Meeting of the EU scientific advice platform on COVID-19

Meeting Report

Thursday 03/12/2020 at 15:30

1. COVID-19 vaccines - State of play and next steps

Commissioner Kyriakides updated participants on the EU Strategy for COVID-19 vaccines. Contracts have been signed with six companies: Astra Zeneca, Johnson & Johnson, Sanofi, mRNA BioNtech/Pfizer, Curevac and Moderna. They aim at ensuring access to safe and effective vaccines for EU citizens and the world as early as possible. Rolling reviews started for three vaccines. Commissioner Kyriakides also updated participants on the discussions at the Health Council the day before, where Member States confirmed their willingness to proceed jointly with a European approach towards a conditional marketing authorisation for COVID-19 vaccines.

Emer Cooke, Director of the European Medicines Agency (EMA), updated the platform on the work of the EMA on COVID-19 vaccines, notably on the agency's role regarding marketing authorisations for future vaccines. Four rolling reviews are ongoing. These ensure that EMA receives data as it is generated. These data are subject to a provisional review, which gives a head start, and helps accelerate the formal evaluation process once it is launched.

The formal process for marketing authorisations started for the BioNTech/Pfizer vaccine (EMA opinion expected by 29/12) and Moderna (EMA opinion expected by 11/1). Ms Cooke informed the platform about the peer review process undertaken by a scientific committee, and how the process has been streamlined without compromising on its rigour. EMA is strongly committed to an independent scientific process. Its assessment and subsequent opinion will be exclusively based on the strength of the quality, safety and efficacy data provided in the applications.

Ms Cooked informed the panel about the specificities of the *conditional* marketing authorisation which is pursued for the first two vaccine candidates. This procedure is designed to provide an authorisation at the earliest point in time when we are confident that the benefits of a vaccine clearly outweigh its risks. Conditional authorisations are limited to one year and include specific obligations to the applicant, such as the timely provision of additional data. The requirements for manufacturing are subject to the same controls as for normal authorisations, with the additional provision of submitting some of the data post-approval when in emergency context.

EMA also informed about how post-marketing monitoring is also being ramped up. Safety will be rigorously monitored through pharmacovigilance, while ECDC and EMA are setting up a platform for the monitoring of the coverage, effectiveness and safety of COVID-19 vaccines. Additional observational studies will help collect data on effectiveness in real use conditions in the population.

Finally, EMA expressed a strong commitment to transparency. The agency will publish its complete assessment report as well as the full clinical trial results that underpin any conditional marketing authorisation. A public stakeholder meeting is scheduled on 11/12 and such will likely be repeated in the future.

Experts from the platform and EMA exchanged views on the approaches of different regulatory bodies, on the properties of different vaccines and on aspects to be considered by public health authorities to refine recommendations on the use of different vaccines in different population groups.

2. COVID-19 vaccination - National strategies for vaccine deployment

Members of the platform exchanged on their national plans for the deployment of COVID-19 vaccines. Several Member States have adopted a national plans and others are in the process of developing it. These plans notably identify priority groups for vaccination which are largely similar across countries, typically consisting of older age groups (including persons in nursing homes), healthcare workers and persons with underlying conditions.

Deployment plans typically consider different phases over time as the amount of vaccine doses available grows. Many countries intend to use existing vaccination structures and delivery services as much as possible, while sometimes bringing in additional support (e.g. through procurement or involvement of other parties such as NGOs or the military).

Experts also discussed the preparatory work underway in Member States to ensure that vaccination can start as soon as possible once a vaccine receives a marketing authorisation. Experts shared experiences in setting up the logistics for vaccination campaigns, considering also the specificities of certain vaccines (e.g. in terms of cold chain) or the fact that public health staff is already under strain due to other COVID-related activities (such as contact tracing).

3. COVID-19 vaccination - Strategic communication plan on vaccines and vaccination

Experts briefly touched upon the issue of communication, perceived as a critical component of a vaccination campaign, especially given the increasing vaccine scepticism fuelled by misinformation on COVID-19 vaccines. Several participants referred to their communication strategies, stressing the importance of participatory approaches, trust and transparency, as well as the crucial role of healthcare workers in conveying messages on vaccination.

The benefit of EU-level action was mentioned, in particular to tackle misinformation on vaccines. While each country is different, vaccine hesitancy and anti-vaccine messages present similar characteristics across borders which could warrant the development of a common approach.

The next meeting of the platform is scheduled on 17/12 at 17:00 CET. The agenda will focus on preparedness for and communication on COVID-19 vaccination, including a presentation by the Commission on a common European strategy on communication and misinformation. EMA and ECDC will also be invited to provide latest updates.

Participation

Platform participants:

1. Professor Markus MÜLLER (Austria)
2. Professor Steven VAN GUCHT (Belgium)
3. Dr. Angel KUNCHEV (Bulgaria)
4. Professor Alemka MARKOTIC (Croatia)
5. Dr Zoe PANA (Cyprus)
6. Dr Roman CHLIBEK, Marika MADAROVA (Czechia)
7. Professor Irja LUTSAR (Estonia)
8. Professor Taneli PUUMALAINEN (Finland)
9. Professor Arnaud FONTANET (France)
10. Dr. Hans-Ulrich HOLTHERM (Germany)
11. Mr Miklós SZOCSKA (Hungary)
12. Mr. Ronan GLYNN (Ireland)
13. Professor Silvio BRUSAFERRO (Italy)
14. Professor Uga DUMPIS (Latvia)
15. Professor Edita FYI SUZIEDELIENE (Lithuania)
16. Dr Charles MALLIA AZZOPARDI (Malta)
17. Dr Aura TIMEN (The Netherlands)
18. Professor Andrzej HORBAN (Poland)
19. Professor Henrique DE BARROS (Portugal)
20. Mrs Diana Loreta PAUN (Romania)
21. Mr. Milan KREK (Slovenia)
22. Mr. Fernando SIMÓN (Spain)

European Commission:

- Commissioner Stella KYRIAKIDES (Chair)
- Prof. Peter PIOT, Special Advisor to the President of the European Commission
- Director General Sandra GALLINA, DG SANTE
- Giorgos ROSSIDES, Head of Cabinet of Commissioner Kyriakides
- Roberto REIG RODRIGO, Member of Cabinet of Commissioner Kyriakides
- Ines PRAINSACK, Member of Cabinet of Commissioner Kyriakides
- Tove ERNST, Member of Cabinet of Commissioner Kyriakides
- Chrystalla PAPANASTASIOU, Member of Cabinet of Commissioner Kyriakides
- Jeremy BRAY, Secretariat General
- Dana SPINANT, Deputy Chief Spokesperson, DG COMMUNICATION
- Roser DOMENECH AMADO, Head of Unit, DG SANTE
- Nicolas PRADALIE, Policy Officer, Secretariat General
- Thomas VAN CANGH, Policy Assistant to Director General Gallina

ECDC:

- Dr Andrea AMMON, Director
- Dr Lucia PASTORE CELENTANO, Head of vaccine-preventable diseases programme

EMA:

- Emer Cooke, Executive Director
- Marco Cavaleri, Head of Biological Health Threats and Vaccines Strategy
- Spiros Vamvakas, Head of Scientific Advice