EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Stakeholders and Communication Division

# First EMA – Vaccines Europe bilateral meeting

## 28 November 2022, Hybrid meeting

Chair: Marie-Helene Pinheiro (EMA)

### 1. Welcome and introduction

EMA Executive Director welcomed the participants and highlighted the timeliness of this meeting in view of the intense past- and current year(s) of particular engagement with Vaccines Europe and some of Vaccines Europe's members during the COVID-19 pandemic period.

### 2. Overall interaction between EMA and VE

- Vaccines Europe presented its short and long-term priorities, in the context of its vaccines' pipeline development perspective, yet highlighting some challenges in terms of European clinical trials performance compare to other regions. In addition, some specific concerns related to the review of the Pharmaceutical Legislation and the EU HTA Regulation were shared.
- In terms of EMA and Vaccines Europe interactions, it was agreed to set up bilateral meetings on an annual basis to continue strategic and corporate discussions .
  In addition, technical and scientific interactions with relevant EMA staff and EU Network should be accommodated within existing fora such as the Vaccine, Biologic and Quality Working Parties - interested Party meetings and/or the Quality Innovation Group, the Emergency Task Force industry Ad Hoc interaction, ISG meetings, etc as appropriate.

### 3. Recent learnings on regulation of vaccines in the EU

- Vaccines Europe presented COVID-19 pandemic learnings and highlighted priority interests such as:
  - the value of **Electronic Patient Information Leaflet (ePIL)** to sustain vaccines supply in Europe was highlighted and the possibility of vaccines to be part of the upcoming ePI pilot planned for 2023 was also noted.
  - The labelling flexibilities and the adoption of common packs for COVID-19 vaccines during the pandemic were considered useful and potentially beneficial for the quick supply of EU markets. It was clarified, however, that allowing an **EU common pack for vaccines**, as a standard practice, is not currently within the intentions of the Member States; this measure should be considered only under exceptional circumstances. A change of the current EU legal framework is required to allow such proposal.
  - Vaccines Europe expressed concerns about the **Genetically Modified Organisms (GMOs) legislation requirements, valued its waivers during the pandemic and highlighted** that if not maintained and/or simplified in the future pharmaceutical Legislation, this may become an obstacle to development and approval of innovative vaccines.

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- Finally, Vaccines Europe highlighted the importance of any review of the **Vaccine definition** in the legislation , looking at harmonisation, while not pre-empting innovative developments and to have a broader scope

- Discussion and exchanges also took place in relation to :
  **- experiences of Rolling review/expedite review** during pandemic crisis period; consideration on its future should be made taking into account long term sustainability and impact on EU expert network capacity and resources.
  - the **Emergency use authorisation**.
  - the **Variation regulation revision** that Vaccines Europe supports in terms of simplification for vaccines life cycle changes maintenance.

## 4. International cooperation/alignment

- VE acknowledged EMA leadership on fostering global harmonisation and convergence in general.

- Information was shared by EMA on status of **ICMRA (International Coalition of Medicines Regulatory Authorities)** pilots' status following call to industry (June 2022). It was clarified that a pilot has started with a narrow scope (biotech/small molecules) however there could be a possible extension to vaccines once more knowledge is available and subject to the experience of the pilot.

- Vaccines Europe also highlighted the benefit of the international **hybrid inspections** used during the pandemic.

- The Agency confirmed its commitment to promote dialogue and reliance which increased during the pandemic at the time of vaccines approval and also during the post authorisation lifecycle phase. EMA confirmed the value of sharing information of successful reliance and also non-reliance of EU Marketing authorisation by non-EU countries and confirmed that Inspection reliance is already in place through the Mutual Recognition Agreement with some Authorities and is used not only in time of crisis.

- EMA clarified that currently four areas included in the **OPEN pilot initiative**: are antimicrobial resistance, collaborative assessment of CMC, PRIME products, COVID-19 learnings/future public health emergencies and stressed the importance of stakeholders feedback.

- Some exchanges took place in relation to **new platform technologies** at global level, and it was highlighted that prior to the pandemic arose, these were already part of scientific discussions on PRIME tool guidance and concept of prior knowledge. In a future revision of the PRIME toolbox guidance, focus can be given to post authorisation lifecycle experience and the scientific principles used.

- Finally, EMA informed industry that guidance alignments with FDA have taken place on several aspects such as control strategy, validation approaches, stability models and some GMP aspects. In addition, the BWP workplan foresees start of work on RNA guidance which can also serve as a mechanism for increased alignment with global regions through comments and consultations.

- EMA informed also about the established of the Quality innovation Group (QIG) (add link web announcement).to support innovative manufacturing approaches, which will also help discussion at global level.

## 5. The expanded mandate of EMA and its impact on vaccines

- In relation to extended mandate and impact that the system being set up, EMA acknowledged that the current IT system limitations and welcome Vaccines Europe members participation to the Industry Standing Group (ISG) operational group to share its experiences. It was also clarified that, in accordance with the regulation, Industry is expected to provide information on stock, supply and demand. EMA invited VE to raise awareness amongst members on the need to provide complete data in order to be able to identify early supply shortage.
- On EMA involvement with the list of critical medicines beyond pandemic, EMA clarified that the current involvement is on crisis preparedness and management. Any future evolution will be built based on this experience and European Commission structured dialogue.

## 6 Cooperation between EMA, HERA, and ECDC

- Vaccines Europe acknowledged the close cooperation between EMA, European Health Emergency Preparedness and Response Authority (HERA) and European Centre for Disease Prevention and Control (ECDC) and enquired on how the interactions are being established. EMA confirmed that the framework of interaction with HERA is being established with the view of maximising synergies and avoiding duplications. Any perceived duplication should be flagged to the Agency.

## 7. Efforts taken to address vaccine hesitancy

- EMA confirmed its concern on the level of mistrusts and hesitancy toward vaccines and is working actively to identify and address issues proactively. Relevant and appropriate interaction(s) with Industry is also important. EMA advocates for the use fact-based science and adequate/meaningful communication.
- EMA flagged how early publication of interim results from companies may create additional confusion if not properly coordinated with authorities. In addition, transparency on clinical study data, was also highlighted as an important element for trust.
- Vaccines Europe underlined that confidence in vaccines is about confidence in the complex vaccination system from in governments, public health authorities and HCPs and vaccine manufacturers. There is no place for silos and more can be achieved together with consistency in messaging.

## 8.AOB

No AOB raised.

## Wrap up / end of meeting

The chair concluded the meeting by thanking Vaccines Europe open and direct with concrete proposals and follow-up actions identified. This being a clear demonstration of the need to continue the interactions and exchanges until next year annual meeting.