EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 30 June 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Draft Summary Report

Chair: Ingrid Keller, European Commission, DG SANTE C

Audio participants: AT, BE, BG, CY, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SE, SI, SK, NO, CH, IS, UK, AD, AL, XK, MD, DG SANTE, DG ECHO, DG MOVE, DG HR, SG, COUNCIL, JRC, EMA, ECDC, WHO

Key Messages

1. EU Digital COVID Certificate (EU DCC) system – follow-up from last week – information/discussion point

On 29 June, two documents on the EU DCC (**Value Sets for EU Digital COVID Certificates; Guidelines on the Validation of EU Digital COVID Certificates in the context of air transport**) were shared with the HSC and eHealth Network.

On the **acceptance of vaccination certificates issued by third countries**, the Commission (COM) reminded Member States (MS) that there is a pending question concerning the cases in which vaccination certificates for vaccines administered in third countries MUST be accepted, and in which cases they MAY be accepted, following the EU DCC regulation. Such an acceptance would not be for administration of vaccines, but for travel and acceptance of third country nationals to the EU.

According to Article 5(5) of the EU DCC Regulation, there are 3 categories of vaccines:

1. Vaccines that have been **granted marketing authorisation with the support of EMA** (which SHALL be accepted).
2. Vaccines that have been **granted marketing authorisation by a competent national authority** (that MAY be accepted)
3. **Vaccines that are on the WHO Emergency Use Listing** (that MAY be accepted).

The EU Digital COVID certificates can be issued to a third country national by a Member State on the basis of a reliable proof of vaccination for a COVID-19 vaccine that correspond to the vaccines under article 5(5) (article 8(1)). Another way of accepting foreign digital COVID certificates is by means of an implementing act, analysing whether COVID-19 certificates issued by third countries are in accordance with standards and technological systems, are interoperable with the trust framework for the EU Digital COVID Certificate, allow for the verification of the authenticity, validity and integrity of the certificate and contain the data set out in the EU Digital COVID Certificate (Article 8(2)).

In order to decide whether a certificate for a vaccine administered in a third country must or may be accepted by EU Member States, the same rules as in Article 5(5) apply for EU Digital COVID Certificates issued on the basis of vaccination in a third country (Article 8(1)).
However, third countries obviously do not administer vaccines on the basis of an EU approval, but on the basis of their own approval (or on the basis of WHO approval). It is thus necessary to determine whether a COVID-19 vaccine administered by a third country corresponds to an EU-authorised vaccine, in order to know whether certificates indicating such vaccines fall under the obligatory acceptance provided for in Article 5(5), first sub-paragraph and what rules are applied to the third country nationals vaccinated with the respective vaccines.

Therefore, in order to support the decision of MS, the COM has requested and received information about the vaccines distributed to third countries. The information was received from marketing authorisation holders (MAH) of EMA-approved vaccines. The information received from MAH shows that for several vaccines (Pfizer, Moderna, Janssen, Astra Zeneca), the vaccine is the same and the MAH is broadly the same as in the EU, with some national variations of the MAH name that applied for authorisation, which however do not impact on the overall producer of these vaccines nor on the fact that it is the same vaccine. However, for Covishield, the MAH is not the same as in the EU, but the company that provided the sublicense (AstraZeneca) provided assurance that the composition and manufacturing processes are the same and the vaccines has completed the WHO listing process.

R-COVI and Covid-19 vaccine (recombinant) are sublicensed vaccines, for which the MAH is not the same as in the EU, but the company that provided the sublicense (AstraZeneca), assured that the composition and manufacturing processes are the same.

The COM inquired with the MS whether they agreed that the first category would entail that the respective vaccination certificates fall under the "SHALL be accepted" provision and asked about their position on "SHALL" or "MAY be accepted" for the sub-licensed vaccines.

DE made reference to its list of EU-authorised vaccines which are authorised abroad (original or licensed productions) and are equivalent to the EU-authorised vaccines for the purposes of demonstrating vaccine protection Paul Ehrlich Institute - Coronavirus and COVID-19Coronavirus and COVID-19 (pei.de).

In addition, **DE** mentioned the acceptance of one or two doses of vaccine in combination with a recovery certificate. The **COM** answered that regarding the acceptance of one or two doses of vaccine in combination with a recovery certificate, a NITAG meeting was previously organised on this subject. The regulation 2021/953 on the EU Digital COVID Certificate does specify how many doses should be administered. The related Council recommendation states that recovered persons can be accepted as "fully vaccinated" on the basis of one dose if it is part of the national vaccination strategy of the country of origin.

FR asked when EMA's procedure for AZ COVISHIELD will be finalised. The **COM** replied that there is no active evaluation on the COVIDSHIELD vaccine by the EMA. In the context of the AZ vaccine, EMA has looked at manufacturing sites that are relevant to the EU supply chain.

AT asked whether certificates issued before 1 July will also be accepted. The **COM** responded that if the issued certificates are in compliance with EU DCC Regulation, the certificate will be accepted.

In addition, **AT** asked if a person who has recovered twice, can ask for a second recovery certificate. The **COM** responded that this is possible.

Furthermore, **AT** pointed out that a device ID is missing from the JRC database for a particular rapid antigen test, which is necessary for the technical implementation. The **COM** replied that two manufacturers have not yet provided all the necessary information and therefore do not yet have a device ID.

2. Access to vaccination for vulnerable groups (presentation by the European Centre for Disease Prevention and Prevention (ECDC) and Belgium) – information/discussion point

Vaccines are being rolled out at an increasing speed in the EU. The COM is confident that in at least some MS will reach the Commission's summer target of having 70 % of the adult population vaccinated. However, it may no longer be about the availability of vaccines, but about increasing the uptake of the vaccines that are available.

On 23 June, the ECDC held a webinar in the context of the NITAGs collaboration, in which European countries and associations presented their experience in vaccinating vulnerable population groups shared best practices in that respect. Socially vulnerable populations have borne a disproportionate burden from restrictive non-pharmaceutical interventions aimed at preventing the spread of COVID-19. Evidence is now emerging that socially vulnerable populations are also falling behind in terms of COVID-19 vaccination uptake. The three main socially vulnerable populations include: 1) people from ethnic minorities; 2) irregular migrants; 3) people experiencing homelessness. ECDC mentioned seven good practices to address inequitable access to COVID-19 vaccines in the EU/EEA: 1) consider how to address the causes of inequalities in vaccination coverage; 2) seize the moment; 3) strengthen partnerships between public health and community organisations; 4) strengthen community engagement; 5) facilitate access to vaccinations; 6) work towards closing the data gap; and 7) conduct evaluations.

The COM mentioned that the new Executive Agency HaDEA organised a similar Webinar on 25-26 May, on "Improving vaccination uptake among disadvantaged and difficult-to-reach population groups". The summary report and presentations are available in the Health Policy Platform.

After the ECDC's presentation, BE shared their experience on reaching vulnerable population groups. BE explained that the responsibility of the vaccination uptake remains within the different regions. In the Walloon Region, the vulnerable target populations include: 1) migrants with or without papers (incl. trans-migrants); 2) homeless people; 3) sex workers; and 4) people with mental health problems or addiction. Several initiatives to reach those vulnerable populations include: coordinating at provincial level; financial support to identified territories; supporting municipalities; involving specialised actors; using proximity field actors to raise awareness; and mobilising health promotion actors in the framework of funding to concerted COVID-19 strategies.

3. CoV-2 variants monitoring in wastewater (sewer systems) (Presentation by the EU Joint Research Centre (JRC) – information point

As part of the European Health Emergency Preparedness and Response Authority (HERA) Incubator initiative, launched in February 2021 and which focuses on the detection of SARS-CoV-2 variants, the COM also initiated work in the area of detection of variants in wastewater. JRC presented on the state of play and next actions regarding the EU's activities regarding sewage water monitoring for COVID-19. Data from wastewater analysis shows that the water contains a mix of all mutations present. Such data should be complemented by clinical data. JRC recommends that MS put a surveillance system in place (covering a sufficient part of the population >150 000 inhabitants) by 1 October 2021, and to take 2 samples a week (adapted to local circumstances/ stages of the pandemic). Results should be shared with the national health authorities and the exchange platform: EU Sewage Sentinel System for SARS-CoV-2 (EU4S). The use of common methods sampling and analysis is important for coherence.

The COM mentioned that the use of monitoring in wastewater could also be relevant for certain large sporting or cultural events. The JRC said that this method will indeed be used during the Olympics in Tokyo monitoring the waste water of the Olympic Village.

4. Weekly ECDC up-date on variant spread and on its enhanced surveillance activities – information point

In the light of the spread of the Delta variant and the on-setting summer travel season, the COM has included this as a regular point on the agenda. The ECDC will update on the latest data on the spread of variants, related threats and on recommended measures.

The ECDC gave an update on the status of the **Delta variant (B.1.617.2)**. By 30 June 2021, the Delta variant has been identified in 24 EU/EEA countries and in 96 countries globally. In week 22-23, it accounted for 0-66% of sequenced samples in the EU/EEA. ECDC mentioned **three key public health actions,** including: 1) intensive representative/targeted sequencing and contact tracing; 2) achieve full vaccination of risk groups in the shortest time possible; and 3) continue with countermeasures until high vaccination coverage of risk groups is achieved.

Furthermore, on 6 May the ECDC published a protocol for outbreak investigations of breakthrough infections in Long-Term Care Facilities (LTCF). Due to recent significant increase of the Delta variant, the ECDC invited and encouraged MS to use this protocol. ECDC has linked the protocol to EpiPulse, where discussions regarding the outbreak can take place. Also EWRS users can directly receive an event summary on the outbreak.

The COM reminder country representatives to notify all cases via EWRS as the main reporting tool.

5. AOB: Reporting COVID-19 cases with possible links to sport events

The COM reminded MS to report COVID-19 cases with possible links to sport events attendance. Infectious diseases cases, in particular COVID-19, related to the UEFA should be notified using EWRS, as through EWRS the WHO is also informed.

FR wanted to know if other countries are considering the use of FFP3 masks for healthcare workers in hospitals to reduce the circulation of the new variant. The **COM** thanked France for its question and asked MS to send their answers in writing.

AOB: Cross border Threats to Health committee meeting (review on the new implementing act Passenger Locator Forms (PLF))

The cross border health threats committee meeting will be held either on 6 July 2021. The meeting will be organised to assess the proposed amendment of the recently adopted implementing act amending Implementing Decision (EU) 2017/253 on alerts triggered by serious cross-border threats to health and for the **contact tracing of exposed persons identified** in the context of the completion of PLF. The meeting's invitation and agenda will be sent on **1 July.**

AOB: Outbreak of SARS-CoV-2 in minks (Poland)

Poland gave an up-date on the recent outbreak of COVID-19 on mink farms in eastern Poland. The situation is currently being monitored by the Polish Public Health Authority.