EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 08 December 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Draft Summary Report

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

Audio participants: AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SE, SI, SK, NO, IS, DG SANTE, DG JUST, DG MOVE, DG ECHO, DG HR, HERA, SG, COUNCIL, EMA, ECDC, WHO

Agenda points:

1. Urgency of implementing swift and targeted public health measures to slow down and contain the spread of the SARS-CoV2 Omicron variant of concern document – for agreement
2. ECDC – Omicron (B.1.1.529) update
3. Acceptance for WHO vaccinations, in particular Covaxin
4. EU Digital COVID Certificate validity of vaccination certificates
5. Passenger Locator Forms – amending the implementing act –DG MOVE
6. 8th update of the RAT common list
7. Joint statement on heterologous boosters by ECDC and EMA
8. AOB: Vaccination supply procurement and joint procurements for therapeutics - HERA

Key messages:

1. <u>Urgency of implementing swift and targeted public health measures to slow down and contain the spread of the SARS-CoV2 Omicron variant of concern document – for agreement</u>

On 6 December, the Health Security Committee discussed a draft paper concerning Omicron public health measures, based on the risk assessment of the European Centre for Disease Prevention and Control (ECDC). The document highlights the urgency of implementing swift and targeted public health measures to slow down and contain the spread of the SARS-CoV2 Omicron variant of concern, while specifying that these measures may be in some cases ideal or subject to legal mandates. On 8 December, Health Security Committee members and observers agreed on the document. It will be made available online.

2. <u>ECDC – Omicron (B.1.1.529) update</u>

ECDC gave a short update on the Omicron variant. There were 315 confirmed cases in 20 EU/EEA countries, and 863 confirmed cases in 33 countries outside the EU/EEA on 8 December, 2021. New

studies on immune escape were published on 8 December. It seems that Omicron has reduced neutralisation in vitro, however, neutralisation does not equate to lower vaccine effectiveness equate severe disease.

3. Acceptance for WHO vaccinations, in particular Covaxin

The vaccine COVAXIN, from Bharat Biotech, has recently been accepted for World Health Organization (WHO) Emergency Use Listing. The **COM** ran a survey to ask Member States what their current position is on the acceptance of this vaccine. The outcome of the survey shows that 10 Member States accept COVAXIN for the purpose of travel (i.e an incoming traveller having been vaccinated with COVAXIN would be regarded as "fully vaccinated"), 16 Member States do not, 5 Member States are undecided or have not submitted their input yet. Overall, all countries accept vaccines corresponding to Pfizer/BioNTech, Moderna, Janssen and AstraZeneca administered by third countries and the Covishield vaccine is accepted by most countries. However, mixed feedback was received regarding other vaccines sub-licenced by AstraZeneca (R-COVI and Covid-19 vaccine (recombinant)) and the WHO Emergency Use Listing vaccines. A final table of accepted vaccines should be available on ReOpenEU before Christmas.

DE is considering taking up COVAXIN in their vaccine list. DE has not yet decided how to proceed further due to the current discussions on accepting WHO Emergency Use Listing vaccines in the Council.

HU accepts all vaccines listed on the WHO Emergency Use Listing. In addition, HU has bilateral agreements with third countries. Once an agreement is established, the vaccines that are officially authorised by that country will be allowed/recognized by HU. In other words, HU has specific country agreements, allowing travellers from certain countries to enter HU with non EU-authorised vaccines.

4. EU Digital COVID Certificate validity of vaccination certificates

The **COM** sent a questionnaire to the Health Security Committee on various scenarios regarding vaccination events with the specific aim to find a common approach on validity. Several conclusions regarding coding needs and solutions were made based on the survey. For example, having received one shot of the Janssen vaccine and then an additional dose of an mRNA-based COVID-19 vaccine should be considered a booster in the point of view of many Member States. Most countries also state that the recovery certificate should remain valid for 180 days. A large majority of the Member States is in favour of finding a common approach to the different EU Digital COVID Certificate validity periods for vaccination certificates. A large majority of Member States is in favour of not setting a validity for boosters for now, largely due to insufficient information available at this stage.

IS is considering a booster validity period of 9 months.

PL is in favour of harmonising the validity period for boosters, in line with the position communicated earlier.

The **COM** mentioned that in parallel, political discussion on this topic were held in the integrated political crisis response (IPCR) Council meetings. The majority of the countries support the nine-month validity period for certificates issued after the primary series. The COM is now looking at the Delegated Act and will come back to the Health Security Committee. In parallel, the rules for the EU Digital COVID Certificates will be adapted.

5. Passenger Locator Forms (PLF)– amending the implementing act – DG MOVE

The new Omicron variant underlines the need for rapid contact tracing and passenger locator forms are essential tools for that. So far, only four Member States are connected to the EU Passenger Locator Form exchange platform and six Member States are connected without a Passenger Locator Form, having the option to use the EU digital template. The COM is proposing an amendment to the implementing act on Passenger Locator Form. The Cross-border Health Threats Comitology Committee will meet on 10 December 2021.

During the meeting, several Member States (**CY, DE, DK, FR)** indicated that more time is needed to connect to the Passenger Locator Form exchange platform due to **technical matters and/or national regulations** that would need to be changed. **SE** also mentioned it would be necessary to look at the cost-benefit of the proposed exchange platform. SE expressed concerns regarding data safety, and mentioned the importance of the use of the already existing Early Warning and Response System (EWRS).

Some Member States voiced reservations about the making the Passenger Locator Form exchange platform obligatory and questioned the legal basis (**CY, DE, DK, FI, SE**).

DE is in favour of the PLF platform. DE already has a similar system in place. However, technical matters and national regulations have to be further adapted. Therefore, it will take at least six months before DE can connect to the EU Passenger Locator Form exchange platform. DE mentioned that Early Warning and Response System can be used in the meantime.

The **COM** understands that countries need more time to connect to the exchange platform. Regarding the legal basis, the COM highlighted that the PLF exchange platform focuses on the cross-border dimension of contact tracing. This is without prejudice to contact-tracing at national level. The COM works towards having all Member States connected to the exchange platform during the spring of 2022.

6. 8th update of the Rapid Antigen Test (RAT) common list

The COM received positive response from the Health Security Committee on the 8th RAT common list update. The update is considered as agreed as of 7 December. Experts are continuing the work and will meet again on 14 December. This will most likely result in a proposal for a 9th update.

7. Joint statement on heterologous boosters by EMA and ECDC

The European Medicines Agency together (EMA), along with the ECDC published a joint statement on heterologous boosters on 7 December. **EMA** mentioned that reactogenicity of heterologous vaccination appears overall similar with respect to homologous regimes. Overall data presented support the use of mixed vector/mRNA schedules. Considerations on heterologous booster after primary series, boosting with an mRNA after a vector primary series is more immunogenic than the reverse. The safety profile of heterologous and homologous booster combinations remains comparable based on available data. Countries therefore could consider a heterologous booster vaccination strategy as an alternative strategy to providing homologous boosters. **ECDC** added that heterologous vaccination is already used for individuals vaccinated with the AstraZeneca vaccine. A combination of vaccines also seems to show a beneficial protection against the new Omicron variant. ECDC and EMA will continue to monitor heterologous vaccination schemes.

8. AOB: Vaccination supply procurement and joint procurements for therapeutics - HERA

HERA gave a brief overview of the current framework contract available under joint procurement. There still are syringes and needles syringes available und several framework contracts , orders should be placed before the expiry of these contracts in December 2021/January 2022. In case of renewed interest for syringes or other vaccination supplies, another joint procured could be considered. The COM will circulate an email with detailed information on the joint procurements for therapeutics.