EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 3 November 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Summary Report

Chair: Head of Unit, European Commission, DG SANTE C3

Audio participants: AT, BE, CZ, DE, DK, EE, EL, FI, FR, HU, IE, IT, LT, LU, MT, NL, PL, RO, SE, SI, NO, CH, LI, UK, AD, AL, SM, DG SANTE, DG HOME, DG MOVE, DG ECHO, SG, COUNCIL, EMA, ECDC, US CDC

Agenda points:
1. Presentation by US CDC on the scientific basis for the new travel guidance to the US
2. Update from EMA on therapeutics
3. Rapidly changing COVID-19 epidemic situation in several countries
4. AOB: ECDC update on COVID-19 variant AY.4.2
5. AOB: Overview on special HSC meeting held on 28 October 2021
6. AOB : Falsified EU Digital COVID Certificates
7. AOB : EU Grants to support EU Digital COVID Certificate
8. AOB: Polio virus in sewage water – NL
9. AOB: RO asked EU/EEA countries assistance for medical evacuation of COVID-19 cases

Key messages:

1. Presentation by US CDC on the scientific basis for the new travel guidance to the US

As of 8 November 2021, the United States (US) is lifting air travel restrictions for certain areas, including from countries of the Schengen area. The US Centers for Disease Control and Prevention (CDC) provided the HSC with an overview on this decision. The US accepts travellers fully vaccinated (+14 days) with any vaccine listed on the World Health Organization (WHO) Emergency Use Listing. Air passengers have to show proof of complete vaccination and a negative COVID-19 test no more than 3 days before departure to the US. Non-vaccinated persons must be tested no more than one day before the flight's departure. All air passengers are required to complete a contact form within 72 hours of their flight's departure.

COMM asked the US to provide details on the scientific reasoning and rationale behind accepting all vaccines by WHO for emergency use. The **US CDC** responded that the US Food and Drug Administration (FDA) approved vaccines are overlapping with the WHO Emergency Use Listing. The US decided to approve travellers with completed vaccination from the full WHO Emergency Use Listing.

IT asked for how long a vaccination certificate from a third country would be considered as valid and if the US takes booster vaccines into account. The **US CDC** responded that there is no expiration date/maximum validity period at this moment. A traveller should have **completed one full vaccination cycle.** A booster vaccine is not required. If a passenger has recovered from a documented COVID-19 infection within the past 90 days, the passenger is exempt from a test 3-5 days after arrival. This rule considers that people can continue to test positive for up to 90 days after diagnosis and not be infectious to others.

DE mentioned that the Sinopharm and Sinovac vaccines listed on the WHO Emergency Use Listing, were added by the WHO before the spread of the Delta variant. The two vaccines have a relatively low efficacy. Therefore, DE wanted to know how the US justifies the acceptance of these vaccines for travel. The **US CDC** replied that the US has decided to use the WHO Emergency Use Listing for vaccines. However, the question from DE would be need to be taken further to the boards and panels that review the data at WHO.

SI asked if people who received a booster shot have to wait some days before they can travel to the US. The **US CDC** responded that there are not additional requirements for travellers who received a booster vaccine. Travellers need to show their full primary series (+14 days).

2. Up-date from EMA on therapeutics

Several requests were received from Member States to discuss monoclonal antibodies. The European Medicines Agency (EMA) gave an update on their work related to monoclonal antibodies and antivirals. EMA ended the rolling review of the antibodies Bamlanivimab and Etesevimab following withdrawal by Eli Lilly. Several other therapeutics are still under review, including Ronapreve (casirivimab / imdevimab by Roche) which is expected to receive approval by the end of November, 2021. Regkirona (redganvimab) is also at an advanced stage to receive an approval.

The **COMM** stressed that countries can still purchase Eli Lilly's therapeutics under the EU's joint procurement if the product has been approved for national emergency authorisation, but there are also contracts for other monoclonal antibodies (Sotrovimab, Ronapreve) available.

Regarding the approval for **COVID-19 vaccines for children under 12 years old**, the US FDA has given the emergency use authorisation for Corminaty. EMA started evaluating the use of COVID-19 vaccine Comirnaty in children aged 5 to 11 only recently, and a potential opinion is expected around mid-December, 2021. EMA expects an application to review the vaccine of Moderna for children under 12 years old in December, 2021.

IE has no experience with monoclonal antibodies and wants to know the experience of other Member States.

The **UK** uses monoclonal antibodies (mainly Ronapreve). Also Dexamethasone is given to COVID-19 patients. They see some reduction in hospitalisation time.

DE procured monoclonal antibodies from Eli Lilly and Roche last year. However, DE experiences moderate uptake of these therapeutics, as practitioners are reluctant on using therapeutics that have not been officially licensed. Moreover, DE was facing difficulties in distributing the monoclonal antibodies since usual distribution chains as for licensed medicinal products could not be used

The **COMM** encourages Member States to send written feedback on which emergency authorisation they have in place, so this can be shared with the Member states.

3. Rapidly changing COVID-19 epidemic situation in several countries

The rapidly changing epidemiological situation of COVID-19 in several countries has been discussed. Several countries intervened and mentioned a rise in COVID-19 cases. Countries that lifted some of their non-pharmaceutical interventions have re-introduced some of them or introduced new measures (extension of the use of the EU Digital COVID Certificate at national level, including limiting issuance to vaccinated and recovered persons, booster vaccines for a specific group of the population, using intensive care units occupancy as a trigger for certain measures, specific measures only geared towards non-vaccinated, etc.).

AT noticed a serious change in the COIVD-19 epidemiological situation and decided to put several non-pharmaceutical interventions back in place. AT introduced a new measurement system based on the number of intensive care unit patients. The system includes three stages. Each stage includes the introduction of stricter measurements (the extension of the EU Digital COVID Certificate at work and in small events, validity of antigen tests reduced from 48h to 24h, etc.).

IE indicated they have never stopped the use of certain non-pharmaceutical interventions (e.g. masks in public transport, EU Digital COVID Certificate for hospital entrance – IE does not accept testing for access to hospitals – they only accept recovery or vaccination certificates). IE still encourages teleworking and has started the administration of booster vaccines to citizens 60 years and older.

In **FR**, the EU Digital COVID Certificate is required for everyone above 12 years old to enter restaurants, bars, museums, and other social activities, since September, 2021. With the winter season approaching, FR launched a campaign to encourage social distancing, mask wearing and other protective measures. Vaccination uptake is still increasing. Since 15 September, COVID-19 vaccination is compulsory for healthcare professionals and professionals working with elderly and vulnerable people.

The **NL** has re-introduced non-pharmaceutical interventions (masks, social distancing). In addition, the NL introduced a new legal measures to extend the use of the EU Digital COVID Certificate (e.g. for concerts, museums, sports, work setting (companies are now allowed to ask vaccination proof from their employees)). The NL advices to work at least 50% from home.

The **UK** has had a high rate of cases for the past weeks. Both the current case rate and the epidemiological situation, as well as the restriction measures and non-pharmaceutical interventions in place, vary among the four nations of the UK. Working from home is encouraged everywhere. Wearing masks is mandatory but the settings vary among the nations. The UK has no unified vaccination/negative test passport system in place. The case rate is currently the highest in children, which is the least vaccinated population group. The UK will launch a booster campaign soon. COVID-19 variant AY.4.2 represents 10-15% of the cases at this stage. So far, this has not resulted in increased hospitalisation or deaths. Studies are ongoing.

In **IT**, the weekly case incidence is increasing, however, no regions show a high epidemic risk so far. Measures will be taken according to the epidemiological situation. In IT, the vaccination rate is very high.

NO noticed an increase in the number of cases, as well as hospitalisations, but not in intensive care unit admissions. Local interventions are put in place. Both COVID-19 and flu vaccination is ongoing, and NO reports sufficient supply.

CH mentioned an increase in the daily infection rates, but only a slightly increase in death rates. In CH it is required to show a certificate to enter nightclubs, cinemas, and restaurants. CH is working towards increasing the vaccination rate in the country.

Any Other Business

4. AOB: ECDC update on COVID-19 variant AY.4.2

The European Centre for Disease Prevention and Control (ECDC) provided the HSC with a short update on the **COVID-19 variant AY.4.2**. The variant shows an increasing trend in the UK and in multiple EU/EEA countries. Preliminary data (UK Health Security Agency) shows a **slight** increase in transmissibility compared to other circulating variants. Logistic growth rates are slightly higher for AY.4.2 than for Delta (19% per week). However, there is no evidence yet of either increased hospitalisation, deaths or drop in vaccine effectiveness caused by this new variant. ECDC is carefully monitoring the situation regarding this sub-lineage and will revisit this assessment when any new information becomes available.

IT asked if there is a specific contract-tracing measure for variants. **ECDC** responded that they evaluate the variants with potential threats for EU/EEA countries on a weekly basis. On **4 November 2021**, there will be a meeting with **WHO** on variants. After this meeting, ECDC will be able to inform Member States about any new information. At this stage, ECDC is not introducing new measures regarding this variant AY.4.2. ECDC will continue to monitor the variant and will be able to give an update in the next HSC meeting.

5. AOB: Overview on special HSC meeting held on 28 October 2021

On 28 October, a special HSC meeting was held with 10 EU countries with a deteriorating epidemiological situation and/or with a low vaccination uptake in order to understand where they are facing challenges and what practices they have put in place to increase vaccination uptake and to address vaccine hesitancy. The aim of the meeting was to take stock of the current situation and brainstorm good practices and possible support the European Commission or the European Centre for Disease Prevention and Control (ECDC) could provide to these Member States.

** EU MS only **

6. **AOB: Falsified EU Digital COVID Certificates**

Last week, the COMM informed the HSC on **falsified EU Digital COVID Certificates**. This topic and next steps to be taken is further discussed in the eHealth Network. Since 27 October 2021, many apps have been updated and no longer show the identified falsified certificates as valid.

7. AOB : EU grants to support EU Digital COVID Certificate

An update was provided regarding **EU grants to support EU Digital COVID Certificates**. Member States already received 70% of the grants. To receive the remaining 30%, Member States have to show proof of the number of EU Digital COVID Certificate based on diagnostic tests.

8. AOB: Polio virus in sewage water – NL

The **NL** has reported to have detected **polio virus in sewage water** near an inactivated polio vaccine production site. Further investigations are ongoing.

9. AOB: RO asked EU/EEA countries assistance for medical evacuation of COVID-19 cases

RO has requested international **assistance to transfer COVID-19 patients** in critical condition to other Member States through the Early Warning and Response System (EWRS) platform.