Meeting of the EU scientific advice platform on COVID-19

Meeting Report

Thursday 15/04/2021 at 17:00

1. COVID-19 Epidemiological update

ECDC provided an update on the epidemiological situation across the EU. The 14-day case notification rate was 464 (country range: 23-861) per 100 000 population. Case notification rates are decreasing, although the absolute values of the indicators remain high, suggesting that transmission is still widespread. The death rate slightly increased over the past week, though it remains too early to determine whether this initiates a change in trend.

The B.1.1.7 variant now represents 77% of all sequenced samples in the EU/EEA countries with the recommended level of sequencing capacity. This variant could now become the starting point for other mutations. The B.1.351 variant is present in some areas while other variants of interest and concern remain sporadic in the EU.

Case notifications and hospitalisations are going down rapidly among older age groups (especially above 80) in countries that achieved a high coverage in this segment of the population. As a consequence, the average hospitalisation age is decreasing, which does not however mean that the risk increased for younger groups.

Members of the platform exchanged on the epidemiological situation, notably regarding variants, vaccination roll out and measures in place in their country. They confirmed the first clear signs of the impact of vaccination observed in the reduction in cases among older age groups where high vaccination coverage is achieved.

2. COVID-19 vaccination – State of play

EMA provided a state of play on the four vaccines centrally authorised at EU level and informed about ongoing efforts to increase manufacturing sites and optimise the logistics of these vaccines. Three more vaccines are under rolling review (Curevac, Novavax, Sputnik V).

EMA informed about the pharmacovigilance situation regarding the Astrazeneca vaccine. The agency reviewed the evidence on 62 cases of cerebral venous sinus thrombosis and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database (EudraVigilance). These very rare events were reported out of 25 million persons that had received the vaccine in Europe. Plausible explanations have been put forward to clarify the mechanism behind this adverse event. Following this in-depth analysis of these cases, which concluded on a plausible link with the vaccine, EMA recommended that a reference to unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria. The Agency also published a letter to healthcare professionals informing about

how to detect and treat this condition. While most cases affected women under 62, it was not possible to find a definitive link to age, gender, or any identifiable risk factor. The benefits of the vaccine still clearly outweigh the risks. In response to a request from the Commission, EMA is now collecting additional data to stratify the risk across 10-year age groups to better contextualise the risk- benefit profile. Preliminary interim results should be available on 22 April. EMA is also looking at measures to be taken for the 2nd dose of this vaccine. While studies on a heterologous booster dose are on-going in the UK, there is currently no data available to support such heterologous schemes. EMA will be however able to gather the rationale for Member States to be taking such decisions.

Some apparently similar events have been observed with the Janssen vaccine. The US registered 6 cases out of 6.8 million persons vaccinated and decided to pause vaccination. The low number of cases only allows for a plausible analogy. EMA is reviewing these events and plans to come up with guidance on 20 April. In the meantime, the company paused its rollout in Europe. If the safety signal is confirmed, warnings should be added and healthcare workers should be informed on what to do in the presence of such adverse events.

EMA is also engaging with experts on risk communication to appropriately communicate on these side effects, as well as on the overall largely positive benefit-risk balance.

Members of the platform exchanged on these pharmacovigilance safety signals and national policies regarding the use of the AstraZeneca and Janssen vaccines. Some countries are recommending the administration of an mRNA vaccine as second dose to those below a certain cut-off age who received a first dose of AstraAZeneca. Experts also indicated that information on possible similar events observed with other adenovirus viral vector vaccines such as Sputnik V would also be very useful to inform future decisions.

3. AOB

The next call is scheduled for 29 April 2021 at 1700 hours

Participation

Platform participants:

1. Professor Markus MULLER (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 PROBST (Denmark)
8. Professor Irja LUTSAR (Estonia)
9. Dr. Hans-Ulrich HOLTHERM (Germany)
10. Dr. Sotiris TSIODRAS (Greece)
11. Mr Miklós SZOCSKA (Hungary)
12. Ms Eibhlin CONNOLLY (Ireland)
13. Professor Silvio BRUSAFERRO (Italy)
14. Professor Uga DUMPIS (Latvia)
15. Professor Edita Sužiédelienė (Lithuania)
16. Jean-Claude Schmit (Luxembourg)
17. Dr Charles Mallia Azzopardi (Malta)
18. Dr Aura Timen (The Netherlands)
19. Professor Andrzej HORBAN (Poland)
20. Professor Henrique DE BARROS (Portugal)
21. Professor Diana Loreta PAUN (Romania)
22. Mr Milan KREK (Slovenia)
23. Professor Pavol JARCUSKA (Slovakia)
24. Fernando SIMON (Spain)
25. Dr Anders TEGNELL (Sweden)

European Commission:

- Commissioner Stella KYRIAKIDES (Chair)
- Giorgos ROSSIDES, Head of Cabinet of Commissioner Kyriakides
- Prof. Peter PIOT, Special Advisor to the President of the European Commission
- Ms Julia SPENCER, Policy Advisor to Prof. Piot
- Sandra GALLINA, Director General, DG SANTE
- Pierre DELSAUX, Deputy Director General, DG SANTE
- Roberto REIG RODRIGO, Member of Cabinet of Commissioner Kyriakides
- Chrystalla PAPANASTASIOU-CONSTANTINOU, Member of Cabinet of Commissioner Kyriakides
- Cristina MODORAN, Policy Assistant to Director General Gallina
- Thomas VAN CANGH, Policy Assistant to Director General Gallina

- Sigrid WEILAND, Scientific Assistant to the Special Advisor to the EC President on COVID-19
- Olga SOLOMON, Head of Unit, Medicines: policy, authorisation and monitoring DG SANTE
- Nicolas PRADALIE, Secretariat General

ECDC

- Dr Andrea AMMON, Director
- Dr Piotr KRAMARZ, PHE Manager
- Dr Julien BEAUTE, PHE Technical Group Leader

EMA

- Emer COOKE, Executive Director
- Catherine COHET, Pharmacoepidemiology/RWE Expert, Data Analytics & Methods Task Force