EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 28 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, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SK, CH, IS, LI, NO, UK, AL, ME, MK, XK, AD, UA, MD, DG SANTE, DG ECHO, DG JUST, DG MOVE, Council, ECDC, EMA, WHO

Key Messages

1. National use of the Digital Green Certificate and acceptance of certificates for vaccines not authorised in the EU – discussion

After the last HSC meeting, there was a request to continue the discussion on the Digital Green Certificate. The legal basis for the Digital Green Certificate rests on travel and free movement. However, this agenda item focused on the possible use at national level as requested.

BE mentioned there are ongoing discussions at expert level: how and whether BE can apply the certificate at national level, e.g. cultural events. The discussion is complex and progressing very slowly, in principle openness/willingness among experts that vaccinated people should have certain freedoms. There is a list of certain objectives for which BE wants to find scientific support. BE offers to share this list.

DE has a strong focus on the implementation of Digital Green Certificate. DE expects to implement this in time within the current implementation period. 30 million doses of vaccines will be delivered by the end of June, which can become a challenge when it comes to handling vaccination certificates. In addition, DE emphasized that there is no concrete solution on how self-tests can be included in the Digital Green Certificate. With regard to the acceptance of certificates not authorized by EMA, there is an ongoing defensive approach. The expert level discussion has just begun. It is not clear how vaccination with non-EU authorised vaccines will affect transmission of the virus.

NL stressed that the acceptance of certificates, which are not authorized by the EMA, is still under discussion. NL welcomes an EU approach to this topic.

PT does not intend to use the Digital Green Certificate other than for travel. However, PT is interested to hear what other MS are discussing/planning.

In addition, following discussion in the last HSC regarding **vaccines not authorised in the EU**, the Commission sent out a short survey on the state of play of national plans on acceptance of those vaccines. So far, the Commission received **18 replies**:

- A national approach to accepting certificates issued for vaccines **not** authorised in the EU is currently under discussion in most MS (12). Two countries have already indicated that they do not intend to accept those certificates. Here the criteria applied by the MS is to follow EMA and EU authorisation only. Three Member States have indicated their intention to accept such certificates. ES is currently preparing a list of vaccines for which certificates will be accepted, based on EMA authorisation or final positive evaluation by WHO.
- The vast majority (15 MS) are in favour of a common approach at EU level with regard to the acceptance of certificates issued for vaccines that are not authorised in the EU. One country does not yet have a formal position and another country is still discussing this issue.
- Responses concerning the criteria to be used at EU level to agree on a common approach appear to be more diverse. This is clearly still debated in many MS. Five MS would accept vaccines for which a positive decision has been made by WHO. Four Member States would accept vaccines on the basis of an opinion from the EMA in accordance with Article 5(3)[1]. Two countries proposed the approval of vaccines approved for use in other Member States.

ES mentioned that discussions on accepting certificates from vaccines not authorised in the EU have just started and are in a preliminary phase.

Follow up:

- *The Commission notes interest in a common approach and invites other MS to also contribute to the survey. The deadline for this survey has now been extended until* ***today COB***.

2. Up-date on the Indian variant from ECDC and measure taken by countries– information/ discussion point

The ECDC has provided an update on the COVID19 variant B.1.617, first detected in India. If the scarce sequence data are representative for India, they indicate that B.1.617 is the driving force behind the rapid increase in COVID-19 cases, possibly surpassing B.1.1.7. Early neutralisation results show only a slight reduction in neutralisation capacity by vaccine (Covaxin) and convalescent sera. Further studies are required to fully assess any impact on neutralisation. The available data is preliminary and the assessment may change. ECDC continues to monitor the situation together with global public health partners. Further details can be found in the ECDC PowerPoint presentation on variants detected in India.

The Commission asked the following questions to the HSC:

1. *Did you change the status of India regarding travel advice?*
2. *If yes, what is the status and the advice; if no, why not / are you planning to do so?*
3. *Did you / are you planning to cut/limit air connections to/from India?*
4. *-Is there a need to coordinate at EU level regarding incoming traveller from India (e.g. entering the EU in one country and then travelling within the EU)?*

[1] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. 2004000089en1-32 1..1 (europa.eu)

AT announced travel restrictions from 29 April (decided today) for travellers from India (quarantine, testing). There are no direct flights. This applies to AT citizens. AT would be open to a coordinated EU approach to travel to/from India.

IT banned entry for travellers from India. IT citizens can enter but must be quarantined. Those who have been in India for the past 14 days and are already in Italy must be tested. Two more cases of this variant were detected in IT today.

NO mentioned that as of today, everyone entering from India, Pakistan, Bangladesh and Iraq are required to quarantine in a hotel upon arrival. So far no travel ban has been put in place, only stricter quarantine enforcement rules. Tests must be taken on arrival.

DE categorised India as an area with SARS-CoV-2 variants of concern, leading to travel restrictions. Only DE citizens can enter from India, testing and quarantine is mandatory upon arrival. An EU approach or at least a rapid exchange of information is needed, as travellers from India can come through different EU countries. DE proposes to have a general discussion on how to improve this coordination with regard to travellers from deviating areas, as other variants may be found in other places. Recommendations on measures should be provided for SARS-CoV-2 variants of concern.

BE has banned travel to/from India, South African and Brazil. Exceptions apply.

FR stressed that passengers arriving from India should undergo a negative PCR test, a 10 day quarantine period at home and a negative test after 10 days.

PT reported to have detected five cases from the new variant. PT has no direct flights from India but is strengthening their border controls and will increase sequencing.

NL has imposed flight bans since 26 April. Dutch and EU citizens in transit are accepted with a negative test. Returning citizens must be quarantined, a negative test on day 5 shortens the 10 days of quarantine.

LT is currently discussing the status of India regarding travel advice. The inclusion of India in the list of countries subject to enhanced control measures is being considered, (i.e. enhanced control on isolated persons, stricter isolation conditions apply, etc.). There are no direct flights to India from LT. A common EU position on measures may be considered.

3. New EpiPulse platform – information point, presentation by ECDC

ECDC recently launched Epi Pulse, a new integrated European Infectious Diseases Surveillance Platform. Data in EpiPulse is divided into three main areas: EpiPulse Cases, EpiPulse Events and Documents, and EpiPulse Molecular Typing. The names TESSy and EPIS will progressively no longer be used as they are the names of former platforms, and as all functionalities are now integrated into a single platform. The name ETMS (Event and Threat Management solution) will no longer be used, as this was the name of the project to integrate event-based surveillance. Further details can be found in the ECDC's PowerPoint presentation on EpiPulse: European surveillance portal for infectious diseases.

WHO mentioned that TESSy is used by all 53 countries in the European region and therefore hopes the new EpiPulse platform will not affect this. **ECDC** pointed out that nothing will change for TESSy and WHO (there will just be a new portal). In case of changes, ECDC will notify WHO.

4. AOB

Two action points on providing data to the ECDC

The Commission called on Member States to improve their reporting on vaccination data and variants of concern to the ECDC.

1. The ECDC is in need of more accurate **data on vaccination by age and of residents of long term care.** Reporting data is crucial, yet, several Members States are not providing enough data which makes it difficult to assess the progress on vaccination targets at EU level.
2. In addition**,** it is essential that **data on the variants of concern** identified by sequencing of samples from COVID-19 cases are uploaded to TESSY promptly. There are many Member States which are not sharing their data on variants of concern with other Member States in time for these data to be useful.

The Commission reminded the Member States that **this information is required under Decision 1082/2013** to enable all Member States and the Commission to coordinate action on combatting COVID-19.

Testing – information/ reminder

The Commission has sent a proposal for an update to the **RAT common list**, based on the wealth of information that was submitted by countries to the HSC Secretariat during the past weeks. The RAT common list will, one more time, be updated using the 'old procedure'. Therefore, the Commission invites the HSC members to review the proposal and provide input by **Monday 3 May 12h00** in case of any objections to the changes proposed.
In parallel to this, the Commission will be setting up a HSC technical working group on rapid antigen tests. Once the technical working group on RAT has been established, one of the tasks will be to start working on the next review and update of the list. As a reminder, Member States were asked to nominate an expert in **by the end of this week**, and let the HSC Secretariat know the contact details of the **nominated expert**.

Finally, the Commission would like to stress the importance of the ongoing trilogue negotiations that are ongoing regarding the Digital Green Certificate. The Commission encourages MS to liaise with their **national health attaché's** to ensure that the draft legal texts are in line with the HSC agreed document on RAT, in particular with Annex II on the common data elements to be included in test result certificates, which was updated by the HSC in March. At this stage in the negotiations, it is important that any comments (even those of a technical nature regarding common data elements) be raised **by the MS themselves**.

EWRS – reminder/ action point

An EWRS EU survey was shared on 14 April 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. So far, only 4 countries provided input. After a discussion with the ECDC, it was agreed to extend the deadline for one additional week: the **new deadline** is **05 May 2021.** Any questions can be sent to SANTE EWRS <SANTE-EWRS@ec.europa.eu>

Passenger Locator Forms (PLF)

The Commission confirms the organisation of the Cross-Border Health Threats Committee meeting on **Tuesday 11 May.** The nomination of the members by the MS and EEA countries

and the specific comments to the draft implementing act text are expected by **Wednesday 5 May**.

[Prepared by D. Pietersz, DG SANTE]