animal health. Over the past year, the European Medicines Regulatory Network implemented its multi-annual AI workplan, focusing on guidance and policy developments, technology frameworks, change management and collaboration, and experimentation. Notable achievements include revising the AI reflection paper, establishing guiding principles for large language models, and preparing for the AI Act. These advancements highlight AI's steady shift from theoretical potential to impactful real-world contributions.

Karl Broich expressed how the joint Heads of Medicines Agencies-European Medicines Agency AI workshop exemplifies the essential role of collaboration in unlocking the transformative potential of Artificial Intelligence for public and animal health. By working together, stakeholders can address AI's unique complexities and challenges more effectively, leveraging diverse insights to ensure safety, equity, and trust. The HMA/EMA multi-annual AI Workplan underscores this collaborative approach through initiatives like skill-building masterclasses, an expert AI community, and models for inter-agency cooperation.

Keynote speeches

***Healthcare needs AI,* Jan Beger, GE Healthcare**

Jan Beger highlighted the transformative potential of Artificial Intelligence in addressing challenges in the healthcare industry, driven by the explosive growth of healthcare data, which now doubles every 72 days. With 30% of global data being healthcare-related and radiologists managing massive workloads – analysing 50,000 images per shift – AI can help process the 97% of unused healthcare data, generating valuable insights. The speaker emphasized AI's role in mitigating the global shortage of healthcare professionals, projected to reach 10 million by 2030, by enhancing care quality and reducing errors. Examples included AI-guided ultrasound imaging and adaptable foundational AI models that expedite development. Jan stressed the importance of AI literacy for healthcare professionals and its potential to restore the human touch by handling routine tasks.

***Patient's perspective on enabling safe and responsible use of AI,* Milana Trucl, European Patient Forum (EPF)**

Milana Trucl, Policy Officer at the European Patient Forum (EPF), discussed the patient perspective on AI in healthcare. EPF is an umbrella organization representing patient groups across Europe. Milana highlighted the importance of digital transformation in healthcare, emphasizing patient-centred care and co-design. EPF has conducted surveys to understand patient organizations' views on AI, identifying key challenges such as data privacy, lack of transparency, and the need for patient involvement. Recommendations included ensuring patient safety, addressing data quality, maintaining human oversight, and prioritizing education and digital literacy for all stakeholders.

***European Testing and Experimentation Facility for Health AI and Robotics* by Petra Ritter, Coordinator TEF-Health**

Petra Ritter leads the European testing and experimentation facility for health AI and robotics, focusing on advancing technologies like digital human brain twins for studying cognitive processes and medical interventions such as deep brain stimulation for Parkinson's disease. In her presentation, she highlighted the importance of data standardization and accessibility for AI models effectiveness. Discussing the European AI Act, the speaker underscored its focus on trustworthiness through criteria like transparency, privacy, and accountability, and emphasized the need for standards and certification. The facility supports high-risk medical AI certification with health data, consulting, and testing services, while advancing secure health data sharing under European Health Data Space initiatives and offering discounted or free services to SMEs.

***AI and pharmacovigilance,* Andrew Bate, GSK**

Andrew Bate, Vice President and Head of Safety Innovation Analytics at GSK, discussed the development of next-generation pharmacovigilance capabilities. He emphasized the importance of collaboration between AI and domain experts to advance the science of pharmacovigilance. He highlighted the challenges and opportunities of using AI in pharmacovigilance, including the need for robust data analysis, handling missing data, and ensuring ethical use. He also mentioned the importance of sectorial harmonization and focusing on outputs to improve patient safety and benefit-risk assessments of medicines and vaccines.

Session 1: From AI policy to medicines regulation

Moderator: Zaide Frias (EMA)

Legal framing: EU AI Act and AI legal ecosystem, by **Laura Jugel, European Commission, AI Office**

Laura Jugel, a Legal and Policy Officer in the European Commission's new AI office, introduced the AI Act, aimed at ensuring trustworthy and safe AI in Europe. Adopted in mid-2024 and effective from August 2024, the Act applies across all sectors, with rules varying by risk level—high-risk systems face stricter requirements, while minimal-risk AI has none. It also addresses general-purpose AI models due to their broad capabilities. The AI office oversees enforcement, fosters innovation, and is preparing guidelines for the Act's implementation.

Regulatory framing: AI Reflection Paper, **by Gabriel Westman head of AI, Swedish Medical Products Agency**

Gabriel Westman addressed the challenges of regulating large language models and AI applications in the EU, noting the challenge related to the rapid pace of AI advancements potentially outpacing regulatory adaptation. Gabriel discussed the reflection paper on AI in the medicinal product life cycle, highlighting AI's potential benefits alongside risks like lack of interpretability and trustworthiness. Stressing the importance of risk management and public trust, the speaker noted that the paper underwent extensive consultation, incorporating over a thousand comments, and was finalized by the CHMP on 30 September 2024.

Session 2: AI applications - Use cases in medicines lifecycles

Moderators: Manuela Messelhäußer (PEI), Hilmar Hamann (EMA)

Knowledge graphs for precision medicine**, by Maria Sorokina, EFPIA**

Maria Sorokina discussed the use of knowledge graphs in precision medicine, focusing on enhancing clinical trial outcomes and patient stratification. She highlighted the complexity of clinical trials and the potential of knowledge graphs to integrate and reuse clinical data, leading to better patient outcomes and more efficient drug development.

Applying AI in ICSR management**, Hans-Jörg Römming, EFPIA**

Hans-Jörg Römming presented on the application of AI in managing individual case safety reports at Merk Healthcare. He detailed the use of AI for translation and case intake, emphasizing the potential for AI to improve efficiency and quality in pharmacovigilance processes, and highlighted the importance of global collaboration and regulatory alignment.

Assessing the use of AI in neo-antigen prediction pipelines, **by Liam Childs, Paul-Ehrlich Institute**

Liam Childs from the Paul Ehrlich Institute shared insights on assessing AI in neo-antigen-based products. He explained the process of using AI to predict immune reactions in cancer treatment and emphasized the importance of risk assessment, validation, and risk management in ensuring the safety and efficacy of AI-driven medicinal products.

***AI@MPA - an AI toolbox for medicines regulation*, by Gabriel Westman, Swedish Medical Products Agency**

Gabriel Westman from the Swedish Medical Products Agency discussed the AI toolbox for medicines regulation. He showcased various AI tools developed for regulatory purposes, including natural language processing for product information, computer vision for drug package similarity, and raw data analysis tools, highlighting their potential to enhance regulatory processes and collaboration among agencies.

***How EMA is advancing AI Integration and Innovation,* Joaquim Berenguer Jornet, EMA**

Joaquim Berenguer from the EMA outlined the EMA's initiative to advance AI integration and innovation. He described the development of a knowledge mining roadmap and the collaborative efforts to implement AI use cases across the network, aiming to improve data handling, efficiency, and regulatory processes through coordinated AI strategies.

Session 3: AI applications: Research priorities

Moderator: Emmanuel Cormier (EMA)

The session included a series of presentations from various perspectives, from different stakeholders. Julian Isla from the DSEF provided the patient's view, followed by Flora Musuamba Tshinanu from the University of Namur who presented the academic perspective. Margarita Kirienko from Fondazione IRCCS Istituto Nazionale dei Tumori shared insights from the healthcare professional's view, while Annika Eberstein from COCIR discussed the MedTech perspective. Finally, Niklas Norén from UMC presented the researcher's view. The session concluded with a 30-minute panel discussion involving all the speakers.

Summary of Key Points from the Discussion on AI Research Agenda:

- **Risk Assessment and Deployment**:
  - Focus on assessing AI use cases and determining associated risks.
  - Experimentation should be conducted in a safe space, while deployment in routine practice requires formal risk assessment and necessary risk mitigation in line with the AI Act.
- **Collaboration and Standards**:
  - Emphasize collaboration between industry, regulators, and academia to develop AI applications and establish technical standards.
  - Public-private partnerships and regulatory sandboxes are needed to provide a safe environment for developing and testing AI applications.
- **Data Access and Interoperability**:
  - Access to high-quality, interoperable data is essential for AI development.
  - The European Health Data Space is seen as a critical initiative to support data exchange and interoperability.
- **Performance Metrics and Evaluation**:
  - Develop performance metrics and benchmark datasets for AI tools to ensure their reliability and effectiveness.

  - Be meticulous with performance evaluation and critical assessment of AI solutions.

- **Education and Engagement**:
  - Educate healthcare professionals and engage them in the use of AI tools to ensure successful implementation.
  - Consider the nuances of human-computer interaction and the variability between humans in AI solutions.

- **Sustainability and Competitiveness**:
  - Consider the environmental impact of AI development and adopt green software coding practices.
  - Enhance Europe's competitiveness in AI through fit-for-purpose regulatory frameworks, collaboration, and investment in infrastructure like the European Health Data Space.

Session 4: HMA/EMA AI workplan: Taking stock and planning forward

Moderators: Peter Arlett (EMA) & Jeppe Larsen (DKMA)

The session began with an overview of the AI workplan's progress by Luis Pinheiro who presented an overview of the deliverables concluded throughout the year noted that the workplan includes an annual review process to adapt to the fast-moving nature of AI.

Tala Fakhouri (FDA) emphasized the importance of international alignment particularly on AI terminology and guiding principles for machine learning, noting these are crucial for global regulatory alignment. Tala suggested that EMA and FDA could work together on these initiatives.

Thomas Brookland (EFPIA) noted that EFPIA sees value in starting guidance development on AI with foundational principle-based recommendations for AI, including an AI terminology paper, good AI machine learning practice principles, and a high-level risk assessment framework. Thomas suggested creating a dedicated Q&A for AI to address specific use cases and emerging questions. This would be a dynamic policy instrument that could be updated more easily than traditional guidance documents.

Florence van Hunsel (Lareb) emphasized the importance of collaboration and transparency in AI development and highlighted the potential for linking different types of data, such as Pharmacovigilance data and knowledge databases, to enhance AI applications.

Jesus Rueda Rodriguez (MedTech Europe) stressed the importance of global engagement and alignment with the AI Act and MDR/IVDR. He highlighted the need for consistent requirements to avoid burdensome compliance processes. Jesus also noted the role of the EMA in encouraging data sharing and building trust in data sharing mechanisms. He suggested that the work plan should better reflect the value of data sharing.

Tjalling van der Schors (EAHP) focused on the importance of real-world data and the need for interoperability and standardized data structures. He highlighted the challenges of accessing and using uncontrolled data from various systems. Furthermore, he emphasized the need for proper training for healthcare providers to discern relevant information and use AI tools effectively. He also mentioned the importance of addressing bias and the information bubble in AI systems.

Jelena Malinina (EURORDIS) stressed the need for global collaboration and the development of multilingual AI tools to support rare diseases. She highlighted the importance of sharing data globally and investing in tools that can be used in lower-resource settings. She also highlighted the importance

of compliance and ethical use of AI, particularly for sensitive data in rare diseases. She called for guidelines to ensure data security and privacy and for developing specific guidelines for AI applications in rare diseases and expanding experimentation cycles to include rare disease AI models.

In summary, the key themes highlighted in the discussion for the update of the AI Workplan were:

- International convergence and strengthened collaboration between global regulators and between different areas (medicines and medical devices)
- Creation of dynamic, foundational guidance, that can adapt to the speed of innovation
- Increase the interoperability of real-world data
- Strengthen AI education across the medicine lifecycle stakeholders