EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

Luxembourg, 16 March 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, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, CH, LI, NO, UK, AL, BiH, BG, MK, RS, XK, UA, MD, AD, DG SANTE, DG CNECT, DG ECHO, DG HR, DG MOVE, EMA, ECDC, WHO, JRC

Key conclusions

1. Halt to AstraZeneca vaccine roll-out

Some Member States have halted the roll-out of the AstraZeneca vaccine after reports of blood clotting.

EMA presented an update on the situation regarding the AstraZeneca vaccine. EMA revealed that the number of reported thromboembolic cases is not higher than expected. Although thromboembolic cases are extremely rare, these cases have been atypical and occurred approximately 10 days after vaccination. Therefore, PRAC is currently investigating cases of thromboembolic events. EMA will discuss the cases with the aim to conclude on Thursday. Today, EMA believes that the benefit of the AstraZeneca vaccine outweighs the potential risks.

As of yesterday afternoon, **ES** temporarily suspends the AZ vaccine until PRAC's position is published. The prevalence of thromboembolism is not high, but occurred in young people and clustering around vaccination is observed. ES understands that benefits outweigh the risks.

DK was one of the first countries to suspend the entire programme. On March 10, the Danish Medicines Agency warned that a 60-year-old Danish woman had developed serious blood clots and died. AT had already suspended a batch of AZ after a similar case. FR and DE also reported a similar case. Therefore, DK decided to temporarily suspend the use of AZ while PRAC investigates the cases. DK considered suspending a single batch, but national experts dealing with the treatment of the deceased woman found it difficult to believe that it was batch-related to become symptomatic after a 10-day interval.

The **NL** took precautionary measure to suspend AZ for two weeks after new information from DK and NO – until 28 March, awaiting the advice from EMA.

DE suspended the vaccination of AZ after scientific recommendation from the Federal Institute for Vaccines in Germany. Thromboembolic events were previously noted, now an accumulation of cases has occurred with short time intervals, 7 cases with fatal outcome. Normally 1 case in 3 or 4 million people per year. Therefore, precautions have been taken and DE is looking into them more deeply and awaiting further guidance from EMA. Ultimately very low risk, but the question must be answered whether it fully justifies the ban on vaccination in the long term and thus misses the benefits offered.

As of yesterday, **FR** suspends AZ vaccination until new information is provided by EMA.

IT suspends AZ vaccination as of yesterday, based on the decision taken by other MS and EMA.

CY suspended vaccination AZ until 18 March, awaiting the investigation by EMA.

SI also decided yesterday evening to temporary suspend AZ vaccination. SI reported no cases but awaits the report from EMA.

EE has not suspended the entire programme so far, the national agency has suspended the specific batch related to the AT case. Recommendation is not to vaccinate people at higher risk of thrombosis. EE reported one case, investigation is ongoing.

AZ vaccination in **LT** is ongoing, but LT suspended the batch related to the AT case as a precautionary measure, while a full investigation is ongoing.

FI continues with the vaccination programme as planned. However, citizens are reluctant and there is lot of media attention. FI has looked into the baseline of thrombotic events, self-controlled case studies were carried out. No increased risk was identified, neither after AZ vaccine, neither after Pfizer/Moderna vaccine. But there is concern among population. FI is looking forward to further advice from EMA.

MT has already used up both batches ABV5300 and ABV2856 by 2nd March. All vaccinated persons have been linked with all admissions and all attendances to emergency department, together with the mortality register. No deaths detected, all causes included. No admissions due to related events (mostly elective admissions), none presented with related complaints in Accident and Emergency. The vaccination programme will continue as planned.

LV suspends AZ vaccination as of yesterday as a precaution. No thrombotic cases have been reported in the country so far.

NO temporarily suspends AZ vaccination, following the decision in DK. Three possible cases involving blood clots and bleeding in younger people were reported in the same hospital. The symptoms occurs 3-10 days after vaccination. 2 fatal events were reported.

IS suspended use of AZ vaccine at 11 March, at that time no thrombotic events were reported after AZ but one for Moderna. As of 16 March, the Icelandic Medicines Agency received 3 reports after COVID vaccination, one for each Comirnaty, Moderna and AZ vaccine.

2. HSC Paper on vaccination, testing and recovery certificates – up-date after comments received, for agreement by the HSC)

On 15 March 2021, the eHealth network agreed on guidelines on COVID-19 citizen recovery certificates. There were three aspects related to these discussions where agreement could not be reached. In the end, the eHealth Network decided that these should be determined at a later stage and by a different entity, most likely the HSC. The three elements in question are:

- The use of **rapid antigen tests** for the purpose of establishing recovery time;
- Validity of the recovery certificate starting from at least **x days** (20?) following the initial positive test result;
- Validity of the recovery certificate limited to **x days** (180?) following the initial positive test result

The Commission is proposing interoperable certificates on COVID-19 vaccination, testing and recovery. The aim is to facilitate free movement in the EU.

HU asked for clarification regarding the aim of the agreement. The **Commission** responded that the discussion paper is setting out the state of play and to ensure that every MS position is well reflected within the document. The agreement is not leading to a decision.

FR, IT, DK asked for more time to send the last comments/agreement.

AT asked who will decide to agree on the three points. The **Commission** responded that it will go to the Council and Parliament. However, we are not looking for an agreement at this point, but at the current position of the MS.

ES mentioned that it is too early to decide, not enough people are vaccinated yet.

EE asked for clarification regarding the use for non-medical purposes of the vaccination certificate, based on which information has this been added to the document? The **Commission** responded that if this seems inappropriate to the countries, a written comment can be send.

MT does not yet feel that evidence supports the use of a recovery certificate for cross-border movement. MT expressed concerns that the European trust framework around Rapid Tests is not yet in place to allow the use of Rapid Tests for cross-border purposes. It is also still unclear how EU citizens living in third countries (e.g. UK, UAE) will be able to fit into the Green Pass system, especially in countries where vaccines not yet used in the EU are being deployed e.g. Sinopharm.

Follow up:

- *MS to send last comments in writing tomorrow by the EOB, no comments is perceived as agreed. Final agreement must be reached, to coincide with the package of measures on travel to be adopted on 17 March.*

3. Update of the common standardised data set to be included in COVID-19 test result certificates (for agreement by the HSC)

On 17 February, the HSC agreed on "A common list of COVID-19 rapid antigen tests, including those of which their test results are mutually recognised, and a common standardised set of data to be included in COVID-19 test result certificates".
The first section of the document includes the common list of RATs and those of which their results are mutually recognised. This list will be updated soon and shared with the MS.

Annex II of this document sets out the common standardised set of data to be included in COVID-19 test result certificates, which will form the basis for the test certificates referred to in the Digital Green Certificate.

- It is important to note that self-tests are not considered in the context of these COVID-19 test result certificates. It only concerns test certificates used in specific contexts, as set out in the Council Recommendation of 21 January and the HSC agreed document of 17 February.
- Based on feedback received from the eHealth network, the Commission updated the annex and circulated the proposal last week to the HSC.
- 8 MS provided feedback (AT, FR, IT, LV, NL, PL, PT and RO)

Most comments were addressed, but there are still **6 pending issues** that we wish to discuss today and to reach agreement on:

1. LV: If a person has undergone two tests with different results (e.g. PCR and RAT), would it be acceptable for the person to use the same certificate with the most favourable result, as do the control services, and should this situation not be mentioned in the document?
2. LV: It should be emphasized in the document that if not all the required information is included in the certificate then the document is not valid
3. LV: It is also important how long it took for the sample to be transported to the laboratory, so to include: "Date and time when the sample was received by the laboratory - Complete date, with time and time zone, following ISO 8601"
4. Result of the test (comments from NL, IT and LV): besides negative and positive we should have a third option (e.g. inconclusive, not-detected, questionable)
5. IT: should the field "testing centre of facility" be required for rapid antigen tests?
6. IT: add details on how the name of the health professional responsible for conducting (and validating) the test: surname(s) and forename(s), in that order

FR, HU and **DE** asked for more time to review the document.

HU mentioned that aim to use a certificate for medical and non-medical purposes are different. The use of a certificate for non-medical purposes is related to political issues. Therefore, more time is needed to go through the document. Regarding testing, a RAT test negative and a confirmatory PCR is required. It is important for patient to have two certificates.

ES agrees with the comments about the tests expressed earlier. There is difference between using the RATs for medical purposes or for travel issues. RATs in asymptomatic people have very low sensitivity. They are recommended for symptomatic in the first 5 days after date of onset.

HR asked which MS are currently accepting a vaccination certificate for the cross-border travel and under which condition i.e. validity of such certificate in the terms of number of received doses and time elapsed since the vaccination? Are vaccinations by the vaccines not yet approved by EMA (e.g. Sputnik V, Sinopharm) accepted? Which MS are currently accepting rapid antigen tests' results for the purpose of border-crossing? Which MS are currently accepting recovery certificate for the purpose of border-crossing and under which condition? HR would be grateful if this information would be collected.

MT mentioned that potential non-medical uses are likely to increase as the science develops. There is definitely a lot of interest from mass event organisers, travel etc. However, we cannot start a document like this with a mind-set based on the current science only but develop an infrastructure that is dynamic and can quickly take on such new scientific evidence to allow for new functions.

Views of Commission on the 6 issues:

1. Up to MS to decide on which test result should be presented and in which context, this goes beyond scope of the document, which is about the selection of data elements to be included in COVID-19 test certificates
2. This could be added, but a HSC agreed document is not a legally binding document.
3. This is not relevant for a COVID-19 test result certificate, what matters is when the sample was taken and when the result was obtained. This is additional information that countries can include if they wish to do so. The HSC agreed document sets out the minimum set of data to be included
4. Yes, we agree to include a third option (inconclusive seems to be best option)
5. Yes, we agree that this could be optional for RAT
6. Yes, we agree to add this to streamline between data elements.

Follow up:

- *MS are to send written comments before tomorrow EOB.*
- *The Commission will send an updated list of RATs to the MS.*
- *The Commission will integrate the received comments and will send a new version of the document.*

4. Medical rescEU capacities (presentation by DG ECHO, discussion)

DG ECHO provided an update on the RescEU stockpiling capacities. Stockpiles for medical equipment are currently available and can be requested by the MS, including masks, respirators, face shields, etc. The PowerPoint will be shared with the MS.

Follow up:

- *The PowerPoint on RescEU will be shared with the MS.*

5. AOB – Passenger Locator Form project update

In the last week, further developments on the PLF front took place, specifically on the legal basis for the PLF exchange platform. Colleagues from different DGs in the Commission worked on an Implementing Act, in a form of amendments to the Implementing Decision 253 from 2017.

Follow up:

- *The proposal will be shared shortly and the HSC will have the opportunity to provide feedback during the public consultation.*