EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 12 January 2022

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, CY, DE, DK, EE, EL, ES, FI, FR, HU, HR, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, CH, IS, LI, UK, AD, BA, RS, DG SANTE, DG MOVE, DG ECHO, DG JUST, DG CNECT, DG HR, HERA, SG, COUNCIL, ECDC, WHO

Agenda points:
1. Omicron update – presentation by ECDC and Tyra Grove Krause, Executive Vice President at the Statens Serum Institute in Denmark
2. Update on quarantine and isolation - presentation by ECDC
3. Update on the surveillance data needs - presentation by ECDC
4. Certification of clinical trial participants
5. EU support for national Omicron response - presentation by DG ECHO
6. AOB: Moving from pandemic to endemic management – Spain
7. AOB: Update on the work of the working group on rapid antigen tests (RAT)

Key messages:

1. Omicron update

Omicron epidemiological update – presentation by ECDC

On 07 January, the **ECDC** published its weekly update on the epidemiological assessment of the Omicron variant. At the end of week 52, the overall epidemiological situation in the EU/EEA was characterised by a high overall case notification rate which has increased rapidly in the past two weeks. This situation is largely driven by the continued circulation of the Delta variant and rapidly increasing spread of the Omicron variant in many countries. The epidemiological situation in the EU is of very high concern. However, vaccination coverage in the population targeted for vaccination is 80%, resulting in the prevention of severe disease and death.

DE asked if the ECDC has information on hospital admissions in young children. **ECDC** will investigate and report back if anything specific is found. Tyra Grove Krause replied that more young children were tested

in hospitals in **DK**, but were quickly sent home. However, if they test positive, they are still registered as hospitalised.

SARS-COV2 Omicron variant driving the COVID-19 pandemic in early 2022 – presentation by Tyra Grove Krause, Executive Vice President at the Statens Serum Institute in Denmark

DK realised that suppression would not be possible to the same extent as for the previous Delta variant. Therefore, DK quickly rolled out the third dose of COVID-19 vaccine for all adults over the age of 18, the coverage is now at 54%. DK also introduced new non-pharmaceutical interventions and contact restrictions (closure of bars/schools/cultural activities and working from home). 97% of COVID-19 cases in DK are due to Omicron. Preliminary data shows a decrease in hospitalisations. The risk of being hospitalized due to an infection with the Omicron variant in the vaccinated is 1/5 to the risk among unvaccinated patients hospitalized due to an infection with Delta. This shows that vaccines are effective to prevent against severe disease also with respect to the Omicron variant. The Statens Serum Institute expects a peak in COVID-19 cases due to Omicron in February. For the next two months, DK will focus on high vaccination coverage and non-pharmaceutical measures. For long-term perspectives, the Statens Serum Institute expects increased population immunity through high vaccination rates and natural immunity. The Institute also expects improved vaccines and treatments becoming available in the future, and a better focus on at-risk populations instead of the entire population taking into account on the overall epidemiological situation and the emergence of possible new variants of concern.

HERA asked if the modelling and data takes into account the booster dose vaccination of the population. **Dr Grove Krause** responded that booster vaccination is included in the models. Other assumptions in the model are that the risk of hospitalisation for Omicron is half as compared to the cases for Delta. This assumption may need to be revised.

SK asked what restrictions will be relaxed in the coming week. **Dr Grove Krause** replied that political decisions in DK will resume on 12 January. However, schools were reopened on 5 January. DK recommends vaccination for children 5 to 11 years old, but the uptake is not high among this age group.

DE asked if the model assumed that protection against severe disease was the same for a full two-dose vaccination versus a booster. DE is currently discussing a second booster for the elderly, therefore, DE asked if Grove Krause believes a second booster may no longer be needed in the endemic situation. **Dr Grove Krause** responded that estimates of vaccine efficacy were used for modelling. It assumed the same reduced risk of hospitalisation among those infected with Omicron compared to Delta, whether or not they received two or three doses. Regarding the deployment of the fourth dose, DK is deploying the third dose for all persons 18 years and older. DK plans to extend a fourth dose to immunocompromised patients. It is currently under discussion whether a fourth dose should also be rolled out for nursing home residents and people over 85 years of age. Dr Grove Krause expects to focus on protecting those most at risk and does not expect a fourth dose to be deployed for the entire population given the current situation. However, that may change if new variants appear.

ECDC asked whether severity is assessed by age group, and whether other age groups stand out, beyond 0-2 year olds. **Dr Grove Krause** replied that hospitalisation data has been stratified for age, and showed the same reduced risk for hospitalisation in all age groups, expect for those under 18 years of age. This increased risk among the younger population is driven by the age 0-2 years old. However, paediatricians report that not a lot of the children are actually admitted with severe COVID-19, the children are mainly attending the emergency units where they are being evaluated and being tested and directly send home.

IE also noticed a very slight increase in hospitalisations among children, but so far, this does not appear to be a major concern.

Andorra asked about changes to DK's testing strategy. **Dr Grove Krause** replied that DK revised their contact-tracing guidance. Close contacts are now only considered as household contacts. Close contacts who received a booster dose, are recommended to take a test. Close contacts who received two doses have to quarantine until they received a negative test result. Unvaccinated individuals should quarantine. Critical staff can go to work if daily tests are performed. For children, self-tests are performed twice a week (regardless of vaccination status).

DE asked about the validity of the certificates with regards to waning immunity. The EU has now a validity of 270 days for vaccine certificates and 180 days for recovery certificates. DE asked whether the validity of the certificates should be adapted for the Omicron variant. **Dr Grove Krause** responded that the validity of the certificates have already be changed in DK to five months. The **DK** HSC representative confirmed.

2. Update on quarantine and isolation – presentation by ECDC and DG SANTE)

On 7 January, **ECDC** published guidance for quarantine and isolation to be adapted in case of high pressure on health care systems and society. These include a shortened duration of quarantine and isolation with adapted testing requirements and takes into account the vaccination status of individuals.

DG SANTE carried out a **follow-up survey** on the roll-out of **non-pharmaceutical measures** and **health care system preparedness**. Results show that national **quarantine recommendations** range from 5 to 14 days, but recommendations are very diverse with many specific recommendations, such as for unvaccinated, vaccinated or boosted individuals. Most countries (22) recommend 10 days for quarantine of close contacts. About half of the countries (14) do not allow the quarantine to be shortened following a negative test. Other countries (14) allow for the quarantine period to be shortened after 7 or 5 days, following a negative test for which many countries accept either PCR tests or RAT. Many countries apply shorter quarantine times for fully vaccinated or boosted individuals.

Isolation measures also range from 5 to 14 days, but recommendations are **diverse and complex** and include different dimensions of vaccination status, severity and onset of symptoms, and options for shortening isolation after a negative test. Most countries (18) recommend isolation of positive cases for 10 days. Most countries (21) do not allow shortening the isolation period, while7 countries allow shortening the isolation after 7 days following a negative test, several accepting PCR tests or RAT. Many countries provide options for shorter isolation periods in case of asymptomatic cases and taking into account the vaccination status of the individual. Countries are putting efforts to shorten the quarantine and isolation measures.

With regard to **non-pharmaceutical preventions** that have been implemented or are planned in EU/EEA Member States before and after the Christmas period, a comparative analysis showed that there are no significant changes in terms of the measures that have been implemented and no significant changes in Member States' health system preparedness and response.

AT, IE and **IS** informed DG SANTE that new recommendations have been adapted. The countries will send DG SANTE an update of these recommendations. **Serbia** also informed the HSC of their changes regarding a shortened isolation period from 14 to 10 days. The **COM** will send an overview document to the HSC.

UK updated their testing requirements; people who tested positive with an LFD-test no longer need to take a follow-up PCR-test. Asymptomatic individuals who have been fully vaccinated are no longer required to book a PCR-test if they have been in close contact with someone who tested positive.

On December 21, 2021, **DE** agreed to shorten quarantine and isolation rules. However, the details are yet to be decided. Regarding Omicron, quarantine and isolation will be shortened to 10 days and there will be a possibility for individuals to shorten this period. A quarantine exemption for contact persons who have received a booster shot is also being discussed.

3. Update on the surveillance data needs – presentation by ECDC

ECDC informed the HSC that a number of countries do not report data to TESSy on hospital or ICU admissions and ICU occupancy. For example, nine (30%) Member States do not report numbers for **hospitalised** patients and 17 (57%) Member States do not report numbers for patients **admitted to ICU. ECDC asked countries for more active reporting, also regarding other variables including contact tracing where** ECDC published a reporting protocol for contract tracing in October 2021. ECDC also encouraged countries to share study results e.g. regarding the incubation period in patients infected with the Omicron variant and viral shedding in such patients. Some countries responded arguing that the current high burden of cases makes it difficult for them to also report to ECDC. COM suggested that the ECDC Advisory Forum or surveillance network could make a suggestions on which are key indicators for which reporting is **essential compared to others.**

IE replied that collecting all the data for ECDC is not realistic, countries should focus on what matters most in the coming weeks. In addition, some citizens do a self-test and do not report their results to the authorities. It is therefore not possible to collect all the data requested. It would be helpful if ECDC selects the key data to be collected. **SI** supports IE's view on surveillance. From an **ECDC** perspective, the completeness of data where variant status is known is most important.

COM suggested to follow-up in the ECDC surveillance network and the Advisory Forum.

4. Certification of clinical trial participants – request from Germany

Last week, **DE** requested further discussing the issue of providing a vaccination certificate to clinical trial participants. Member States made several comments about how they deal with this in their country e.g. providing a specific certificate that is only valid nationally but is equivalent to a "normal" COVID-19 vaccination pass.

DE was informed by a pharmaceutical company that it is difficult to find participants for clinical trials with a variant-specific booster dose. These participants have already received their primary vaccination and their status is fully vaccinated. These participants fear losing this status because the variant-specific booster dose used in clinical trials is not yet authorised. Many participants would prefer to prolong their vaccinated status by taking an authorised booster rather than participating in or following-up with a clinical trial. DE would like to receive advice on how to handle this problem.

FR does not plan to have any specific measures for people who participate in clinical trials.

ES mentioned that a few months ago a group of experts from different European countries wrote a letter on this topic to the European Commission. ES mentioned that the validity of participants taking part in clinical trials should not be a national decision, but a common EU approach. **COM** replied to be aware of this letter and that the validity of the certificates of participants taking part in clinical trials has been addressed several times within the HSC. However, this had not led to discussion joint conclusion.

CZ is not aware that any clinical trials of vaccines are taking place in the Czech Republic. Therefore, this topic was never raised in the national Ministry of Health. CZ is not aware that there is a problem with the recognition of certificates issued to clinical trial participants by other countries.

AT currently has no ongoing clinical trials.

In **BE**, participants taking part in clinical trials can only be issued a certificate when they have received vaccines authorised by the EMA.

In **IT**, people who are vaccinated in the context of the clinical trial, receive an authorised mRNA booster dose five months after the last shot to make sure they receive the relevant COVID-19 certificates.

UK has their own COVID-19 certificates in place. Participants of clinical trials receive a special certificate, but that overall looks the same. The UK also informed about a meeting on this topic convened by WHO to take place in February 2022.

The **NL** only provides a local vaccination certificate to trial participants, no international Digital COVID Certificate. This means that the certificate is only recognized in NL. The QR code does not show information about the type of vaccination for privacy reasons. The local certificate also makes no distinction between vaccination, recovery or testing certificate. A certificate is issued if the pilot vaccine offers sufficient protection or if one or more additional doses from an accepted vaccine are necessary.

DG JUST mentioned that when it comes to the **cross-border recognition of certificates**, there must be an agreed coding system in place.

The **COM** suggested further discussion of this topic.

5. EU support for national Omicron response - presentation by DG ECHO

DG ECHO gave a brief presentation on the European Union Civil Protection Mechanism (UCPM). ECHO recalled the available support instruments that can be mobilised at countries' request, mainly related to rescEU medical stockpile for COVID-19 and assistance. ECHO provided some data about the stocks of personal protective equipment, ventilators etc. available under rescEU. It also spoke about its numerous interventions in EU and other countries due to the pandemic in the last two years (58 in 2020 and 70 in 2021), which included: vaccine sharing, medical staff support, provision of medical countermeasures etc.

6. AOB: Moving from pandemic to endemic management – Spain

ES is discussing the possibility of adapting their COVID-19 management from treating it as a pandemic towards using instruments that are applied for endemic diseases. This is not to be implemented now, but rather to start discussing it as theCOVID-19 situation has changed compared to a year ago before the introduction of COVID-19 vaccines and self-tests. ES suggests to introduce a new control and surveillance system with a common EU approach. A more in-depth discussion will follow during the next HSC meeting.

7. AOB: Update on the work of the working group on rapid antigen tests (RAT)

On 11 January, the 18th meeting of the technical working group took place. The COM circulated a flash report to the HSC members. A **proposal for a 10th update** of the rapid antigen tests common list will be sent to the HSC for review, as well as a further **background documents** prepared by the technical working group. The COM will also circulate a **survey dedicated to the EU Digital COVID Certificate**, including the use of rapid antigen tests for the recovery certificate.