EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 21 April 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Summary Report

Chair: Stefan Schreck, European Commission, DG SANTE C ADV01

Audio participants: AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LV, NL, PL, PT, RO, SE, SI, SK, NO, CH, UK, AL, BA, LI, MG, XK, UA, AD, DG SANTE, DG ECHO, HR, SecGen, ECDC, WHO

1. Digital Green Certificate – up-date from DG SANTE, Unit B3

DG SANTE gave a presentation on the Digital Green Certificate. Currently, all Member States have different types of certificates, data fields, verification and authentication systems. Therefore, the Commission proposed to facilitate safe free movement during the pandemic by establishing a common framework – the Digital Green Certificate. The European Parliament is expected to adopt its position at the plenary on 26-29 April. Further details can be found in the Digital Green Certificate PowerPoint shared to the HSC.

DE is a big Member State and therefore needs a transition period to fully integrate the Digital Green Certificate where paper certificates will still be accepted. The **Commission** replied that discussions has taken place in the Council on a transition period (of six weeks).

BE asked how the Digital Green Certificate can be used for national use (restaurants, bars, etc.). The **Commission** explained that the purpose of the certificate is to support free movement, but it does not preclude its use for other purposes. To use it for national purposes, there must be a national provision in place.

EE asked whether the Member States should have a list of authorised verifiers, or if anybody can check the validity of the certificate? The **Commission** replied that the architecture can be found in the PowerPoint (slide 9). The Commission distributes the keys to the national backend. The national backend should distribute it to verifiers in that specific country (e.g. airlines and other authorities to perform the verification). Any national use needs to be declared in national law.

The **Italian** government is accelerating the conditions for the first use of the Digital Green Certificate and also for the movement between different regions in Italy. Therefore, IT could perhaps contribute to the general EU discussions on this topic.

Regarding the recovery certificate, **NL** believes that in the current proposal it is not possible to use the Rapid Antigen Test (RAT) as the underlying test. NL would like to receive more information on the consideration of not including the RAT. The **Commission** replied that this issue was also raised during the discussions in the Council, however, there is no definitive result yet.

In **FR**, the Digital Green Certificate is supported and integrated into the COVID-19 application. FR will test the new validity system on flights between Corsica and the French islands (Réunion, Guadeloupe, etc.). France asked about the position of the WHO on the Digital Green Certificate. The **Commission** replied that the WHO position is similar to what they previously claimed. However, the Commission sees some changes in the text - the previous text did not refer to test results or certificates as clearly as in the current version. The WHO referred to the condition for entry, the Digital Green Certificate should not become a condition for entry, as there should be alternatives to enter another country (testing, recovery certificate) to avoid discrimination.

2. COVID-19 testing (RAT and self-tests) – up-date from DG SANTE and discussion

A survey on the use of **rapid antigen self-tests** was distributed to EU countries: 26 countries responded (20 Member States). Of the responding countries, 10 countries have COVID-19 antigen self-tests available and 7 countries will soon be putting this into practice. Further details can be found in the PowerPoint on Responses received to the second survey on rapid antigen self-tests.

With regards to the common list of COVID-19 rapid antigen tests, and a common standardised set of data to be included in COVID-19 test result certificates, the HSC was requested to provide the Commission with new information and data - in particular on validation studies - on the RATs used in practice. This new data and information will form the basis for a proposal for the next update of the common RAT list agreed by HSC, as well as a selection of RATs whose results will be mutually recognized. The Commission is still waiting for further input from some countries and expects to send a proposal for further updates to the HSC shortly.

In parallel, DG SANTE has worked with the JRC to establish a more robust and technical procedure to update the RAT lists in the future. The HSC common RAT list and the list of mutually recognized RATs will also play an important role in the development of the Digital Green Certificate. It is therefore crucial to put in place a structured procedure that ensures that all relevant info and data is recorded and discussed at the appropriate technical level. Further details can be found in the PowerPoint presentation on HSC agreed common RAT list & the list of mutually recognised RATs.

SI would like to know what will happen until the new procedure takes effect. The **Commission** replied that it is already introducing some new elements, however, there is need for an update. The aim is to distribute a new proposal at the end of this week (to continue the old procedure for the last time until the new procedure is running).

HU pointed out that the nomination process remains unclear. The **Commission** explained that the objective of the RAT technical working group is to distance itself from the political discussions and conduct scientific technical discussions on the types of criteria and information submitted. So it is important to select someone with biological or technical background who has an overview of what is going on in the country, and on the types of tests used/ validated.

The results of this working group will be forwarded to the HSC where the final decision on the list will be made.

3. Vaccination certificate – acceptance of certificates for vaccines that are not authorized in the EU – for discussion

The compromise text on the so-called "Digital Green Certificate" regulation refers to the WHO Emergency Use Listing when it comes to accepting vaccination certificates issued for vaccines that are not authorized in the EU. Therefore, the Commission would like to have a reflection with the HSC members on the WHO list and on the vaccines included. Further details can be found in the PowerPoint presentation on WHO Emergency Use Listing.

DE stressed that although vaccines prevent severe courses of the disease and creates immunity, very little data is available on the infection rates of vaccinated people.

AT asked if and when incidence reaches such a low point that the current Schengen border controls will no longer be necessary, how will the Digital Green Certificate issued for vaccines not authorised in the EU but being accepted by individual Member States be used within Schengen and external border controls (when e.g. the final destination which issued a Green Certificate is not the country of first contact in the EU which does not accept the certain vaccine)?

The **Commission** mentioned that it would therefore be valuable to have a coordinated approach among the Member States on this part of the regulation, which encourages Member States to also accept vaccines not authorised within the EU based on the WHO list.

FI highly values the recommendations from EMA. When trying to formulate a common list with vaccines not evaluated by EMA, it is important not to make decisions based on politics, but on available data.

HU emphasized that other vaccines should also be included in the Digital Green Certificate.

4. Follow-up vaccination with the COVID-19 (AZ – J&J) – for discussion

The latest developments around the **AstraZeneca** vaccine are as following:

- Following the latest meeting of the European Medicines agency PRAC committee, [Public health communication on 7 April] and based on the latest evidence from vaccination with this vaccine, the conclusion is that the occurrence of the blood clots combined with low levels of blood platelets occurring within 2 weeks of vaccination are a very rare event and the benefit-risk related to the use of the vaccine remains positive. Specific risk factors have not been confirmed.
- The marketing authorisation for the vaccine has been updated to include more information for healthcare professionals and citizens who are vaccinated with the AstraZeneca vaccine on these risks and the symptoms associated with thromboembolic events.
- The PRAC has requested more studies to identify the occurrence of the rare blood clot events.
- On 9 April, the Commission requested the European Medicines Agency, to carry out a further analysis and stratification of data per age group, gender and possible other risk factors. This includes vaccination data, and data on disease epidemiology including infection rates, hospitalisations, morbidity and mortality.

- Moreover, the Agency (EMA) has been asked to provide, if possible, a recommendation on the administration of the second dose of the AstraZeneca [Commercial name: Vaxzevria] vaccine on the basis of the available data.
- The European Centre for Disease Prevention and Control (ECDC) is gathering information on the use of the AstraZeneca vaccine in Member States' vaccination programmes [and EEA countries].

The latest developments around the **Johnson & Johnson** vaccine are as follows:

- On 13 April the US FDA and US CDC recommended that the use of the Johnson & Johnson (Janssen) COVID-19 vaccine should be paused due to very rare cases of unusual blood clots that occurred following the use the vaccine, out of an abundance of caution. On the same day the vaccine manufacturer Johnson & Johnson announced the decision to proactively delay the rollout of the Janssen vaccine in the EU while investigations continue. EMA's safety committee (PRAC) informed that it is reviewing the very rare cases of unusual blood clots that occurred in the US following the use of the vaccine. It is investigating all the cases reported and will decide whether regulatory action is necessary.
- All Member States have now received the Johnson & Johnson vaccine, most of them are waiting for more information on whether or not to start vaccinating with this vaccine.

The following questions were sent to the HSC before the meeting:

1. What implications have the safety issues around the AZ and J&J vaccines for the overall vaccination roll-out in your country? (E.g. did you introduce or plan to introduce any restrictions to vaccination with AZ vaccine by age or risk groups? If so, what is your rationale?
2. Are there any changes in the time schedule for the overall vaccination campaign?
3. Do you have plans for changing the vaccine and/or the time interval between the 1st and 2nd doses?
4. Do you plan to give patients informed choice of vaccine?
5. Following recent safety concerns do you observe any increase of vaccine hesitancy to the AZ vaccine (Vaxzevria) or in general?
6. Does your country have plans to open Covid-19 vaccination to all adult age groups in the near future and if so, how will it be managed (special logistics, trainings)?

FI stressed the importance of taking the data on side effects seriously and wondered whether side effects are taken seriously enough.

DK agrees with Finland - side effects should be taken seriously. Therefore, DK decided to discontinue the AZ vaccine roll-out. DK explained that the risk-benefit is negative given the current epidemiological situation. DK agrees with EMA's assessment that the overall benefit-risk balance of the vaccine remains positive, but DK also follows EMA's recommendation that the decision whether or not to use the vaccine in a national context should be based on the national situation, the availability of other vaccines, and the pattern of resistance due to variants of concern. In DK, the national vaccine programme has progressed rapidly, DK has vaccinated all people at increased risk based on their disease status or situation of living (e.g. nursing homes). DK is now rolling out vaccines based on age, (inviting everyone above the age of 65). 25% of those aged 65-74 have now initiated their vaccine in DK. The epidemiological situation in DK is about 150 hospital admissions per week, of which about 12 people end up in the ICU. If this situation would be the same in one month, and DK would decide to vaccinate people aged 65-69 with AZ, it would prevent 1 IC admission and cause 5 VITT cases. Therefore DK decided to discontinue AZ. With this decision, the full roll-out of vaccination will be delayed

by approximately 3 weeks. In addition, there is a lot of vaccine hesitance towards AZ and J&J. On April 26, a national expert group will advise DK on the use of the J&J vaccine. **ECDC** asked if the Danish study is public, if not, if the analysis could be shared with the ECDC.

In **FR,** people aged 55-59 receive the AZ vaccine. People of 60 years and older can choose their vaccine (Pfizer, Moderna, AZ). People who received AZ as their first dose can be vaccinated with another vaccine for the second dose. People with an age below 55 receive Pfizer or Moderna.

In **BE**, AZ is used for people of 55 years and older. This does not influence the vaccination strategy. The vaccine roll-out for J&J has not started yet. In BE, people cannot choose their vaccine, as it is based on age and risk factors. There is no vaccination hesitancy for AZ. The latest survey showed a vaccination willingness of 80%.

ES has imposed a temporary restriction on the administration of the AZ vaccine to people under the age of 60. A study is ongoing to determine which vaccine can be given as the second dose to people under the age of 60 who received AZ as the first dose (mRNA vaccine, AZ, no second dose). AZ is currently given to people aged 60-79 years old. There is already a high vaccination coverage among people of 80 years and older (about 98% received their first dose). There is almost no vaccine hesitancy (also not for AZ).

DE has made quite a few serious adverse advances in the past 55 cases, mainly in young women vaccinated with AZ. However, there were also cases among men. DE limits the AZ vaccine for people under the age of 60. DE has not yet made a decision on the J&J vaccine. Regarding vaccination hesitancy, the latest survey shows a clear difference between hesitancy for any COVID19 vaccine (6%) and the AZ vaccine (60%). Since there are other vaccines available, it was an easy decision to give other vaccines to people below 60 years old.

The **EE** situation is comparable to BE. EE recommends AZ to people over the age of 60. This does not have a major impact on the overall vaccination roll-out. Discussions are ongoing on whether to vaccinate people under 60 with AZ. EE continues with a second dose of AZ, no reports on blood clots so far. At present, vaccine recipients do not have a choice of vaccines. The overall vaccine acceptance appears to be high (75%), however, there is increased hesitancy toward the AZ vaccine.

LV does not impose any restrictions on the use of AZ. LV follows the EMA findings that vaccines are safe for all age groups. At the same time, guidelines for the treatment of thromboembolism have been developed and implemented. At present, vaccine recipients do not have a choice of vaccines. Vaccine hesitancy regards AZ is increasing.

IT reported that AZ is approved from the age of 18 years, and based on current data, taking into account the low risk of thromboembolic adverse events versus the high mortality from COVID-19 in older age groups. However, it is recommended to use AZ preferably for those over 60 years old. Based on the data available to date, people who have already received a first dose of AZ vaccine can complete the vaccination cycle with the same vaccine.

Andorra is not limiting the use of the AZ vaccine or of any other vaccine. AD is following the guidelines of the WHO and EMA.

5. Framework for tuning response measures: practical demo (ECDC)

In a recent HSC call, ECDC had informed the HSC about the non-pharmaceutical intervention tracker. Since the concept note was last presented, development of the tool/software (covering COVID cases and deaths) is near completion. Therefore, the ECDC gave a more detailed demonstration of the tool.

IE thinks it would be helpful if countries could work with the new tool first and see how it syncs with their own models before making it public.

The **Commission** encourages Member States to actively use the tool for their national activities.

6. UEFA –The Union of European Football Associations – Covid19 –for discussion

The Commission and the HSC received a request from UEFA concerning the European Championship (UEFA EURO 2020), which will take place this summer, after having been cancelled last year. **UEFA** requests the Commission to endorse COVID-19 vaccination of players, support staff, service providers and other individuals involved in the delivery of UEFA EURO 2020, by means of a vaccination campaign taking place in parallel with the ongoing large-scale vaccination in EU Member States. For that purpose, UEFA has entered into negotiations with a vaccine manufacturer. It would be important for the Commission to receive comments from the HSC. The UEFA request was shared with the HSC before the meeting. The Commission is preparing a **reply for UEFA** and will integrate comments from the HSC.

HU is one of the host countries of this football event. HU thinks it is good to vaccinate as many people as possible to reduce the risk of COVID19 spreading during the event. HU believes it is important that the UEFA informs the public health authorities in the country about the event.

According to **SE**, vaccination should be based on medical needs. SE highlighted the possible risk that the approach proposed in the letter would have on the vaccination rollout, as there is a shortage of vaccines and the rollout of vaccines is slower than expected in many places. In addition, SE expressed concern that this could create some priority for other large companies. Regarding the Olympics, SE heard an offer from the Chinese authorities to vaccinate people with the Chinese vaccine, SE does not know how this proposal was handled.

BE agrees with SE and does not approve of such request. Exception of vaccination should be limited in order to prioritise the vaccination for those at risk.

DE mentioned that from a national perspective, this request would jeopardize the official recommendations on prioritisation as provided by the standing council on vaccinations. In addition, DE thinks it would be a fatal signal in terms of communication. UEFA stated that football players could be a role-model regarding vaccination adherence, however, DE is still in a stage where there is shortage of vaccines. Therefore, people might not need a role model at the moment, but access to vaccination itself. Besides, it probably will lead to more similar requests (as mentioned by SE).

ES agrees with the comments made by HU, SE, BE and DE. This is a policy issue, jumping the queue would not be a good message. ES already received a lot of requests, everyone wants to be vaccinated first, but they will be vaccinated when it is their turn. The UEFA event will take place at the end of June, maybe during that period of time, many people will have already been vaccinated.

WHO has raised the topic of international travellers. What will be the policy to allow international travellers into the stadiums? The WHO understood that the EU countries said

internally that only domestic spectators would be admitted. And with regard to the epidemiological situation, how many spectator seats would be allowed? It seems there is now more pressure to admit international spectators.

7. AOB

Up-date on the India variant B.1.617

Variant B.1.617 has first been identified in India and about 70 cases have been found in England and Scotland. If the scarce sequence data are representative for the country, they indicate that B.1.617 is driving the rapid increase in COVID-19 cases in India The mutation profile for B.1.617 suggests that the variant will be less susceptible to neutralisation by antibodies, which may lead to higher rates of reinfections and breakthrough infections. It is unlikely but not impossible that the variant will pose an increased public health threat for the EU/EEA compared to variants B.1.351 and P.1 More data is required to provide a full assessment. Further details can be found in the PowerPoint Variants detected in India.

Two action points on PLF and EWRS

The MS Passenger Locator Forms comments can be sent through the open consultation or directly to the SANTE C3 HSC <SANTE-C3-HSC@ec.europa.eu, by **22/04/2021**.

An EWRS EU survey was shared on 14/04 as selective message, on the use of the EWRS modules during the COVID-19 epidemics and possible future developments in line with the EU Health Union proposal, the MS and EEA countries are invited to provide their input until **28/04/2021**, any questions can be send to the SANTE EWRS <SANTE-EWRS@ec.europa.eu>

Action point on ESI –Rapid Antigen Tests

Concerning the ESI – Rapid Antigen Tests, the Commission reminded the Member States that a deadline was set **yesterday** for returning the signed donation contracts. Many thanks to all that have already sent their completed contracts. If you have not already done so, **please urgently send the signed donation contracts to the Commission**. All **Abbott** and **Roche donation contracts** have been sent out to the Member States. **Shipments** are in full swing. Almost all **Abbott** deliveries have arrived in the Member States. For **Roche**, most shipments have been made and further shipments are expected soon. Please be reminded that shipments can only start after the Commission confirms that all parties have signed the donation contract.