14 October 2025

European Medicines Agency

Highlights – 4th EMA- Vaccines Europe bilateral meeting

Chaired by Juan Garcia Burgos, Head of Public and Stakeholder Engagement

1. Welcome and introductions

The Chair and the EMA Executive Director welcomed the Vaccines Europe delegation, highlighting the importance of active engagement in this sector, given the opportunities represented by vaccines, and many other relevant aspects, including the challenges faced due to mis- and disinformation.

Vaccines Europe welcomed the opportunity for a strategic discussion with the Agency, emphasising the importance of collaboration in enhancing the EU's attractiveness to vaccine developers.

2. Vaccines Europe Strategy and Roadmap until 2027

Vaccines Europe presented the updated strategy to 2024-2027 confirming the focus on "fostering innovation and value recognition of life course immunisation in Europe to protect people against evolving health challenges". Details on the objectives and key priorities included in the strategy (such as addressing the complexities arising from the Clinical Trial Regulation, enhancing the use of electronic patient information and the EU common pack for vaccines, ensuring successful implementation of the Health Technology Assessment Regulation (HTAR), combating misinformation and boost vaccines confidence) were briefly outlined.

The EMA welcomed the overview provided confirming alignment with most of the network priorities to boost innovation and science-based narrative in this sector.

Clarifications were provided on the opportunities for engagement with National Immunisation Technical Advisory Group (NITAG) and European Centre for Disease and Control (ECDC).

3. Vaccines Europe 4th pipeline edition 2025

Vaccines Europe shared an overview of the 4th pipeline edition confirming that the vaccine industry is investing in innovative and diverse products that tackle a variety of diseases using different platforms,

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including mRNA. The importance of ensuing inclusion of the right expertise in the assessment of vaccines and the need to improve vaccination rates was emphasised.

The Agency provided clarifications on its responsibilities and role towards the implementation of the HTAR and encouraged Vaccines Europe to continue their dialogue with the HTA Secretariat on the relevance of interaction with NITAGs in the context of evidence planning.

In terms of pipelines trends, Vaccines Europe members were encouraged to consider alternative routes of administration; to also work on pathogens for which no vaccination is available and for developers to seek for scientific advice as soon as possible.

4. Regulatory and innovation (EMANS N3): global harmonization of vaccines licensing

Vaccines Europe discussed the importance of global reliance on vaccines assessment as this can foster development and trials of vaccines globally. The EMA acknowledged the considerations made and confirmed the importance of the mechanisms in place enabling dialogue with international authorities. This includes discussion at ICH level, the dialogue with WHO and the use of established clusters, the parallel scientific advice and OPEN procedure. This latter was recently enhanced following feedback received from Industry stakeholders.

Vaccines Europe was reminded of non-product specific mechanisms in place at the Agency to support innovation. In this context Vaccines Europe was encouraged to take part to the ongoing call for nominations to for an industry AI focus group. Industry was invited to use the advice provided by the Innovation Task Force (ITF), the Portfolio and Technology Meetings (PTMs), Small-, Medium- Size Enterprises (SME) briefing meetings and Quality Innovation Group (QIG).

General clarifications on the Agency’s regulatory framework for therapeutic vaccines were provided.

5. EMA leadership in restoring vaccines confidence

Vaccines Europe provided an overview of their initiatives aiming at restoring confidence in vaccines and in addressing mis- and dis -information.

The Agency was pleased to learn about the initiatives, and confirmed that restoring confidence in vaccines and tackling mis- and disinformation were also among its key priorities. An overview of ongoing and planned activities was provided. These included initiatives to identify communication gaps and misconceptions, and to engage in collaboration with regulatory partners and stakeholders on infodemic management and building trust, especially with younger generations through social media, content creators, and podcasts. Specific vaccine initiatives included a vaccine outreach strategy, monitoring vaccine concerns and addressing them with clear, simple narratives. The Agency is piloting a proactive communication initiative with vaccine essentials info sheets prepared jointly with healthcare professional organisations.

In this context, Vaccines Europe was encouraged to disseminate the Agency's material as widely as possible.

6. Emergency Task Force (ETF): EMA- VE exchange of views and recommendations

Vaccines Europe expressed appreciation for the support and open dialogue provided by the ETF and requested further guidance on the scientific advice procedure and on the interactions of the ETF with other EMA working parties and working groups.

The Agency thanked Vaccines Europe for the feedback based on experience and confirmed that the knowledge gained since the establishment of the ETF during the pandemic has been used to ensure clear links with the relevant committees and working groups. It was also clarified that the ETF's scientific advice procedure, which has the listed pathogens in scope, aligns operationally with regular scientific advice provided through SAWP; both are adopted by the CHMP.

Vaccines Europe was informed of the intention to update the corporate website and to publish additional guidance to ensure clarity on ETF roles and procedures including the scientific advice of clinical trials involving nominated experts from MedEthicsEU and from the Clinical Trials Coordination Group (CTCG). Vaccines Europe was asked to encourage its members to apply for this type of advice.

7. Conclusions and next steps

The meeting provided an opportunity to discuss how to enhance innovation in Europe and continue the collaboration in promoting scientific evidence-based approach.