Meeting of the EU scientific advice platform on COVID-19

Meeting Report

Thursday 7/01/2021 at 17:00

1. COVID-19 vaccines - Epidemiological update by ECDC

Vaccination roll out has started, important game changer.

ECDC updated participants on the <u>epidemiological situation</u>. Indicators so far can be affected by delays due to the holiday season.

Only Norway and Iceland have not a serious concern situation. Decreasing trends but at high level. Two countries with increasing trends. Seven countries continue to report increasing death rates. Nine countries with increases in hospitalisations. Widespread transmission, no signs that public health measures can be lifted.

Regarding the UK variant, the ECDC referred to its risk assessment published in December. The variant has higher transmissibility in all age groups. The variant has been reported so far in 17 countries.

The Commissioner stressed the importance of maintaining close monitoring and strong measures. It was requested to share all sequencing information with the ECDC.

2. COVID-19 vaccination – State of play by EMA and DG SANTE

EMA provided an update on the marketing authorisation process of different vaccine candidates. Conditional marketing authorisation have been granted to BioNTech/Pfizer and Moderna. The latter was authorised yesterday and the roll out will begin in the weeks.

In addition, two rolling reviews are ongoing, for the AstraZeneca/Oxford and Johnson & Johnson vaccine candidates.

The application for conditional marketing authorisation from AstraZeneca/Oxford should arrive on Monday 11 January. Johnson & Johnson CMA application is expected in mid-February.

Regarding the number of doses, the BioNTech/Pfizer initial authorisation was for 5 doses per vial, after additional information received it appears 6 doses can be extracted. The product information for this vaccine has been official updated and now the vials are 6-dose.

Regarding the dosing schedules, there have been questions on the interval between two doses. For BioNTech/Pfizer, the interval has been established as 21 days, during the clinical trials there was an interval window from 18 to 42 days.

In the case of Moderna the interval is set at 28 days while the clinical trials had an interval window from 25 to 35 days.

In order to support longer intervals, more data would be needed.

The Platform discussed several other technical issues related to the vaccines and the new variants.

The Commission requested official transmission by Member States of vaccination numbers to the ECDC and the Health Security Committee.

3. COVID-19 vaccination – EU Clinical Trials Network

The Commission presented its work regarding the EU COVID-19 vaccines Clinical Trials Network.

The already established <u>COVID-10 data sharing portal</u> has gathered more than 110.000 users, and 130.000 publications available.

A COVID-19 vaccines clinical trial network is being established to connect clinical trial platforms across the EU. It will be up and running in two months, it is being coordinated by Germany.

It will provide basis to address questions such as optimal use of vaccines in limited availability, possibility of vaccinating with combination of vaccines, possibility of revaccination with different vaccines.

In addition, the "Orchestra project" is a cohort study that will identify and enrol 300.000 people (COVID-19, healthcare workers, vulnerable population, etc.). By taking samples and measurements at regular intervals, the project will provide information on vaccination strategies.

Invitation to the Platform to input in the design and work of the clinical trials and Orchestra work.

A short note describing the above projects will be circulated.

4. COVID-19 vaccination – Update on proof of vaccination

The Commission outlined the work regarding the COVID-19 proof of vaccination at EU level. The purpose is to have a single common identifier. This will allow compatibility of the information across all Member States.

The Platform discussed the implementation issues surrounding proof of vaccination. The use of proof of vaccination should be up to each Member State.

5. Conclusions and suggestions for future agenda points

Commissioner Kyriakides thanked all platform participants, ECDC and EMA. The next meeting will take place on 21 January 2021 at 17:00.

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. Dr Helene Bilsted PROBST (Denmark)
- 8. Professor Taneli PUUMALAINEN (Finland)
- 9. Professor Arnaud FONTANET (France)
- 10. Dr. Hans-Ulrich HOLTHERM (Germany)
- 11. Dr. Sotiris TSIODRAS (GREECE)
- 12. Mr Miklós SZOCSKA (Hungary)
- 13. Mr Fergal GOODMAN, Ms Darina O'Flanagan (Ireland)
- 14. Professor Silvio BRUSAFERRO (Italy)
- 15. Professor Uga DUMPIS (Latvia)
- 16. Professor Edita FYI SUZIEDELIENE (Lithuania)
- 17. Dr Charles MALLIA AZZOPARDI (Malta)
- 18. Dr Aura TIMEN (The Netherlands)
- 19. Professor Andrzej HORBAN (Poland)
- 20. Professor Henrique DE BARROS (Portugal)
- 21. Mrs Diana Loreta PAUN (Romania)
- 22. Professor Pavol JARCUSKA (Slovakia)
- 23. Dr Anders TEGNELL (Sweden)

European Commission:

- Commissioner Stella KYRIAKIDES (Chair)
- Prof. Peter PIOT, Special Advisor to the President of the European Commission
- Ms Julia SPENCER, Policy Advisor to Prof. Piot
- Giorgos ROSSIDES, Head of Cabinet of Commissioner Kyriakides
- Roberto REIG RODRIGO, Member of Cabinet of Commissioner Kyriakides
- Chiara SALVELLI, Deputy Head of Cabinet of Commissioner Gabriel
- Chrystalla PAPANASTASIOU-CONSTANTINOU, Policy Assistant Cabinet of Commissioner Kyriakides
- Peter WAGNER, Secretariat General
- Nicolas PRADALIE, Secretariat General
- Jeremy BRAY, Secretariat General
- Director General Sandra GALLINA, DG SANTE
- Director General Jean-Eric PAQUET, DG RTD

- Deputy Director General Pierre DELSAUX, DG SANTE
- Cristina MODORAN, Policy Assistant to Director General Gallina
- Irene NORSTEDT, DG RTD
- Sigrid WEILAND, DG RTD
- Barbara KERSTIENS, DG RTD

ECDC

• Dr Andrea AMMON, Director

EMA

• Ms Emer COOKE, Executive Director