EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 22 December 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, BG, CZ, CY, DE, DK, EE, EL, ES, FI, FR, HU, HR, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, CH, LI, UK, AD, BA, RS, SM, DG SANTE, DG MOVE, DG HR, RTD, JRC, SG, EMA, ECDC, WHO

Agenda points:
1. Omicron update – presentation by the Western Cape Department of Health and University of Cape Town South Africa, ECDC and JRC
2. Non-pharmaceutical interventions – survey results
3. Booster vaccines, new vaccines and therapeutics – presentation by EMA
4. Up-date on COVID-19 research projects – presentation by RTD
5. AOB: Delegated Act
6. AOB: 9th Update of the rapid antigen test (RAT) common list
7. AOB: Update Passenger Locator Forms (PLF)

Key messages:

1. **Omicron update – presentation by the Western Cape Department of Health and University of Cape Town South Africa, ECDC and JRC**

The **Western Cape Department of Health and University of Cape Town** presented their latest available data on COVID-19 infections due to the SARS-Cov2 Omicron variant. There is some evidence of lower risk of severe disease outcomes in adults but this attenuates if adjusted with prior infection and vaccination. So far, there is no evidence of increased risk of severe outcomes in children. Risk of severe outcomes are relative to the previous Delta wave after adjusting the re-infection and vaccination coverage. Risk of severe outcomes are relative compared to the third wave (Delta) after adjusting for re-infection and vaccination. When comparing September and October with November 2021, there is no evidence of attenuation in protection for the Omicron variant from prior infection or vaccination in adults.

The **European Centre for Disease Prevention and Control** (ECDC) provided an epidemiological and situation update on the Omicron variant in the EU/EEA. The overall epidemiological situation in the EU/EEA is characterised by a high overall case notification rate and a slowly increasing death rate. The case notification rates are currently the highest among age groups under 50 years old. There is an increase

of cases in several EU/EEA countries and regions. Vaccination coverage in the total population is 67.3% which is **insufficient** to stop transmission. According to data that EU MS provide to ECDC via TESSy, the majority of Omicron cases (89%) were locally-acquired. So far, there are no reported ICU cases/deaths reported in EU/EEA. Most reported cases are asymptomatic.

The **Joint Research Centre** (JRC) has been able to propose a PCR test that is specific to Omicron. Using this specific method is much quicker than sequencing. The test is currently a *theoretically* valid test based on bioinformatics, JRC still needs to validate its results on *real* samples. The application of this method should aid and speed up the monitoring of the spread of the Omicron variant globally.

PT mentioned that at this moment the proportion of Omicron in Portugal is over 46%.

DE asked if travel restrictions have any impact at this stage, as the Omicron transmission is high. The **ECDC** replied that travel restrictions are likely to have a small effect on the overall transmission, given the already high transfer rate in the community.

DK has a high increase in Omicron incidence, which is mainly detected due to DK's comprehensive testing strategy (and specific variant detection method).

2. Non-pharmaceutical interventions – survey results

In response to the latest ECDC Rapid Risk Assessment on the emergence and potential impact of Omicron in context of ongoing Delta transmission published on 15 December, the Commission launched a survey among the HSC members. The aim of the survey was to take stock of how countries are preparing for the upcoming weeks and what measures they have already put in place or are planning to implement. The results of the survey show that healthcare systems and healthcare workers are suffering across the EU. Some countries are putting in place all the necessary non-pharmaceutical interventions and are restricting Christmas and end of year events. Other countries are trying to delay these decisions until 2022. Regarding vaccination, most countries recommend a booster dose 3 to 6 months after completion of the primary series. All responding countries are implementing/planning vaccination strategies for adolescents 12 to 17 years old. All responding countries, except SE, are implementing/planning vaccination strategies for children 5 to 11 year old. Risk communication in Member States focuses on the delta and omicron vairants. A detailed document with the outcome of the survey will be distributed among the HSC members.

Several countries provided information regarding their latest introduced measures:

AT updated its entry regulations on 20 December. Travellers entering from a country that is not on the virus variant list, proof of vaccination or recovery certificate is required along with an additional PCR test taken 72 hours before entering the country. Without an additional PCR test, individuals must be quarantined until they receive a negative test result. When a booster dose is received, no additional PCR test is required. Travellers without a vaccination/recovery certificate must quarantine for 10 days, which can be shortened after 5 days in the event of a negative PCR test result. General access is prohibited for travellers arriving from a country on the virus variant list. There is currently a landing ban in place for 10 South African countries. However, people living in the EU can enter but must undergo quarantine. AT is also considering adding four Member States (DK, NL, NO, UK) to the list of virus variants.
IT gave a short presentation on the new cross-border measures introduced on 16 December to delay the spread of Omicron. Passengers arriving from EU/EEA countries have to fill out a Passenger Locator Form (PLF) and have to show a negative PCR (48h before entry) /antigenic (24h before entry) swab test. If not

vaccinated/recovered, travellers have to undergo five days of quarantine with a PCR/antigenic test at the end. For the rest of the world, non-essential travel is forbidden.

The **NL** introduced a lockdown until 14 January 2022 to slow down the spread of the Omicron variant and not to overload hospitals. Schools closed earlier than the initial start of the holidays. All non-essential shops are closed, and gatherings are limited to 2-4 people. The booster campaign has started. Quarantine measures are in place for travellers from countries classified as high-risk countries, not recovered/ vaccinated travellers not excluded. There are no EU countries on the list classified as high-risk.

DE considers the booster campaign as highly important. DE is preparing for possible obligation for vaccination and bringing the 2G rule into place. DE recommends everyone to test before attending Christmas dinners and New Year's Eve gatherings. Big events are closed, e.g. no spectators allowed for sport events. DE updated its booster advice on 21 December and booster vaccination is now possible after three months (not six months) after the primary series. Regarding travel restrictions, DE is currently analysing and discussing data on the spread of the Omicron variant. At the moment, only certain persons, e.g. German citizens or residents can come back from the South African countries on the list. The situation is very dynamic.

DK recently decided that everyone over the age of 18 will be offered a booster dose after 140 days.

FI has updated the measures taken regarding travel/entry into the country; a negative test (RAT/PCR test) and a digital EU-COVID certificate are required for anyone entering the country. This measure will be in effect until 16 January 2022. There are some exceptions for Swedish citizens.

IE is removing all African states from scheduled countries requiring special quarantine.

UK has put in place testing measures for travellers. A PCR test two days before departure and one on arrival is required, along with a PLF. Also quarantine measures are in place for both vaccinated and unvaccinated travellers. Additional measures differ per country (England, Scotland, Wales, Northern Ireland), including for social distancing measures and showing a vaccination card.

3. Booster vaccines, new vaccines and therapeutics – presentation by EMA

EMA up-dated about the authorization of the Novavax vaccine (Nuvaxovid), a protein-based vaccine. It is an important addition to what is currently available as it can be manufactured in large amounts and it is an alternative for those persons who would not like to be/ cannot be vaccinated with an mRNA vaccine. The current approval is for a primary series, EMA expects that data for a possible booster authorization should be submitted in early 2022. The current data show good efficacy also against the Delta variant. There is no data available for the Omicron variant. EMA expects the neutralization not to be much different from the other vaccines. It is authorized for individuals 18 years and older, vaccine batches may be available starting in February/March in Europe. There are some manufacturing aspects that still needs to be considered, hence the authorization is conditional at the moment.

Sotrovimab (Xevudy) – EMA's human medicines committee has recommended authorising the monoclonal antibody Xevudy (sotrovimab) for the treatment of COVID-19. It is active against Omicron. Approval is only for mild/moderate cases in outpatient settings. GSK has not tested it for prophylactic use.

Kineret – this is a repurposed drug. It is now also recommend for treatment of COVID-19 in adult patients with pneumonia requiring supplemental oxygen (low or high flow oxygen) and who are at risk of developing severe respiratory failure.

Remdesivir (Veklury) – the use is extended now for the treatment of adults who do not require supplemental oxygen and who are at increased risk of progressing to severe COVID-19 to its indication.

A scientific opinion on Paxlovid was issued and it shows high efficacy in the clinical trials. It should be available as of 2022. The administration is orally which makes it easy to use in the community.

EMA is working with vaccine manufactures to discuss the modification of vaccine composition in the light of the Omicron variant. EMA is also discussing the possible approval of a booster dose for adolescents.

4. Up-date on COVID-19 research projects – presentation by RTD

The **Research and Innovation** unit of the Commission gave an update on research on the Omicron variant. There has been a lot of EU-funded research on pandemic preparedness and response. A 5th meeting on COVID-19 research to policy in action was held on 17 December. The outcomes of this meeting will be distributed to the HSC. RTD also informed the HSC on the EU-wide COVID-19 clinical trial networks. Several fragmentation of study initiatives have been observed, as well as the use of potential therapeutics outside of study/trial context. Several challenges related to the trials have been identified with regulations, ethics, legal, administrative, financial and/or political matters. To overcome barriers for multi-state trials in the EU, there is need for engagement of both health and research authorities. RTD mentioned that suggestions from the HSC members to overcome these barriers are welcome.

In addition, DG SANTE explained that the Clinical trials Regulation will become applicable from 31 January 2022. It will require close coordination between ethics committees and national competent authorities at national level and, for multinational trials, between Member States concerned for robust and agile assessments of clinical trial applications. It is vital that all Member States ensure timely and appropriate implementation of the Regulation including the reorganisation of and coordination with ethics committees.

5. AOB: Delegated Act

The **delegated act** amending the EU Digital COVID Certificate Regulation, establishing a standard acceptance period of **270 days** for vaccination certificates indicating the completion of the primary vaccination series, was adopted on 21 December 2021. The regulation will enter into application on **01 February 2022**. The objection period for the Parliament and Council runs until 21 January 2022. The Commission will continuously monitor whether further adaptations might be needed based on newly emerging scientific evidence. In parallel, an **implementing act** was also adopted, changing the coding rules, to be able to make a differentiation between primary vaccination series and booster doses in all cases. These new coding rules will apply as of **01 February 2022**; Member States shall need to (automatically or upon request) re-issue certificates where necessary.

HU asked if the validity of the EU Digital COVID Certificate could differ for the national certificates used for national measures. The **COM** responded that the EU Digital COVID Certificate is used for travel purposes. National measures are in the hands of the Member States, therefore, the validity of national certificates is up to them.

6. AOB: 9th Update RAT common list

The 9th update of the RAT common list was published on 21 December. The update concerns the inclusion of 11 new RATs, the removal of two RATs, and the inclusion of a paragraph referring to the ongoing work by the Technical Working Group with regards to the Omicron variant and its possible impact on the performance of RATs. The next meeting of the Technical Working Group is on **11 January 2022**.

7. AOB: Update Passenger Locator Forms (PLF)

The Commission is currently not pursuing an implementing act on Passenger Locator Form. Further discussions on this topic will be held in the HSC in January, starting with a survey to assess in detail the current practices in the EU/EEA countries.