27 November 2023
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Highlights second EMA-Vaccines Europe bilateral meeting

27 November 2023 - Chaired by Marie-Hélène Pinheiro

1. Welcome and introduction

The EMA Executive Director and the Chair welcomed all participants, highlighting the importance of Vaccines Europe's views on the topics planned for discussion given their impact to vaccines authorisation, and expressed support in exploring solutions as required.

Vaccines Europe welcomed the opportunity to bring to the EMA their members' perspectives and positions especially in the context of the fast evolving innovation and technologies advancements and the upcoming new EU pharmaceutical Legislation.

2. Vaccines Europe Strategy for 2024-2026

Vaccines Europe's 2024-2026 strategy was presented, highlighting the vision to "foster innovation & value recognition of life course immunisation in Europe to protect people against evolving health challenges". Vaccines Europe's four strategy objectives and related enablers have the aim to ensure a future strong pharmaceutical industry. The importance of prevention through immunisation, the role of vaccination in AMR and the therapeutic advances of vaccine development was highlighted. The need for cooperation with EMA on several aspects linked to new vaccines manufacturing and adapted regulatory framework was considered key to the fast evolving vaccines and technology pipeline.

3. Vaccines Europe Pipeline Review - 2nd edition: presentation and discussion about submission predictability

An updated snapshot of upcoming vaccines' pipeline was provided, highlighting a noticeable shift in development of candidates in the field of respiratory diseases (mainly combo-vaccines), resistant pathogens (i.e., antimicrobial resistance candidates, at this regards the publication of Vaccines Europe White Paper on the role of vaccination in the fight against antimicrobial resistance was noted), technology platforms, therapeutic vaccines and monoclonal antibodies. The need to support innovation against emerging threats was highlighted.

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The EMA acknowledged the trends presented and flagged the importance of early engagement with Vaccines Europe affiliated members through business pipeline meetings, scientific advice etc. EMA also emphasised the mutual benefits and needs to increase submission predictability and applicant's dossiers maturity in order to ensure adequate EU Network expertise and resources' allocation; in that respect, clarifications on the EMA recent changes to the Letter of Intent (annex) submission context and rationale was given by EMA together with its date of coming into effect as of 1st January 2024.

4. Vaccines Europe report on "Improving the Attractiveness of the Vaccines Industry in the European Union": presentation and strategic discussion on several regulatory issues, incl. RWE on vaccines

According to Vaccines Europe, although the EU showed global leadership in vaccines arena during the COVID-19 pandemic, the current trends are showing a decline in the share of global vaccines clinical trials and innovation. EMA highlighted the current developments and support available for clinical trials topics and encouraged Vaccines Europe to take part in all the multi-stakeholder available initiatives, including those foreseen for the implementation of the Clinical Trial Regulation and Accelerating Clinical Trials in the EU (ACT EU) workplan.

EMA provided clarifications on the Vaccine Monitoring Platform (VMP) and its research agenda agreed with the European Centre for Disease Prevention and Control (ECDC). The main goal of the VMP is the generation of independent, EU-funded, Real World Evidence (RWE) on vaccine safety and effectiveness. Additional activities aiming at further developing a framework for vaccine RWE are ongoing (e.g., through DARWIN EU®).

5. VE position on EC public consultation on General Pharmaceutical Legislation: EMA governance (Vaccine WP future), TEMA, INN for vaccines, master file for platform technology, AMR, etc

Vaccines Europe views on the proposed Reform of the EU Pharma legislation were presented with focus on impact on vaccines industry sector.

The EMA acknowledged the points made and expressed openness to further discuss specific examples. The need to ensure retention of expertise and sharing of information especially on novel technologies (also with the Quality Innovation Group, Biologic and Quality Working Parties) was stressed.

The EMA welcomes the publication of the European Commission's legal proposal for the revision of the EU pharmaceutical legislation and the EMA Executive Director stated that this revision is a unique opportunity to reshape medicines regulation in the EU and make the EU regulatory framework fit for purpose for the next 20 years, taking account medicines, vaccines and technologies' advances, to promote greater access to medicines for patients and to address the major public health challenges of the future. It was also clarified that EMA, not being an official party to the legislative process, will therefore not comment on any of the proposals made but referred Industry stakeholders to the European Commission and thanked Vaccines Europe for sharing their positions.

EMA has not yet started any formal activities related to the implementation of future changes linked to the revision of the pharmaceutical legislation and has not yet started engaging directly with

stakeholders. Once preparations for the implementation begin, EMA will involve relevant stakeholders as needed.

6. Vaccines Europe update on public health emergency preparedness framework and interaction activities with HERA

Vaccines Europe presented an update on the collaboration with Health Emergency Preparedness and Response Agency (HERA) highlighting the need for more concrete and streamlined approaches. EMA asked for more transparency on activities where there could be possible interlinks.

7. Timely strain selection and framework for COVID vaccines

The ongoing EMA activities on the identification of a global framework for the yearly strain announcement for COVID-19 vaccines was discussed, flagging the importance for Industry stakeholders to participate and provide input on the challenges experienced when working on vaccines candidates update and their commercial batch scale up.

8. International cooperation/alignment

EMA leadership at international level was recognised. The recent extension of the Opening procedures at EMA to non-EU authorities (OPEN) initiative to other products was welcomed by Vaccines Europe who expressed interest in participating. In order to enable international regulatory alignment through OPEN, EMA stressed the importance of a globally aligned regulatory strategy and acknowledge the value of having preliminary dialogues with applicants.

Vaccines Europe expressed interest in the African Medicines Agency given overlapping projects. EMA invited Vaccines Europe to provide their key contribution by taking part in the planned future pilot phases which are expected to focus on a continental approach for medicine valuation and Good Manufacturing Practices (GMP) inspections.

9. AOB

N/A

10. Summary of follow up items, Close of meeting

Both parties welcomed the open exchange and acknowledged the importance to maintain the fruitful interactions on all the common areas.