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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Luxembourg, 2 February 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Summary Report

Chair: Wolfgang Philipp, European Commission, DG SANTE C3

Audio participants: AT, BE, BG, CY, CZ, DE, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, IS, CH, UK, AL, BiH, MK, RS, XK, UA, AD, DG SANTE, DG MOVE, DG ECHO, DG CNECT, DG HR, Council Secretariat, ECDC, EMA, EFSA, WHO

Key Conclusions

1. Progress with vaccination certificates

On 10-11 December, the European Council called for a **coordinated approach to vaccination certificates**. On 21 January, the European Council agreed to work on a standardised and interoperable form of proof of vaccination for medical purposes. The certificates would allow people to use their medical records in other Member States; other possible use of such certificates will be discussed at a later stage.

There is an overall consensus among Member States on the use of such certificates for medical purposes (continuity of care, e.g. to ensure proper follow up between 1st and 2nd dose). Member States are working on and some are issuing vaccination certificates already. Both paper and digital solutions are supported.

On 27 January, the eHealth Network adopted Guidelines on proof of vaccination for medical purposes[1]. The guidelines define the central interoperability elements: a minimum dataset for vaccination certificates, and a unique identifier. They also set out the basis for a trust framework on which further work will be carried out in the eHealth Network, in collaboration with the World Health Organization, the HSC and the National advisory committees on immunization (NITAG) in order to achieve an EU-global approach.

Preliminary deliberations on the possible use the vaccination certificates include options of providing a proof to avoid or shorten a quarantine period during or after travel, or to allow participation in certain (e.g., leisure) events. Options should also enable support for proof for

[1] https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

people who cannot get vaccinated due to medical reasons or receive the next dose. Possible extensions may include proof of negative test results or previous COVID-19 infections.

NL reported that the discussion on vaccination certificates is still ongoing.
BE mentioned almost all people in retirement homes have been vaccinated.
BE, DE, FR, IT and **SE** highlighted that for the moment, no relaxation/exception of measures will be introduced for vaccinated people.
DE will still use the yellow Vaccination booklet, an electronic vaccination pass is to be introduced only in 2022 as part of the Electronic Health Records. An intermediate e-solution is however under discussion, where one particular focus is on the additional workload of such a system for the medical staff in the vaccination centres and physician's offices, thus a batch number is not foreseen (as in compliance with the eHealth Network guidelines).
MT asked if other vaccines will be included in the digital vaccination certificate, as it would be an advantage to have everything in one digital form.
WHO is currently updating the yellow booklet. More digital solutions are expected, but this will not lead to a full replacement of the paper version.
RO is already issuing an electronic and paper version of vaccinated people.

Follow-up:

- *Vaccination certificates will continue to be discussed in the next HSC meetings.*
- *Countries to inform the Commission on plans regarding persons with vaccination certificates showing that they have been vaccinated with a vaccine without authorization in the EU.*
- *The Commission will circulate a short survey to the HSC concerning the possible use of vaccination certificates.*

2. Non-pharmaceutical countermeasures: use of face masks, measures concerning schools

Some countries introducing measures on the use of **face masks,** in view of the emergence of new variants with higher transmissibility. Guidance from ECDC was circulated to the HSC noting that the stricter recommendation for the use of FFP2 masks in place of other types of face masks in the community is currently not justified because of the very low anticipated added value to prevent transmission of SARS-CoV-2.

The **ECDC** explained that the new variants of concern do not require other recommendations on masks and respirators. Evidence for use of different face mask types in the community is currently very limited. Nonetheless, it should be emphasised that not all masks on the market/homemade are preventing the spread of droplets similarly. There are currently studies ongoing in some countries that have introduced the use of a certain type of masks for the population. However, compliance/adherence remains of high importance. The ECDC is currently updating recommendations on mask, expected to be published mid-Feb 2021.

The emergence of fast-spreading coronavirus variants has once again put a spotlight on the **role of schools** in this pandemic. Currently, 17 Members States are implementing primary school closures and 16 are implementing secondary school closures, either at national or at subnational level. Monitoring the impact of social distancing measures remain very important.

The **ECDC** published a school guidance on the 23 December 2020[2]. In case of closure, secondary schools are recommended to be closed first (less transmission among smaller children). So far, no changes are made to the earlier published recommendations.

IT reopened secondary school mid-January, at 50%-75% of their capacity. Kindergartens reopened at the beginning of January. Children above 6 years old have to wear a facemask.
DE mentioned that the incidences rate are higher in secondary schools. Different measures are in place across Germany. Schools and kindergartens are closed, but emergency kindergartens are open. There has been a decrease of cases after Christmas since lockdown measures have been stricter including closure of schools – so a certain impact of the measures is visible.
NL will reopen kindergartens and primary school as of 8 February. Secondary schools and higher education remain closed for now.

Follow-up:

- *The HSC to provide new information on the monitoring of the impact of social distancing measures, such as school closures, as well as response measures and planning for the next months, in particular on the parameters and thresholds for decision making.*

3. Viral genome sequencing

The HSC has underlined in several discussions the importance of genome sequencing, which is needed to be able to identify variants of concern, such as the so called UK, South African and Brazil variants and to adjust responses.

The Commission has called for Member States to increase their sequencing to at least 5% of all positive tests and ideally to 10%. The Commission is well aware that this is a challenge for some Member States and is exploring options for support. Member States were asked to provide information on their strategies to reach targets and on the needed support.

The **ECDC** has provided sequencing support to Member States; so far only 4 countries made use of this service. The ECDC is currently in discussion with the Commission how to further support countries. The ECDC is able to offer more volume sequencing from next week onwards. Therefore, the ECDC made a selection of Member States that have limited capacity for genome sequencing and will get in contact with these Member States.

Follow-up:

- *ECDC to publish written report in the coming days.*
- *Member States to inform the Commission on their strategies to increase sequencing and needed support.*

4. Use of rapid antigen tests (RAT), progress

The Council Recommendation on rapid antigen tests adopted on 21 January calls on Member States to agree on the following points:

- **a common list of rapid antigen tests** that:

[2] https://www.ecdc.europa.eu/en/publications-data/children-and-school-settings-covid-19-transmission

- are considered appropriate for use for the settings and situations described in the Council Recommendation;
- carry CE marking;
- meet the minimum performance requirements of ≥ 90% sensitivity and ≥ 97% specificity;
- have been validated by at least one MS, providing details on such studies.

Member States should agree on a **selection of RATs** included in the common list of which they will mutually recognise the test results for public health measures.

- **a common standardised set of data to be included in the COVID-19 test results certificate.**

Regarding the common list of RAT, the JRC will be revising its *COVID-19 In Vitro Diagnostic Devices and Test Methods Database* to include the relevant information and to ensure online access to such a list. They will present a proposal for the restructuring of the database to the HSC in due time.

In the meantime, the detailed information collected through the HSC on the use and validation of RATs in Europe, allows for the adoption of a first version of the common list. A draft of this list was circulated to the HSC. Moreover, regarding the standardised set of data for COVID-19 test result forms, this is a topic that has already been addressed by the HSC through a survey that was circulated in November 2020. Therefore, the Commission proposed to prepare a document that brings these two elements together with the goal to reach HSC agreement.

BE asked how other MS validate the RAT of passengers (fake tests, etc.).
DE mentioned the access to RAT validation protocols used by other Member States – link/description how tests are validated as countries use different types of validation. In addition, DE asked whether there is a possibility to de-list a test that does not perform well (question of document access and update).

SANTE will prepare a document on this topic for the next HSC meeting – including legal requirements and in line with scientific evidence

Follow-up:

- *The HSC to review the draft common list circulated (Excel file) and the information on countries, and provide comments including any further details on validation studies carried out, by **4 February**.*
- *The Commission to circulate a first draft of the document to be agreed by the HSC addressing both the common list of RAT and the common data to be included in the COVID-19 test forms, to be agreed with the HSC.*

5. Update on Passenger Locator Forms

The Commission is working alongside the Joint Action Healthy Gateways and the European Aviation Safety Agency on a common digital passenger locator forms single entry point and an exchange platform.

DG MOVE with the support of the European Union Aviation Safety Agency (EASA) has developed a platform that enables the exchange of data between the digital passenger locator forms systems of the Member States (i.e. exchange platform); while the EU Healthy Gateways Joint Action project, funded by the EU health programme and managed by DG SANTE, has

developed a web portal, EUdPLF, with a template for an EU passenger locator form covering all transport modes.

Both projects are in progress. For the EASA strand of the project, the digital passenger locator forms systems of Italy, Spain and Slovakia are connected to the exchange platform. FR and PT have requested observer status. Discussions are advanced with BE, HR, CY, LT, LV and MT, also ongoing with AT, DK, EE and DE. On the EUdPLF side, discussions are ongoing with 13 countries, covering one or several transport modes.

The two projects are complementary. The EU Healthy Gateways project does not include a tool enabling data exchange between participating Member States in the EU Healthy Gateways Portal. The exchange platform might serve this purpose, in addition to connecting the digital passenger locator form systems of those Member States who do not rely on the solution provide by EU Healthy Gateways.

Technical discussions are ongoing between EASA and EU Healthy Gateways to make the two solutions interoperable (i.e. make the two systems interconnected). The aim is that where a Member State adopts the EU Healthy Gateways solution, it is also ready to connect with the exchange platform. In addition, the legal basis is being explored for the data to be exchanged and functioning. The planned timeline is beginning of June 2021 for the systems to be live, usable and interoperable in time for the opening of the travel season.

ES mentioned that there is still a long way to put these forms into practice. Among others, coordination work has to be done with Healthy Gateways as well as the establishment of common data collection. SANTE also mentioned the work to be done regarding the legal aspects. Until the project is finalised, Member States can make use of the EWRS.

Follow-up:

- *Member States to share with the Commission their intentions to join the PLF project or the usage of PLF in general in their country.*

6. Update on Health Emergency Preparedness and Response Authority (HERA) – inception impact assessment

In the 2020 State of the Union address, President von der Leyen called on Europe to draw lessons from the current crisis and build a European Health Union, including a 'European BARDA – an agency for biomedical advanced research and development' to support capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin.

The broad premise of HERA was put forward in the Commission's Communication of 11 November on building a strong EU Health Union. As outlined in the Communication, the mission of such an organisation is to enable the EU and its Member States to rapidly deploy the most advanced medical and other measures in the event of a health emergency, by covering the whole value chain from conception to distribution and use; from horizon scanning to the development of countermeasures; and ensuring that sufficient production capacity will be available when necessary, as well as arrangements for stockpiling and distribution.

HERA is an important element for a strong EU Health Union. It will help to anticipate threats and identify responses.

Preparatory actions, on emerging biological threats to human health and antimicrobial resistance, will be launched in 2021, incorporating work on a European bio-defence response being further developed, oriented to funding the design and development of vaccines, the scale up of manufacturing and also to target COVID-19 variants. Across this endeavor, industry will be an important partner.

To this end, President von der Leyen held a videoconference with CEOs of pharmaceutical companies on 31 January, in order to launch work on European bio-defence preparedness.

The Inception Impact Assessment was published[3] last week of January. This outlines the main challenges, potential tasks and policy options towards a proposal for HERA. The document is open for feedback for 4 weeks.

Follow-up:

- *Member States are invited to read the inception impact assessment. The HSC continues to be updated on developments.*

7. AOB - First cases of infected minks in Poland

It has been confirmed by the Polish competent authorities that cases of SARS-CoV-2 infection in mink have been detected in one farm in Poland. Samples were taken 27 January 2021. These cases were detected in the region of Pomeranian Voivodeship in the county of Kartuzy.

SARS-CoV-2 virus in mink is not unique to PL, there have been reports in nine countries across the EU. SANTE recalled the Danish variant and the great concerns that were raised for human and animal health only a few weeks ago.

PL informed that these cases were detected as a result of active surveillance and screening. Four of 20 animals tested were positive and non-pharmaceutical measures are being taken.

SANTE encouraged active dialogue between human- and animal-health counterparts, taking a one-health approach amongst competent authorities.

DG SANTE Head of Unit on Animal health informed that SANTE are in-touch with the competent authorities in PL and they are monitoring the situation. EFSA have been requested help to set-up an EU wide monitoring system complementing the already adopted EU harmonised approach on COVID-19 reporting. A scientific report on monitoring SARS-CoV-2 infection in mustelids requested by SANTE will be published by EFSA, ECDC in the coming weeks. EFSA further emphasised that all farms should be considered at risk of infection and that there is a need for enhanced testing and sequencing for monitoring and early detection. ECDC further informed that they are monitoring infections through various platforms. WHO informed that they are working with some Member States and also neighbourhood countries. A tripartite (WHO, OIE, FAO) risk assessment report on this matter will soon be published.

Member States were encouraged to re-visit options for response from the ECDC Rapid-Risk-Assessment from 12 November 2020:

- Human testing, sequencing and characterisation of antigenic properties
- Infection prevention and control measures for mink farm workers and visitors
- Animal testing and prevention of spread from animals

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-

- One-health preparedness and response strategies

8. AOB - Epidemiological situation in Portugal regarding COVID-19

PT expressed appreciation for the manifestations of European solidarity from MS in this severe COVID-19 wave.

PT reported on the epidemiological situation: The number of cases has consistently grown since the 25th of December, reaching a 14-day case notification rate of 1600 cases per 100 000 inhabitants. PT highlighted that, at the moment, there is a decrease in new cases and the transmission rate (Rt) is below 1.

The Lisbon area presents the severest numbers in the current Covid-19 wave, with a prevalence of 50% for the variant of concern associated with the UK (B.1.1.7.). The national prevalence of the variant of concern associated with the UK (B.1.1.7.) is 30% of new infections. Concerning the South Africa variant, only two cases have been confirmed.

Lastly, PT informed it made efforts to increase the sequencing capacity.