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European Medicines Agency

Summary - European Medicines Agency meeting with senior representatives of pharmaceutical companies - 17 April 2026

1. Welcoming and opening of the meeting

The Executive Director of the European Medicines Agency (EMA) opened the meeting by welcoming participants and underlining the significance of the dialogue at a critical turning point for the European pharmaceutical ecosystem. The meeting brought together senior executive-level representatives from 24 biopharmaceutical companies and three major trade associations for innovative human medicines (EFPIA, EuropaBio, and EUCOPE), reflecting a strong shared interest in the future direction of the EU pharmaceutical system.

The meeting was also attended by representatives from the Heads of Medicines Agencies (HMA), the Chair of the Committee for Medicinal Products for Human Use (CHMP), and the European Commission, alongside EMA's Executive Director and senior leadership team.

In a video message, EU Commissioner for Health, Olivér Várhelyi highlighted the importance of fully using the tools provided by the reformed pharmaceutical legislation, together with initiatives such as the Biotech Act and the European Health Data Space, EHDS. Referring to the recent kick off meeting of the Health Industry Roundtable, he underlined the shared call from industry for coherent action to support a competitive ecosystem. He emphasised that the new, clearer pharmaceutical rules and their timely and proportionate implementation are key to boosting innovation and ensuring patient access to medicines.

The Executive Director framed the discussion around the need for open, continuous, and constructive dialogue between regulators and industry, noting that decisions being taken now will shape Europe's competitiveness, resilience, and public trust in the years ahead. The objectives and format of the three roundtable discussions were then introduced.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

2. The EU pharmaceutical system today: views on current strengths and priority areas for improvement

Participants emphasised that Europe is at a critical inflection point and must continue to adapt to remain globally competitive in pharmaceutical innovation. While recognising Europe's scientific excellence and regulatory credibility as strengths, attendees highlighted a number of areas which could be improved.

A central message was that speed, flexibility, and predictability are essential to bring medicines to patients earlier and to retain innovation in Europe. Clinical trials were identified as an area to be prioritised, including improving coordination and harmonisation across Member States, consistency of requirements, and shortening approval timelines, areas where the EU regulatory network is already working to deliver improvements.

Participants stressed the importance of:

- Early and integrated engagement across the product lifecycle, ensuring predictability from development through authorisation and beyond.
- More agile, open dialogue and iterative scientific advice, particularly for novel therapies and new technologies.
- Ensuring alignment across regulatory and HTA decisions, as predictability across these domains is a key driver of global investment decisions.

Overall, participants welcomed EMA's openness to listen and engage and to fully use available tools, including patient-level data and real-world evidence, to support faster patient access.

Several participants raised concerns that recent US policy developments (e.g. MFN) are having an impact on the discovery, development, manufacturing and marketing of pharmaceuticals.

3. Global perspectives convergence and reliance

The second roundtable focused on the global regulatory environment and the importance of convergence, reliance, and international cooperation. Participants highlighted the important role EMA plays in coordinating scientific excellence, regulatory innovation, and the adoption of new technologies at both EU and global levels.

Discussions highlighted the value of:

- Global convergence through ICH, reliance mechanisms, and collaborative assessment and inspection activities.
- Strengthened cooperation on emerging areas, including artificial intelligence, advanced therapies, and digital tools.
- Building on Europe's assets, such as high-quality data, scientific expertise, ethical standards. Vaccines were cited as an example where EU leadership is key.

Participants emphasised that Europe has strong foundational assets that provide further opportunities for Europe to lead globally. There was a strong willingness from industry to collaborate closely with EMA and other stakeholders to build further on international reliance

4. Future EU regulatory system to 2030 and beyond

Looking beyond 2030, participants discussed how the EU pharmaceutical system will need to further evolve to remain future-proof in the face of rapid technological change. There was broad agreement that technology, data, and AI are reshaping medicines development and regulation faster than current systems can accommodate.

Key messages included:

- Data as the foundation of future innovation, with high-quality, large-scale, multi-source data (beyond clinical trials) seen as playing an increasingly prominent role. This is an area in which the EU Regulatory Network is actively advancing its work, and the progress already made could be leveraged to support the effective implementation of EHDS which was identified as an important enabler.
- Europe can play an important role in driving lifecycle evidence generation, building on EMA's current approach to integrate clinical trials, registries, real-world data, and patient experience data (PED) through coordinated EU approaches.
- EMA's potential pivotal role in coordinating technological transformation across Member States. The need to address digital infrastructure, data privacy, and trust together, through collaborative action by EU regulators, stakeholders, and Member States.
- AI was viewed as transformative, but only if supported by harmonised data standards, methodologies, and interoperable systems.

Public trust was repeatedly highlighted as central. The COVID-19 response was cited as a good example of what the EU can achieve when scientific rigor, regulatory credibility, and trust-based decision-making align under strong leadership of the EU regulatory Network.

5. Summary and closing of the meeting

The meeting provided a valuable opportunity for high-level, strategic exchange between EMA, HMA and senior pharmaceutical industry leaders. It was highlighted that Europe possesses strong scientific, regulatory, and societal foundations, and now needs to accelerate, reinforce coherence, and embrace data and novel methods to remain competitive. Participants noted that, while important progress is being made, incremental optimisation alone will not be sufficient to meet the challenges facing the EU pharmaceutical system.

Key priorities emerging from the discussions included strengthening patient centricity, sustaining public trust, reducing fragmentation, accelerating innovation, and ensuring that ongoing legislative and policy initiatives translate into real-world impact. In this context, participants emphasised the need to address structural challenges across the system, including further modernisation of regulatory processes and practices, greater support for early stage development in Europe, and improved coherence between regulatory decision making and pricing and reimbursement pathways.

Participants expressed strong commitment to continued collaboration and dialogue to help shape a resilient, innovative, and future-ready European pharmaceutical system.