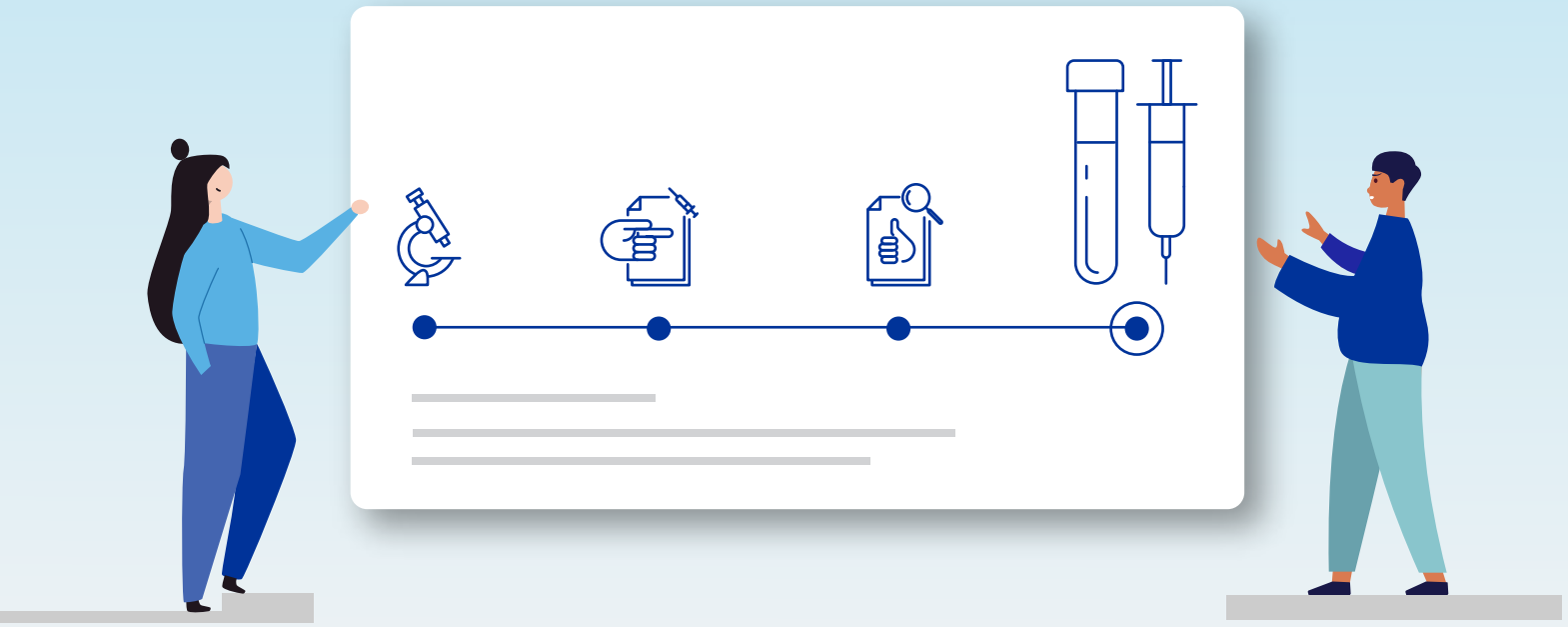

# EMA public stakeholder meeting

## on the approval and roll-out of COVID-19 vaccines in the EU

**08 January 2021, 13.00 – 15.15**

VIRTUAL MEETING

## Background and objectives

Together with the EU regulatory network, EMA has been working around the clock to bring much needed COVID-19 vaccines to EU citizens as quickly as possible, while keeping the same rigorous standards of approval as for all vaccines.

EMA is convening a second public meeting to provide detailed information to EU citizens about the assessment, approval and roll-out of new COVID-19 vaccines.

The COVID-19 pandemic has caused suffering and hardship for many people across the world. In only eleven months, thanks to the joint efforts of scientists, doctors, developers, regulatory experts as well all the volunteers participating in large scale studies, new vaccines have been developed and submitted for marketing approval.

This meeting will be an opportunity to inform about the data underpinning the approval of new vaccines and the subsequent steps towards a rapid distribution to the public.

EMA is organising this open event to:

- Explain the basis for the approval and use of the new vaccines and how the safety of the vaccines will be assured;
- Provide information on the role of the European Commission and the national public health authorities on the roll-out of the vaccines;
- Listen to the public and stakeholders on their needs, expectations and any concerns.

**This event will be broadcast live.**

# EMA public stakeholder meeting on COVID-19

*Chaired by Noel Wathion (EMA)*

## Introduction

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| **12:45 – 13:00** | **Joining and technical checks** | **15'** |
| **13:00 – 13.05** | **Opening remarks**<br>*Emer Cooke (EMA Executive Director)* | **5'** |
| **13:05 – 13.10** | **Welcome and introduction**<br>*Noel Wathion (EMA Deputy Executive Director)* | **5'** |

## Approval and roll-out of COVID-19 vaccines in the EU

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| **13:10 – 14:10** | **Basis for the EU approval of new vaccines**<br>*Harald Enzmann (Chair of human medicines committee: CHMP)* | **60'** |
| | **How the safety of the new COVID-19 vaccines will be monitored**<br>*Sabine Straus (Chair of safety committee: PRAC)* | |
| | **The European Commission's role in the authorisation process and facilitation of roll-out vaccination**<br>*John Ryan (Director for Public Health, DG SANTE, EC)* | |
| | **Ongoing actions for roll-out vaccination at national level**<br>*Nikolai Brun (on behalf of Heads of Medicines Agencies)* | |
| **14:10 – 14:15** | **Break** | |

## Public session with speakers and panel experts

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| **14:15 – 15:05** | **Comments and questions from the public**<br>***Panel experts:***<br>*Melanie Carr (Head of Stakeholders and Communication Division, EMA)*<br>*Fergus Sweeney (Head of Clinical Studies and Manufacturing, EMA)*<br>*Peter Arlett (Head of Data Analytics and Methods, EMA)*<br>*Marco Cavaleri (Head of Biological Health Threats and Vaccines Strategy, EMA)* | **50'** |

## Conclusion

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| **15:05 – 15:15** | **Wrap up and end of meeting**<br>*Noel Wathion (EMA Deputy Executive Director)* | **10'** |