EMA public stakeholder meeting

on COVID-19 vaccines and therapeutics in the EU

25 November 2021, 13.00 – 15.15 (CET)

VIRTUAL MEETING, THE EVENT WILL BE BROADCAST LIVE

Background and objectives

While we have a number of vaccines and therapeutic products already authorised for use in the EU, EMA continues to rapidly assess data on promising new candidates, with several marketing application evaluations ongoing.

EMA, together with the EU medicines regulatory network, also continues to monitor the safety and efficacy of these medicines, especially in the context of new variants.

Looking ahead, the Agency is evaluating emerging data to extend the use of vaccines, including data to support extra doses and use in younger age groups.

Transparency remains a high priority for EMA and regular updates for the public will continue to be provided.

EMA is organising this open event to:

- Provide an update of COVID-19 therapeutics and vaccines in the EU, including vaccine effectiveness, and the use of booster and third dose in national vaccination campaigns
- Present an update on vaccine safety information
- Highlight the COVID-19 epidemiological situation and vaccination coverage in the EU
- Address misinformation on COVID-19 vaccines
- Listen to the public and stakeholders on their needs, expectations and any concerns.

Please feel free to ask questions during the meeting by connecting to www.sli.do using **#EMAPublicMeeting4**

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Chaired by Fergus Sweeney (EMA)

Introduction

12:45 – 13:00	**Joining and technical checks**	**15'**
13:00 – 13.05	**Opening remarks** *Emer Cooke (EMA Executive Director)*	**5'**
13:05 – 13.10	**Welcome and introduction** *Fergus Sweeney (Head of Clinical Studies and Manufacturing Task Force, EMA)*	**5'**

Approval of COVID-19 vaccines and therapeutics in the EU

13:10 – 14:10	**Update on approved and candidate COVID-19 vaccines and therapeutics** *Marco Cavaleri (Head of Biological Health Threats and Vaccines Strategy, EMA)* **Update on vaccine safety monitoring** *Georgy Genov (Head of Pharmacovigilance, EMA)* **COVID-19 surveillance and vaccination coverage in the EU** *Piotr Kramarz (Deputy Head of Unit and Deputy Chief Scientist, ECDC)* **Addressing misinformation on COVID-19 vaccines** *Melanie Carr (Head of Stakeholders and Communication Division, EMA)*	**60'**
14:10 – 14:15	**Break**	**5'**

Public session with panel experts *(moderated by Fergus Sweeney)*

14:15 – 15:00	**Comments and questions from the public** *Emer Cooke (Executive Director, EMA)* *Marco Cavaleri (Head of Biological Health Threats and Vaccines Strategy, EMA)* *Georgy Genov (Head of Pharmacovigilance, EMA)* *Piotr Kramarz (Deputy Head of Unit and Deputy Chief Scientist, ECDC)* *Melanie Carr (Head of Stakeholders and Communication Division, EMA)* *Peter Arlett (Head of Data Analytics and Methods, EMA)*	**45'**

Conclusion

15:00 – 15:15	**Wrap up and end of meeting** *Fergus Sweeney (Head of Clinical Studies and Manufacturing Task Force, EMA)*	**15'**