25 November 2024
EMA/539768/2024
European Medicines Agency

Highlights 3rd EMA- Vaccines Europe bilateral meeting

25 November 2024 – Chaired by Marie- Hélène Pinheiro, EMA Industry Corporate Liaison

1. Welcome and introduction

The Chair welcomed the Vaccines Europe delegation and emphasised that this is a critical time for the pharmaceutical sector given the current discussions on the reform of the EU pharmaceutical legislation and the attention given to health threats, antimicrobial resistance.

Vaccines Europe welcomed the timely opportunity to discuss topics of mutual interest and exchange on respective priorities to foster availability of innovative vaccines in the EU.

2. Vaccines Europe priorities taking into account EC Competitiveness agenda and EMAN Strategy to 2028 and pipeline review

Vaccines Europe presented the overview of the 2024 pipeline review highlighting the critical role of innovation in the vaccine ecosystem and the pharmaceutical industry's commitment to providing innovative vaccines in order to ensure lifelong immunisation and to address several global health threats including anti-microbial resistance (AMR) and pathogens emerging due to climate change. The complexities associated with vaccine research, development and manufacturing and the need to ensure a flexible regulatory approach were highlighted.

The EMA welcomed the review and encouraged Vaccines Europe members not to limit their efforts to known pathogens, but also to address multi-resistant pathogens and to consider different routes of administration. The need to ensure predictability of submissions and the development of specific scientific/regulatory guidance in that context was emphasised. For the latter, the on-going VWP Work Programme external consultation was highlighted.

The preliminary feedback on the European Medicines Agency Network Strategy (EMANS) to 2028 was provided by Vaccines Europe highlighting challenges to enhance EU innovation, competitiveness and immunisation (e.g. EU clinical trials; expertise/capacity building; cooperation with other authorities/decision makers; role of vaccines in fighting AMR).

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The EMA welcomed the preliminary feedback received and encouraged Vaccines Europe to provide more details on the specific challenges faced and recommendations for appropriate solutions as part of their written feedback to the open consultation (deadline 30th November 2024). The Agency confirmed the inclusion of stakeholders feedback in several activities related to clinical trials (i.e. ACT EU initiative, clinical trial regulation (CTR) implementation, CTR collaborate initiative). As presented during the 11th Industry Standing Group meeting, the feedback received from stakeholders on the EMANS to 2028 will be discussed in a dedicated stakeholder meeting expected to be held (virtually) on the 13th of February 2025.

3. Vaccines Europe positions on the General Pharmaceutical Legislation (GPL) including future of VWP and ETF activities

Vaccines Europe shared their positions on the European Commission's legal proposal for the revision of the EU pharmaceutical legislation.

It was clarified that EMA, not being an official party to the legislative process, was not in position to comment on any of the proposals made. Vaccines Europe was encouraged to bring their comments to the European Commission and to follow the ongoing scientific discussions on platform technologies with the Quality Innovation Group and on the activities linked to the e-Product Information (ePI).

Preliminary feedback was also provided on the Vaccines Working Party (VWP) workplan highlighting the need to ensure synergies between the VWP and other relevant groups such as the Emergency Task Force (ETF), the Biologics Working Party (BWP) as well as the World Health Organisation (WHO) and the related National Immunisation Technical Advisory Groups (NITAGs). The EMA confirmed the cooperation between VWP, BWP and ETF experts. The role of ETF as advisory and support body during activities in preparation for and during a public-health emergency and its role in providing scientific advice assessment on selected pathogens was clarified. Interactions with other stakeholders as well as with European and international organisations were also noted.

4. EMA-ECDC-Vaccines MAHs cooperation update

Vaccines Europe flagged the need to enhance the dialogue on health priorities, potential new threats, and exchange of knowledge and information on the vaccines pipeline between relevant authorities including NITAGs and the European Centre for Disease Prevention and Control (ECDC).

The EMA acknowledged the points made and confirmed collaboration with ECDC on vaccines related topics.

5. EMA International Reliance activities of relevance to Vaccines and impact in relation to Post Approval Changes (PACs)/LCM and new application

Vaccines Europe stressed the benefits of international reliance in ensuring global vaccines supply and Chemistry Manufacturing and Control (CMC) changes and acknowledged the benefits of having the EMA focus group on regulatory reliance established as part of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

The Agency acknowledged the importance of reliance activities and flagged already established systems such as the Mutual Recognition Agreements (MRA), reliance pilots on post approval changes, ICMRA pilots on collaborative assessment and inspections, clusters collaboration.

Vaccines Europe members were encouraged to share adequately redacted assessment reports with other international regulators in order to facilitate reliance.

6. Periodic strain update and guidelines status for COVID-19 and seasonal Influenza and global harmonisation

Vaccines Europe welcomed the consultation on the Concept paper on the revision of the COVID-19 vaccines guidance documents and highlighted the need for additional guidance on submission and procedural requirements for Covid-19 vaccines and annual strain update.

The EMA informed of upcoming plans to issue guidance on mRNA vaccines and encouraged Vaccines Europe members to use the early engagement tools and identify any gaps or challenges to build the necessary network support.

7. Summary of follow up items and close of meeting

Both parties acknowledged the importance of discussing vaccines related challenges experienced by industry stakeholders and potential solutions enabling availablity of innovative vaccines to patients.