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Summary notes of the HMA-EMA group focused on AI with industry stakeholders kick-off meeting

7 November 2025, - co-chaired by Joerg Zinserling (BfArM) and Peter Arlett (EMA), Virtual

1. Welcome and tour de table

The Co-Chairs opened the meeting by welcoming participants and presenting the agenda.

Attendees included representatives from regulatory bodies and 22 industry associations. Each participant was invited to introduce themselves.

Co-Chair, Peter Arlett (EMA) emphasised that, in line with the group's mandate, EMA has asked the industry associations to coordinate amongst themselves and reduce industry nominations to 12 standing representatives. Non-standing representatives will remain on the distribution list to receive information and may join meetings when agenda topics are relevant to them.

2. Group's purpose and ways of working

Co-Chair, Joerg Zinserling (BfArM) outlined the purpose and structure of the focus group:

- The primary aim of this group is to facilitate open dialogue between regulators and industry stakeholder on AI in the medicines lifecycle.
- The group was established as part of an action under the Network Data Steering Group Workplan 2025-2028 .
- Meetings will be held 2-4 times per year, lasting 90 minutes each.
- Future meetings will be topic-driven, with members consulted in advance to shape the agenda.
- No product-specific discussions or assessments will be conducted.

3. Update on AI

Luis Pinheiro (EMA) provided a high-level overview of the HMA-EMA AI workplan-workstream embedded within the broader NDSG workplan on Data and AI in medicines regulation. Key highlights across the four pillars include:

1. Guidance, policy and product support

- Ongoing work is focused on developing AI guidance for pharmacovigilance guidance and initiating early scoping for clinical development guidance.

- The AI Observatory Report summarising 2024 experiences and horizon scanning has been published and preparation for the next edition is ongoing.
- Collaboration with FDA on AI principles and terminology aims to support potential future regulatory alignment.

2. Tools and Technology

- AI priority use cases have been identified through consultation with the European Medicines Regulatory Network and a delivery plan is currently being developed.
- Work is progressing toward finalising an AI tools framework designed to enable responsible and effective sharing of AI tools across the European Medicines Regulatory Network.

3. Collaboration and change management:

- An EMA-wide AI literacy campaign has been launched, building on the Guiding Principles for the Use of Large Language Models with planning underway for a broader initiative across the European Medicines Regulatory Network.
- Continues engagement at European and international levels through initiatives such as ICMRA, the International Coalition of Medicines Regulatory Authorities, and the EU Agency Network Working Group on Artificial Intelligence.
- The fourth HMA/EMA Workshop on AI is scheduled for 20–21 November.

4. Experimentation:

- The Experimentation Runway - a new initiative to accelerate strategic innovation at EMA has been launched.
- Collection of responses for the research priorities survey has been completed and an analysis is underway.

4. Industry's future discussion priorities

Industry participants shared priorities and suggestions for future meetings and revisions to the AI workplan with further input opportunities at the AI workshop on 21 November 2025. Key themes included:

- Sharing AI use cases and experiences from regulators and industry.
- Risk assessment and frameworks: Desire for clearer guidance on assessing AI-related risks, including patient safety and regulatory impact and criteria for high and low risk zones.
- Progress updates on AI workplan activities.
- AI tools development: Review gaps in current guidance and expand reflection paper to provide future guidance to progress AI use cases across the medicine lifecycle.

- Legislative initiatives (e.g., AI Act Implementation): Address concerns about over-interpretation and need for practical guidance, especially for SMEs and niche sectors. Interest in exploring sandbox modalities for AI in the medicine lifecycle.
- Data Structuring & Access: Calls for better access to structured data and APIs to support AI-driven analysis including research-ready metadata from CHMP opinions (e.g., trials listings).
- Retrospective Data Enrichment: Proposal to allow voluntary submission of historical patient-level data to enhance regulatory insights.
- Horizon Scanning: Suggestion to proactively explore future AI trends and their impact on regulation such as digital twins, synthetic data, virtual controls and how AI fits with the wider EU landscape including Biotech Act and the Innovation Act.
- Regulatory clarity on AI prompts and algorithms: Need for clear guidance and shared understanding of regulatory expectations to ensure data validity and strengthen structures for leveraging large datasets in regulatory decision-making.
- Veterinary use cases: can offer complementary approaches to human medicine, leveraging differences e.g. in data availability or governance to develop methods that may provide transferable insights and foster collaboration.

5. AOB

The meeting concluded with no additional items for discussion.

The next meeting will take place in the New Year, and details will be communicated in due course.