



EMA public stakeholder meeting on the approval, safety monitoring and impact of COVID-19 vaccines in the EU

26 March 2021, 13.00 – 15.15 (CET)

VIRTUAL MEETING, THE EVENT WILL BE BROADCAST LIVE

Background and objectives

EMA is continuing to rapidly evaluate applications for new COVID-19 vaccines, and data from promising vaccine candidates. As a result, several such vaccines have already been authorised for use in the EU. Having multiple vaccines approved is expected to increase availability and provide more options to different population groups in the EU Member States, hence supporting vaccination campaigns across the Union.

As new coronavirus variants emerge, EMA is also working to address any potential threat derived from the new variants. This includes developing guidance for manufacturers on how to change existing COVID-19 vaccines to tackle new virus variants.

Together with the EU regulatory network, EMA continues to collect and assess data on the vaccines already in use to ensure they remain safe and work as expected. EMA will also continue to be transparent about its work with COVID-19 vaccines and will provide the public with regular updates.

This third public meeting will provide an update to EU citizens about the continued assessment, approval and safety monitoring of COVID-19 vaccines, as well as their expected impact at community level. This public event will:

- Give an overview of COVID-19 vaccines approved in the EU and those which are currently under review
- Provide an update of post-authorisation activities, including emerging safety data since EU authorisation of the first COVID-19 vaccines, and ongoing work to address new variants
- Provide an overview on the expected impact of COVID-19 vaccination on our society
- Update on transparency and publication of clinical data for COVID-19 vaccines
- Allow the public and stakeholders to further inform us of their needs, expectations and any concern



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Chaired by Noël Wathion (EMA)

Introduction

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| 12:45 – 13:00 | Joining and technical checks | 15' |
| 13:00 – 13:05 | Opening remarks <i>Emer Cooke (EMA Executive Director)</i> | 5' |
| 13:05 – 13:10 | Welcome and introduction <i>Noël Wathion (EMA Deputy Executive Director)</i> | 5' |

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| 13:10 – 14:10 | Update on approved and candidate COVID-19 vaccines in the EU <i>Marco Cavaleri (Head of Biological Health Threats and Vaccines Strategy, EMA)</i> | 60' |
| | Vaccines safety monitoring – update on emerging data since EU authorisations <i>Peter Arlett (Head of Data Analytics and Methods, EMA)</i> | |
| | Expected impact of COVID-19 vaccination in the European Union <i>Edoardo Colzani (Principal Expert Vaccine-Preventable Diseases, ECDC)</i> | |
| | Transparency and publication of clinical data for COVID-19 vaccines <i>Melanie Carr (Head of Stakeholders and Communication Division, EMA)</i> | |
| 14:10 – 14:15 | Break | 15' |

Public session with speakers and panel experts

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| 14:15 – 15:00 | Comments and questions from the public | 45' |
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Conclusion

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| 15:00 – 15:15 | Wrap up and end of meeting <i>Noël Wathion (EMA Deputy Executive Director)</i> | 15' |
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