Meeting of the EU scientific advice platform on COVID-19

Meeting Report

Wednesday 20/01/2021 at 17:00

1. COVID-19 Epidemiological update by ECDC

ECDC provided an update on the epidemiological situation across the EU which remains extremely serious. Transmission remains active in EU countries, largely stable but at high levels, with increases observed in some Member States both in terms of case notifications and deaths. ECDC will publish updated epidemiological data as well as an updated risk assessment on SARS-CoV-2 variants of concern on 21 January. The key message of the risk assessment for Member States is to prepare for a rapid escalation of the stringency of response measures to safeguard healthcare capacity and to accelerate vaccination campaigns, in order to protect those most at risk and reduce the burden on health systems.

ECDC is also developing a dashboard for vaccine monitoring. Eleven Member States provided data so far. Commissioner Kyriakides urged Member States to share data on vaccination deployment with ECDC at least twice a week.

2. COVID-19 vaccines - State of play by EMA

EMA informed about the latest developments in the area of COVID-19 vaccines. Two vaccines have received conditional marketing authorisations in the EU so far: Pfizer-BioNTech (Comirnaty) and Moderna. These vaccines are currently being rolled out in the EU.

The revised <u>Summary of Product Characteristics</u> of the Pfizer-BioNTech vaccine formally state that a vial contains six doses. Efforts with companies to increase production capacity are also ongoing with the company.

EMA has now received a formal application for marketing authorisation from Astra Zeneca. The current tentative timetable is to finalise an opinion by 29 January.

EMA also continues to work with other developers, both at rolling review and scientific advice stages.

Reports of possible deaths associated with the Pfizer-BioNTech vaccine in elderly home in Norway are being analysed. Preliminary findings are that these deaths are not related to the vaccine. EMA continues to monitor the situation and will produce a complete pharmacovigilance report.

Finally, EMA provided brief information on intervals between vaccine doses: 3 weeks between doses for Pfizer-BioNTech and 4 weeks for Moderna, with margins of a few weeks. Since clinical trials largely adhered to the recommended schedule, there is no clinical data to support further prolonging the interval between doses beyond a few weeks. The situation

may differ and will need to be assessed for other types of vaccines (e.g. adenovirus vector). The topic will be discussed in more depth at the next meeting.

3. SARS-CoV-2 variants of concern

Several participants reported on the situation regarding variants of concern in their country. France informed about a recent initiative to get a comprehensive picture of the situation. PCR positive tests on a given day presenting an S-gene drop out (i.e. 4%) were sequenced. Of these 4%, 50% appeared to be the B.1.1.7 (or VOC 202012/01) variant. Repeating this approach is a useful mechanism to understand the way variants are progressing and helps complement the picture gathered through the ad-hoc detection of clusters.

Belgium, currently ramping up its genomic sequencing capacity, presented similar figures, although the prevalence of the B.1.1.7 seems to be increasing.

Spain witnessed a significant increase in transmission after the holiday period, though mostly attributable to behavioural patterns rather than to the circulation of variants of concern. Interestingly, the incidence of COVID-19 cases among people over 65 years old residing in nursing homes is now lower than for the same age group outside nursing homes. This could point to early positive signs of the impact of vaccination, already after 1 dose. There are also early indications that outbreaks in nursing homes seem to be less severe than what was witnessed before.

The Netherlands also observe outbreaks of the B.1.1.7 variant both in schools and nursing homes. Sentinel surveillance data shows that new variant strains now represent 5% of cases. Modelling shows this proportion is likely to increase dramatically in the coming months.

Overall, experts from EU Member States insisted on the importance of monitoring closely the emergence and circulation of variants and confirmed that detection and sequencing efforts are being scaled up.

Participants briefly exchanged on the need for vaccinated persons to continue respecting public health recommendations because of the unknowns surrounding transmission by vaccinated people (e.g. in terms of quarantine following exposure to a case). As long as we don't know whether immunised people can still transmit the disease, everyone should to follow the rules in place. In parallel, it is important to continue research on this issue and learn from countries that are more advanced in terms of vaccine deployment.

4. COVID-19 Communication: "A united front to beat COVID-19"

Commissioner Kyriakides informed participants about the content of a <u>Communication</u> prepared ahead of a discussion among European Leaders on 21 January. The Communication calls for united action focusing on four important areas: speed up vaccination and vaccine supplies, increase testing and sequencing (to 5-10% of positive samples), safeguard the functioning of the single market, and ensure European leadership and international solidarity.

President von der Leyen joined an exchange of views on the Communication with the experts from the platform. She expressed her concern regarding the current epidemiological situation, notably in relation to the variants of concern. While the deployment of vaccines is a European success story that offers an encouraging perspective, we should brace for difficult weeks ahead. President von der Leyen also enquired about the experts' views on a possible closer alignment and coordination of response measures based on common epidemiological thresholds, allowing to act as one epidemiological area. Epidemiological indicators (e.g. based on incidence rates) could be associated with similar measures across Member States in order to control the pandemic.

Experts welcomed the Communication from the Commission and provided valuable feedback. They agreed with the importance of timely vaccination rollout and of ramping up testing and sequencing capacity, in response to the appearance of new variants of concern. Several experts also spoke in favour of a better synchronisation of measures and approaches between countries. The application of comparable measures with clear activation thresholds in areas experiencing similar epidemiological situations could be a way to avoid the reintroduction of travel restrictions and internal border closure in the EU. Italy's experience with monitoring different measures applied in different situations by different regions could provide useful insights to identify appropriate sets of measures. In the future, it could also be useful to better link information from passenger locator forms with healthcare data, so that contacts can rapidly be notified as soon as a case is diagnosed. Many experts also emphasised the importance of international collaboration and solidarity, not only as a moral imperative, but also as the appropriate thing to do from an epidemiological standpoint.

President von der Leyen concluded on the importance of sustaining public health measures as vaccination is being rolled out.

5. Suggestions for future agenda points

The next meeting is scheduled on 5 February at 17:00.

Participants are invited to submit suggestions for discussion topics. Proposals include the interval between vaccine doses, and the vaccination deployment schedules.

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. Marika MADAROVA (Czechia)
- 7. Dr Helene Bilsted PROBST (Denmark)
- 8. Professor Irja LUTSAR (Estonia)
- 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 (Ireland)
- 14. Professor Silvio BRUSAFERRO (Italy)
- 15. Professor Uga DUMPIS (Latvia)
- 16. Professor Edita SUZIEDELIENE (Lithuania)
- 17. Jean-Claude SCHMIT (Luxembourg)
- 18. Dr Charles MALLIA AZZOPARDI (Malta)
- 19. Dr Aura TIMEN (The Netherlands)
- 20. Professor Andrzej HORBAN (Poland)
- 21. Professor Henrique DE BARROS (Portugal)
- 22. Mrs Diana Loreta PAUN (Romania)
- 23. Professor Pavol JARCUSKA (Slovakia)
- 24. Fernando SIMON (Spain)
- 25. Dr Anders TEGNELL (Sweden)

European Commission:

- President Ursula VON DER LEYEN
- Commissioner Stella KYRIAKIDES (Chair)
- Prof. Peter PIOT, Special Advisor to the President of the European Commission
- Ms Julia SPENCER, Policy Advisor to Prof. Piot
- Gionrgos ROSSIDES, Head of Cabinet of Commissioner Kyriakides
- Kurt VANDENBERGHE, Member of Cabinet of President von der Leyen
- Roberto REIG RODRIGO, Member of Cabinet of Commissioner Kyriakides
- Peter WAGNER, Secretariat General
- Nicolas PRADALIE, Secretariat General
- Jeremy BRAY, Secretariat General
- Deputy Director General Pierre DELSAUX, DG SANTE

- Cristina MODORAN, Policy Assistant to Director General Gallina
- Thomas VAN CANGH, Policy Assistant to Director General Gallina
- Sigrid WEILAND, DG RTD

ECDC

- Dr Andrea AMMON, Director
- Dr Piotr KRAMARZ, Public Health Event Manager

EMA

- Ms Emer COOKE, Executive Director
- Marco CAVALLERI, Head of the office Anti-infectives and Vaccines