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

4 February 2026, - co-chaired by Joerg Zinserling (BfArM) and Peter Arlett (EMA), Virtual

1. Welcome and adoption of draft agenda

Co-chair, Peter Arlett (EMA) opened the meeting by welcoming participants and presented the agenda which was adopted with no changes.

2. Guiding principles and terminology

Co-chair, Joerg Zinserling (BfArM) gave an update on the activities related to the EMA and FDA collaboration on AI guiding principles and terminology noting that:

- Guiding principles of good AI practice in drug development were jointly published by EMA and FDA in January 2026. The work on the European side was supported by a drafting group comprising 15 representatives of the European Medicines Regulatory Network.
- Work is ongoing to develop a glossary of AI related terms. This involves mapping the terminology used by EMA and FDA to reach a consensus on the use of terms where possible, acknowledging differences in legal definitions across jurisdictions.
- Both agencies will keep exploring opportunities for further convergence.

Industry welcomed the work on AI principles and terminology and praised the international collaboration underpinning it. Industry participants highlighted the importance of expanding collaboration beyond EMA and FDA and sought clarity about long-term strategic intentions for international harmonisation.

EMA confirmed that AI principles were drafted to apply to both human and veterinary domains and acknowledged the need for clear communication on this point.

3. Guidance development and Biotech Act

Luis Pinheiro (EMA) presented an overview of ongoing and planned AI guidance under the Methodology Working Party (MWP) workplan, EU Good Manufacturing Practice (GMP) Annex 22 and the implications of the newly proposed Biotech Act.

Current guidance development activities include:

- Guidance on AI in clinical development (concept paper expected before full draft guidance).

- Guidance on AI in pharmacovigilance, to be developed jointly with PRAC as a Q&A style instrument.
- GMP Annex 22 on AI in manufacturing, which following public consultation received ~1,300 public comments and is undergoing revision. The final document is expected to be published by the end of the year.

The proposed Biotech Act introduces legally binding expectations for EMA to develop AI guidance in different areas including pre-clinical research, clinical development and trials, manufacturing, post authorisation and monitoring phases as well as procedures for authorisation of medicinal products. This guidance is to be developed, updated and published in agreement and consultation with the European Commission, including the AI Office.

EMA noted that work will begin before the Biotech Act is formally adopted, and a roadmap and revised processes for AI guidance development will be explored in light of the proposed requirements in the legal proposal for a Biotech Act.

Industry interventions

Industry associations (AESGP, AnimalhealthEurope, EFPIA, EUCOPE, EuropaBio, Europharm SMC) expressed their priorities and needs on AI guidance.

Key needs identified included:

- Practical, operational guidance beyond high-level principles including templates, checklists or examples on evidence, validation and documentation when AI is used.
- Risk-based, proportionate frameworks that differentiate high vs. low-risk AI use cases and acknowledge the specific needs for small and medium-sized enterprises (SMEs).
- Coherence across sandboxes being developed under different regulations
- Regulatory clarity on use of generative AI, including:
  - acceptable vs unacceptable uses in regulatory submissions;
  - transparency expectations when AI generated content is used;
  - boundaries between decision-support tools and software regulated under other frameworks (e.g. medical devices).
- Data structuring, access and reuse, particularly structured regulatory data and leveraging APIs to enable AI-driven analysis.
- Consistency in terminology and alignment of principles avoiding overlap and duplication where possible.
- A more flexible approach to the use of AI in GMP, including the potential for generative AI and large language models (LLMs) in critical GMP applications if supported by a robust risk-based framework.

Regulators' remarks:

- The Network remains in listening mode for industry's needs and areas where AI guidance would be helpful. There is no current regulatory position on the points raised by industry during the meeting. Industry's expressed for wishes and expectations to feed into the scoping discussions on the AI guidance development.

- It is important to manage expectations about how detailed regulatory guidance on AI can be, noting that ultimate responsibility for compliant practices lies with sponsors and applicants. While guidance can indicate possible approaches, many issues depend on context, therefore very detailed rules may not be feasible.
- Veterinary medicines fall within the scope of Article 31 under the legal proposal for the Biotech Act.
- The industry feedback provided during the meeting on the GMP guideline will be forwarded to the colleagues leading on the review of the public consultation on EU GMP Annex 22.
- The regulatory system needs to enable responsible innovation while avoiding administrative burden that could hinder it.

4. AI in pharmacovigilance

Luis Pinheiro presented a review of key initiatives from the past year:

- Ongoing EMA-FDA pharmacovigilance AI cluster, with PMDA and Health Canada as observers (human).
- Network-wide "SMART Methods" group under the Pharmacovigilance Risk Assessment Committee examining innovative methods including AI (human). It also collaborates with the Uppsala Monitoring Center on exploring use of large language models in pharmacovigilance.
- CIOMS report on AI in pharmacovigilance providing an important foundation for future regulatory guidance (human).
- Network-wide collection and prioritisation of AI use cases, although not pharmacovigilance specific, the initiative highlighted a number of critical business value issues/use cases that will need to be addressed in the future (human and veterinary).
- IHI AI in PV project – a consortium is being formed.

Luis Pinheiro also provided an overview of emerging use cases across the European Network's signal detection workflow, including:

1. Literature screening for ICSRs;
2. Triaging serious reports;
3. AI detection and validation of drug reactions in RWD;
4. Literature monitoring for signals;
5. ADR data extraction (human and veterinary);
6. AI-enhanced case adjudication;
7. Knowledge base of signal reviews.

Most of these use cases were predominantly focused on the human domain (except No. 5) but given the similarities in processes for individual case safety reports across human and veterinary sectors, they could potentially be applicable to the veterinary domain as well. Future updates will need to make the touchpoints and the provisions on the veterinary side more explicit.

Regulators noted that pharmacovigilance is a particularly promising area for AI adoption, given the shared processes between industry and regulators and the significant opportunities for efficiency gains and greater consistency.

5. Organisational matters

EMA acknowledged the challenge for industry associations in coordinating their priorities and topics for discussion as a collective input and encouraged industry to prioritise and align proposals where possible.

Next focus group meetings are scheduled for:

- 2 June 2026
- 5 October 2026

6. AOB and close

The meeting concluded with no additional items for discussion.

The Co-chairs thanked all participants for the active dialogue, noting the shared commitment for better drug development, improved lifecycle management and strengthened medicines regulation.