EMA public stakeholder meeting on COVID-19

How safe and effective vaccines are developed and authorised in the EU

11 December 2020, 13:00 – 16:30 (CET)

VIRTUAL MEETING

Background and objectives

The scale of the COVID-19 public health crisis has led to unprecedented efforts by all those involved in the development and regulation of vaccines and other medicines to treat and prevent COVID-19.

EMA and the national competent authorities have diverted resources to expedite advice and evaluation processes, applying the same high regulatory standards in terms of pharmaceutical quality, safety and efficacy. Every effort has been made to provide a high level of transparency.

To provide further insight into the ongoing work on COVID-19 vaccines, EMA is organising an open event with the following objectives:

- To inform the public and stakeholders about the EU regulatory process for approval of COVID-19 vaccines and on EMA's role in their development, evaluation and approval;
- To listen to the public and stakeholder groups on their needs, expectations and any concerns, so that these can be considered in the relevant regulatory processes.

Some aspects of COVID-19 vaccines that are relevant to the public such as access and vaccination campaigns, lie outside the remit of EMA and will not be covered in this event. However, this meeting is an opportunity to share information and views on those aspects that are part of EMA's responsibilities.

This event will be broadcast live.

EMA public stakeholder meeting on COVID-19: how safe and effective vaccines are developed and authorised in the EU

Chaired by Noël Wathion (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** Noël Wathion (EMA Deputy Executive Director)	**5′**

Development, evaluation and approval of COVID-19 vaccines

13:10 – 14:25	**How are COVID-19 vaccines developed?** Marco Cavaleri (Head of Biological Health Threats and Vaccines Strategy) **EU's regulatory process for evaluation and approval of vaccines** Fergus Sweeney (Head of Clinical Studies and Manufacturing) **Safety monitoring of COVID-19 vaccines** Peter Arlett (Head of Data Analytics and Methods) **Transparency, engagement and communication** Melanie Carr (Head of Stakeholders and Communication)	**75′**
14:25 – 14:30	**Break**	**5′**

Public interventions

14:30 – 16:15 (4 minutes each)	**Patients/Carers** *Speaker 1* **Marilena Vrana**, European Heart Network (EHN), Belgium *Speaker 2* **Peggy Maguire**, European Institute of Women's Health (EIWH), Ireland *Speaker 3* **François Houÿez**, European Organisation for Rare Diseases (EURORDIS), France	**105′**

Consumers/Citizens

Speaker 4

Ancel·la Santos, The European Consumer Organisation (BEUC), Belgium

Speaker 5

Michèle Rivasi, Member of European Parliament, France

Speaker 6

Norbert Oberndorfer, Austria

Speaker 7

Phanos Anastasiou, Netherlands

Industry

Speaker 8

Sue Middleton, Vaccines Europe, Belgium

Healthcare professionals

Speaker 9

Tjalling van der Schors, European Association of Hospital Pharmacists (EAHP), Netherlands & Ilaria Passarani, Pharmaceutical Group of the European Union (PGEU), Belgium

Speaker 10

Angeliki Ladia, Private Geriatric Clinic Evagelistria, Greece

Speaker 11

Tiago Villanueva, European Union of General Practitioners (UEMO), Portugal & Sally Kendall, European Forum for Primary Care (EFPC), United Kingdom

Speaker 12

Sandra Alexiu, Bucharest Association on Family Doctors, Romania

Speaker 13

Ole Weis Bjerrum, European Hematology Association (EHA), Denmark

Academics

Speaker 14

Nikolas Dietis, University of Cyprus, Cyprus

Speaker 15

Carlos Alberto Guzman, Helmholtz Centre for Infection Research GmbH, Germany

Conclusion

16:15 – 16:30	**Wrap up and end of meeting** Noël Wathion (EMA Deputy Executive Director)	**15'**