Luxembourg, 2 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, CZ, CY, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, LI, NO, CH, UK, AL, ME, XK, AD, DG SANTE, DG CNECT, DG JUST, DG ECHO, DG MOVE, DG REFORM, DG HR, COUNCIL, ECDC, WHO

Key Messages

1. <u>EC commitment to support EU Member States with €100 million to purchase tests</u> in the framework of the European digital COVID certificate – information point

The Emergency Support Instrument (ESI) will be used to provide financial support to MS to support the accessibility of tests in the frame of the European Digital COVID Certificates (EUDCC). In order to identify the final beneficiaries of this funding, the Commission will ask MS to identify the national authorities that will act as contact point for receiving the invitation to submit a proposal and to sign the grant agreement. The national authorities should express interest in applying for funding (written communication to follow after this meeting). The Commission is currently studying the allocation of these funds. A questionnaire (deadline 3 June) has been distributed among the MS to seek their inputs on the potential use of the funds.

The intention is to support MS in their efforts to increase accessibility of citizens to diagnostic tests that qualify for the issuance of a test certificate pursuant to the Regulation on EUDCC. In view of the different needs, technologies used and practices in different MS with regards to testing, this support will be provided in the form of grants that MS can use for the procurement and operation of tests. Such tests should be made available, as a priority, to persons who cross borders and intend to obtain a EUDCC. The grants will consist of a lump sum. The available €100 million would be allocated to MS on a pro rata basis, taking population into account. National authorities will need to demonstrate that they have performed those tests, evidenced by the number of EUDCC based on diagnostic tests delivered.

SI asked whether MS have to prove that the tests will be used for the EUDCC. And if paper certificates would be possible. **DE** commented that their EUDCC would be in both paper and digital forms.

FR asked if they have to prove that the test is used for travel only. The **Commission** clarified that would need to know if the tests are linked to the EUDCC (i.e. through countries reporting the number of EUDCC issued based on tests), but that the Commission would not ask if the tests are specifically used for travelling or for other purposes.

BE brought up the use of RAT in the context of the EUDCC. BE encounters problems in entering the producing company or RAT name into the EUDCC, as required in the data –set agreed in the Regulation. BE considered to modify its IT system, but this does not seem feasible. Hence, BE proposed to include an option of choosing "EU validated test" instead of the company. The **Commission** took note of this point and referred to earlier discussion with BE on this point¹. This issue could also be discussed in the eHealth Network. EE noted the same problem.

DE mentioned that the data set for the EUDCC is already set. Perhaps there is a technical solution in the coding.

LV asked about the criteria for the allocation of the grants for the countries. The Commission responded that this information will be provided. The criteria will be based on the number of tests, possibility to use different tests and will also consider population size.

2. Technical Working Group RAT – information point

As presented and discussed at an earlier meeting, a Technical Working Group (TWG) will be set up on rapid antigen tests (RATs). The aim of this group is to have more detailed and technical discussions as well as in-depth reviews of relevant information and data resulting in proposals for updates of the RAT common list. The TWG will also work on other aspects, such as discussing whether a common protocol can be agreed for the validation of RATs. The HSC TWG will be chaired by the JRC (and co-chaired by SANTE), and will thus be the main vehicle for discussing which rapid antigen tests should be added or removed from the list. This will be based on information submitted by companies (through a form that is available on the website of the JRC database) as well as info submitted by countries. A specific form will be created for countries to submit information, so that all the information is collected in a coherent manner. So far, over 20 companies have submitted information for their RAT to be included in the list. In parallel, some countries have reached out to the HSC Secretariat with new suggestions of tests to be included. There is thus already quite a substantial body of information available and ready to be reviewed by the new TWG.

The **first TWG** on RATs will be held on **10 June.** As a first task, the TWG will start looking into the new info submitted by countries and manufacturers. The aim is to have a proposal ready by the TWG for an update as soon as possible. This proposal will then be presented to the HSC for final agreement. The overall goal is to reach agreement on the next update of the RAT common list in the HSC meeting on **16 June.**

DE identified gaps between the tests used at national level and the EU lists. DE emphasised that it is necessary to update the list fast. DE also had a question regarding the sensitivity of the tests. In Germany, the minimum criteria to be reimbursed is a test with a sensitivity of 80%, which in the EU list is of 90%. DE wanted to know therefore if the criteria for sensitivity would be further discussed in the TWG. The **Commission** replied that the approach at the moment is to give companies who received the information on the EUDCC some time to enter the information in the JRC portal, so when the expert group meets on 10 June, they have a long list to review. The Commission encourages MS to inform the companies to subscribe for the EU

¹ In the follow-up to the discussions BE notified the Commission that it would comply with the EUDCC Regulation.

list. Regarding the sensitivity of tests, the criterion of 90% sensitivity was agreed in the Council recommendation².

3. EU Digital COVID Certificate (survey results) – information/discussion point

In the context of the EUDCC, a shorty survey on different aspects of vaccination, testing and recovery certificates was distributed among the HSC. Nearly half of the MS waive restrictions for vaccinated persons, for a quarter of the countries this is not the case, in the remaining countries this topic is still under discussion. In addition, the majority of the countries waives restrictions for recovered persons. Regarding the approach to the vaccination of recovered persons, the majority of the countries recommend a single dose. With regards to travel and testing, most countries accept a SARS-CoV-2 test that is taken within the last 72 hours, only a few countries accept tests taken within the last 24-48 hours. Nearly half of the countries only accept Nucleic Acid Amplification Tests (NAATs) tests, the other half of the countries only accept NAAT and RAT tests. For travellers from third countries, nearly half of the countries only accept NAAT, 37% accept both RAT and NAAT.

DE mentioned that the procedure for documenting vaccination for recovered persons is still pending. DE emphasizes the acceptance time-frame and validity of NAAT. When entering DE from areas of variants of concern, this time frame of validity is reduced to 24 hours for RAT. **EC** mentioned that the single doses for recovered person are also mentioned in the proposal for the updated Council recommendation on EU travel.

FR would like to have an exchange with the MS on the vaccination scheme for recovered persons. Especially with regards to the acceptance of one or two doses regarding the travel certificate. FR recommends only a single dose (booster effect) to people who were previously infected. This would also be important to discuss regarding asymptomatic adolescents. **EC** will organise a joint HSC – NITAG meeting to further discuss this topic.

4. AOB - ECDC update on SARS-CoV-2 variant B.1.617.2 and report from Vietnam

The **UK variant of concern**-list is identical to that of ECDC. The global WHO list differs slightly by not having B.1.1.7+E484K as a separate entity (ECDC has a definition that is slightly different from WHO, since the assessment of the ECDC focuses on the epidemiological situation of the EU/EEA).

The overall **vaccine effectiveness** is slightly to moderately reduced:

- 50.2% to 33.2% after one dose (increase in relative risk from 40.8% to 66.8%)
- 88.4% to 80.8% after two doses (increase in relative risk from 11.6% to 19.2%)

These data show that accelerating administration of the **second dose** should be considered.

B.1.617.2+Δ**144 reported in Vietnam** is by itself very unlikely to cause any significant change affecting transmissibility, immunity or severity. This variant has been reported 27 times in GISAID EpiCoV from 10 countries, apart from Vietnam (first detection 1 April 2021 in India).

AOB - ECDC information on Health Emergency Preparedness and Response Authority (HERA) Incubator

In preparation of the formal establishment of HERA, several preparatory actions are being launched in 2021 that will serve as a blueprint for the EU's long term preparedness for health emergencies and will pilot some of the aspects that will be covered by the new Authority. One

² https://data.consilium.europa.eu/doc/document/ST-5451-2021-INIT/en/pdf

of the five HERA incubators is the **rapid detection of SARS-CoV-2 variants**. The Financial aspects of this area include: outsourced whole genome sequencing support through external contractor under existing framework contracts, national infrastructure support programme through action grants based on national applications, and cross-border capacity-building support programme, possibly established following calls for tender.

➤ Questions can be sent to the HERA grant email address: HERA.Grant@ecdc.europa.eu

AOB – Conclusions ComNet meeting

There have been four meetings so far of the ComNet this year, mainly dedicated to communication around COVID-19 vaccination. Participation was extended to more non-EU/EEA countries, namely UK, Switzerland, Serbia, Kosovo, Montenegro, Albania, Moldova, Ukraine and Andorra. ECDC, EMA and WHO/Europe also give regular updates during these meetings. Contacts have also been made with the Council's Working Party on Information, which is also supporting COVID-19 risk communication activities of Member States, including with materials from all EU institutions gathered in a single platform – the Council's Communicators' Platform. Members of the ComNet were encouraged to get in contact with their country's representative in the Council Working party to get access (direct exchange of contacts was not possible due to data protection reasons).

The last ComNet audio meeting of 27 May was especially interesting, dedicated to the topic of EU Digital COVID Certificates, with lots of questions on various aspects regarding the roll-out of the certificates. This topic will generate the need for further information to citizens, especially on the practicalities, e.g. where to get it, how to use it, what advantages does it provide, what it does <u>not</u> regulate, etc. The Certificate and other topics related to travel and culture are likely to predominate the needs for risk communication over the coming weeks. The EC stands ready to clarify and support MS with the risk communication over the summer.

The next ComNet meeting will likely take place still in June or early July at the latest and will be dedicated to risk communication over the summer, focusing on the need to strike a balance between the willingness to travel and gather, while also maintaining protective measures.

AOB - Specific HSC EWRS meeting

The implementing act amending Implementing Decision (EU) 2017/253 as regards to alerts triggered by serious cross-border threats to health and for the contact tracing of passengers identified through Passenger Locator Forms (PLF) was adopted by the Commission on 27 May 2021 and has entered into force on 01 June 2021. In line with the implementing decision, the EWRS competent authorities participating in the PLF exchange platform should determine together the purpose and means of processing of personal data in the PLF exchange platform, and therefore are joint controllers. Article 26 of Regulation (EU) 2016/679 places an obligation on joint controllers to determine, in a transparent manner, their respective responsibilities for compliance with the obligations under the Regulation. It also provides for the possibility to have those responsibilities determined by Union or Member State law to which the controllers are subject. This Decision should therefore determine the respective roles and responsibilities of the joint controllers. DG SANTE will be organising a specific meeting of the HSC EWRS working group for the set-up of the PLF Joint controllers group, which will be held on 10 June from 10h30-12h00. All EU and EEA countries are invited to participate.

AOB - Special HSC meeting - Action point

An email was sent out the EU27 HSC members on 1 May regarding the special HSC meeting. This meeting will not discuss urgent political matters, but rather new ideas, new tools, best practices and long term improvements. MS are encouraged to send a proposal on what they

would like to present, discuss, or to be presented by a third party. Based on the proposals, the EC will draft the agenda for this meeting, which should take place in the second half of June.