Meeting of the EU scientific advice platform on COVID-19

Meeting Report

Thursday 18/02/2021 at 17:00

1. COVID-19 Epidemiological update

ECDC provided an update on the epidemiological situation across the EU, which remains mostly unchanged compared to the previous week. A global slowly decreasing trend is observed at EU level, which has been ongoing for 4 weeks. Seven countries still report notification rates above 500/100,000 over 14 days. All indicators are still very high, except in few countries. ECDC does therefore not recommend the easing of any measures, as indicated in its latest risk assessment.

Since 17 February, an updated version of the ECDC vaccine tracker shows more data and further developments are planned in the coming weeks. The full version should be online by mid-March. Member States currently submit data at least once a week. Yet, uploads can be done at any time (and appear online the next day).

Member States' experts shared their experience at national level.

A growing number of countries are reporting that the B.1.1.7 variant appears to be on its way to becoming the dominant strain. The B.1.351 variant is the second most frequent, although far behind B.1.1.7, present in single cases as well as in some local outbreaks. Member States are introducing strict control measures to tackle such outbreaks of variants. Overall, non-pharmaceutical interventions used against the wild type virus appear effective against circulating variants. A number of Member States reported decreasing trends in cases in spite of an increasing circulation of variants of concern.

Experts also shared their experience with vaccination and first signs of its impact. Several Member States that have reached high vaccination coverage among elderly populations or in long term care settings, start to observe reductions in cases, hospitalisations and deaths among those population groups.

2. COVID-19 vaccination – State of play

EMA is currently reviewing the application for a conditional marketing authorisation by Janssen for an adenovirus vector-based vaccine. The evaluation started on 16 February and EMA aims at issuing an opinion in mid-March. This is a one-dose vaccine, although some trials are also being conducted with a 2-dose regimen. 40,000 subjects were included in the dataset, including 25% elderly population.

Rolling Reviews are ongoing for the Curevac mRNA vaccine and the Novavax recombinant SARS-CoV-2 nanoparticle vaccine.

EMA is also actively engaged in post authorisation work on the Comirnaty and Astra Zeneca vacines, as several new production sites are being introduced.

EMA is developing guidance for manufacturers planning changes to the existing COVID-19 vaccines to tackle the new virus variants. A reflection paper should be published next week, developed in consultation with international regulators (such as FDA) to promote alignment globally on this issue. The paper addresses the clinical data to submit when developers want to update their vaccine.

EMA is in contact with representatives for the Russian Sputnik vaccine and is waiting to receive data that would allow launching a rolling review, and eventually conduct inspection once sufficient data is submitted.

Work is also ongoing to monitor the safety of vaccines that received a conditional marketing authorisation.

Experts exchanged on a range of topics such as the reactogenicity of different vaccines, the immunity conferred after one dose only, or emerging discussions on "mix and match" tactics, combining doses of two different vaccines. On the latter issue, there is insufficient data to draw any conclusion. EMA recalled that companies submitted a dossier for authorisation based on a two-dose regimen with a specific interval, and that clinical trial data showed a significant benefit of the second dose. EMA also noted that the observed reactogenicity from real world data doesn't seem to be higher than what was observed in clinical trials.

3. Presentation of the Commission's Communication adopted on 17/02

The Commission announced on 17 February its plans for an 'HERA incubator', the EU preparedness initiative to address the threat of SARS-CoV-2 variants of concern.

The initiative focuses on five aspects:

- Diagnostics, including sequencing. ECDC plays a key role in providing scientific guidance and supporting Member States with sequencing. The Commission will provide additional funding to support Member States' capacity to better sequence genomes of positive samples and detect variants
- Research to accelerate the development of new generation vaccines. 150 million will be dedicated to supporting research against variants of concern. The Commission is setting up a clinical trials network – Vaccelerate – open to all Member States and beyond. This network will be a valuable instrument for the development of the next generation of vaccines.
- Purchase agreements, which have already been a key instrument so far in the EU vaccine strategy.

- Regulatory processes. Measures are being introduced to facilitate the approval of new vaccines when they are based on existing ones. One possibility to be explored will be the possibility to have an EU-level emergency authorisation scheme.
- Industrial capacity. The Commission will promote cooperation between private actors to scale up production capacity.

All these efforts reflect the notion that speed is of the essence in the fight against variants. These proposals will be submitted to EU Leaders in view of their discussion on COVID-19 planned on 25-26 February.

4. AOB

The next meeting is scheduled on 5 March at 17:00.
Platform members will soon receive a short survey to express their views and suggestions on the format, content, and substance of the meetings.

Participation

Platform participants:

1. Professor Steven VAN GUCHT (Belgium)
2. Dr. Angel KUNCHEV (Bulgaria)
3. Alemka MARKOTIC (Croatia)
4. Dr Zoe PANA (Cyprus)
5. Marika MADAROVA (Czechia)
6. Dr Helene Bilsted PROBST (Denmark)
7. Professor Irja LUTSAR (Estonia)
8. Professor Arnaud FONTANET (France)
9. Dr. Sotiris TSIODRAS (Greece)
10. Mr Miklós SZOCSKA (Hungary)
11. Darina O FLANNAGAN (Ireland)
12. Professor Silvio BRUSAFERRO (Italy)
13. Professor Uga DUMPIS (Latvia)
14. Professor Edita SUZIEDELIENE (Lithuania)
15. Dr Charles MALLIA AZZOPARDI (Malta)
16. Professor Andrzej HORBAN (Poland)
17. Professor Henrique DE BARROS (Portugal)
18. Mrs Diana Loreta PAUN; Roxana HAINAGIU (Romania)
19. Professor Pavol JARCUSKA (Slovakia)
20. Fernando SIMON (Spain)
21. 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
- Kurt VANDENBERGHE, Member of Cabinet of President von der Leyen
- Daphne VON BUXHOEVEDEN, Member of Cabinet of Commissioner Kyriakides
- Roberto REIG RODRIGO, Member of Cabinet of Commissioner Kyriakides
- Stalo PAPANASTASIOU, Member of Cabinet of Commissioner Kyriakides
- Peter WAGNER, 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 Josep JANSA, Public Health Event Manager

EMA

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