EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Luxembourg, 22 January 2020

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, DK, 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, RS, XK, UA, AD, DG SANTE, DG MOVE, DG ECHO, DG JRC, DG HR, Council Secretariat, EMA, ECDC, WHO

Key Conclusions

1. Commission Communication - A united front to beat COVID-19

The Commission Communication adopted on 19 January on *A united front to beat COVID-19*[1] sets out key actions for Member States, the Commission, the ECDC and EMA in order to reduce risks and keep the virus under control. It builds on the 'Staying safe from COVID-19 during winter' Communication of 2 December 2020.

The Commission informed about key elements of the Communication, including calls on Member States to accelerate the roll-out of vaccination across the EU, to continue to apply physical distancing, limit social contacts, fight disinformation, coordinate travel restrictions, ramp up testing, and increase contact tracing and genome sequencing to face up to the risk from new variants of the virus.

In the context of sequencing targets of the Communication, **AT** noted difficulties with uploading the data on sequencing, resulting in an inaccurate presentation of the data (page 6). The current sequencing volume is 0.255%; the data will be uploaded accordingly. AT is monitoring the situation and is increasing its screening and variant sequencing capacity.

FR will not be able to achieve the goal to reach the sequencing of 5-10% of the positive cases. The national goal is to achieve between 2000 and 4000 samples of sequencing of the positive cases per week.

Regarding passenger location forms (PLF), **ES** noted that the tool for information exchange was tested with ES participating; the tool needs further development to be operational. ES

[1] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_143

mentioned that information about cases are often available in health system databases, but not within the databases for the passenger location form, which needs to be addressed.

Follow-up:

- *An update on the progress with PLF will be provided at the next meeting.*

2. Response to COVID-19 including new variants

Rapidly spreading variants of SARS-CoV-2 that have arisen in the United Kingdom, South Africa and Brazil share the spike N501Y mutations, implicated to increase transmissibility. As of 19 January, UK reported 16800 cases of the UK variant of concern. In the EU/EEA, about 1300 cases have been identified in 23 countries. For the South African variant, 501Y.V2, approximately 570 cases have been identified in 23 countries, including 27 cases in 10 EU/EEA countries. Finally, the P1 variant, originating from Brazil was reported by Japan, followed by reports of identified cases in Manaus, Brazil. So far, no EU/EEA countries have reported identification of this variant.

Early results on the South African variant showing resistance or reduced neutralisation by several monoclonal antibodies, convalescent plasma and sera are of concern, as it could increase the risk of reinfection or vaccine breakthrough infections. For the Brazilian variant, no information on neutralising antibodies is available yet, but mutations in the spike region may also have a potential impact on vaccine effectiveness. In view of the rapid spread of the new variants in Europe and potentially worldwide due to their higher infectivity, the need of reformulation of vaccines must be investigated as quick as possible.

EMA is already discussing the regulatory path for a rapid approval for any changes to be made in the composition of the COVID-19 vaccines. EMA is looking at the experiences with the annual update of the influenza vaccine, in order to see to what extent that pathway can be used for the approval of changes in the COVID-19 vaccines. With respect to the needs of clinical evidence, it is under discussion whether new evidence/studies for changes in the vaccine should be provided pre- or post-approval. EMA will discuss with vaccine developers whether studies can be launched for possible vaccine changes to speed up the process.

The **ECDC** presented an updated risk assessment related to COVID-19 variants of concern in the EU/EEA[2]. Approximately 2000 cases of the variant VOC 202012/01 have been identified in 60 other countries than the UK. The risk associated with the introduction and community spread of the VOC's is assessed to be high/very high, based on the probability of introduction and community spread of VOC and the impact of the introduction and community spread of variants of concern.

The options for a response include surveillance, testing and detection of the merging variants including timely, targeted and representative sequencing of community cases, laboratory preparedness, diagnostic pre-screening for variants of concern, human and material resources and increased sequencing capacity.
Non-pharmaceutical interventions should continue to be implemented, such as community measures, shielding medically and socially vulnerable populations, considerations for school settings, contact tracing, measures for travellers (avoiding non-essential travel, travel restrictions for those with active infection, testing and quarantining for travellers), hospital and

[2] https://www.ecdc.europa.eu/en/publications-data/covid-19-risk-assessment-spread-new-variants-concern-eueea-first-update

healthcare preparedness (activation of surge capacity plans to address the expected high demand for care, maintain care for other diseases, with strict infection prevention and control precautions).

Regarding vaccination and the risk related to the spread of COVID-19 variants, the ECDC noted that it is important to monitor breakthrough infections following vaccination (occurring >14 days after vaccination). The level of cross-protection could vary for different variants, particularly 501Y.V2 variant, it is important to accelerate vaccination campaigns and vaccine effectiveness studies. During vaccine roll-out, surveillance and sequencing needs to continue to provide vaccine product-specific effectiveness results and also variant-specific vaccine effectiveness results.

DE is establishing a strategy group and will increase genome sequencing. Community measures are in place, schools are closed, testing and quarantine measures are in place with regard to virus mutation areas (UK, South Africa and Ireland). DE asked about the new data map concerning COVID-19 variant areas/countries will be in place (discussed under the EU Council). DE noted the special attention on mutation and high-risk areas and asked for daily data provision/maps by ECDC instead of weekly updates. In the meantime, DE refers to WHO data.

ECDC noted that a weekly data representation is more accurate/stable compared to a daily update, which would not provide additional information on the variants. The ECDC is working on the provision of maps.

The **Commission** asked countries regarding their interest to receive day-to-day data on the COVID-19 variants. The Commission noted that the JRC continues to collect data on a daily basis[3].

EE asked if the ECDC is planning to provide more data/analysis on the question of exempting travellers with a vaccination certificate from control measures.

The **ECDC** noted that there are currently few doses available, raising ethical concerns regarding the use the vaccine certificate as a passport, such as discrimination towards people who did not had the chance to get vaccinated. There is currently no evidence that vaccines can prevent transmission of the virus, this data is currently collected. There is also a question on how long the certificate remains valid, which may differ among the different vaccines. Therefore, more information is needed to develop guidance.

The **Commission** noted that the use of vaccine certificates will be further discussed in detail during the next HSC meeting.

CH has two systems in place to detect COVID-19 variants. CH would like to know if other countries also have mutation specific PCR tests in place. CH aims to screen 50% of all positive samples with a mutation specific PCR to recognise all the three variants of concern. This is done within 12 hours after a positive PCR test, variants will be reported to contact-tracing teams (quarantine contacts of contacts, extensive testing). Regarding genome surveillance, CH expects in 1-2 weeks to sequence 10% of the cases (2000 per week).

[3] https://covid-statistics.jrc.ec.europa.eu/.

In the context of the Pfizer quantities being reduced for all Member States, **HR** raised if Member States are considering to change their vaccination schedule (e.g., to give a first dose to a larger population).

The **Commission** noted that Pfizer communicated to deliver as normal from next week onwards. This topic is discussed in more detail in the Steering Board on vaccines.

FR is sequencing for the new variants, 200 new variant cases are tested per day, the sequencing capacity will be increased. FR has reinforced the contact-tracing process and people coming from the UK and South Africa have to show a negative COVID-19 test and stay in quarantine for 7 days. FR does no longer allow self-made (cloth) facemasks in public transport ((surgical) masks with category 1 to avoid spread of the new variant). FR asked for an EU coordination and guidelines from the ECDC regarding facemasks in public transport to control further spread of the new COVID-19 variant.

DE confirmed more strict use of facemasks in public transport/public spaces (differs per region: filter/respirator facemask, surgical facemasks).

BE noted that in hospitals, cloth face masks are no longer allowed, surgical masks are provided to patients/visitors by the entrance of the hospital. Moreover, the use of facemasks among young children is currently under discussion.

The **Commission** noted that there are several offers of companies that are able to provide face masks, countries are asked to inform the Commission in case of shortages. **DE** noted that there is no shortage of FFP2 masks currently and that guidance is available who to re-use masks.

WHO/Europe informed that there is a global IPC experts meeting between WHO, ECDC and US CDC to agree on a common position re: FFP2 or N95 masks. For the time being, there is no evidence that the variants would have any change in modes of transmission to require this, but we will learn about the joint global position on this.

The **Commission** raised the topic of strategic choices for pandemic responses, in particular the elimination strategy, for reflection in the HSC, as this is currently discussed by several countries and scientific fora.

Follow-up:

- *An update on the PLF will be provided at the next meeting.*
- *Measures around schools, use of face masks, and vaccination certificates will be discussed at the next HSC meeting.*
- *Countries to provide an update on response measures and planning for the next months, in particular on whether they have cut-off points/thresholds on key indicators for handling changing epidemiological situations.*

3. Update on COVID-19 treatments and joint procurement

EMA provided an update on monoclonal antibodies that are possible COVID-19 therapeutics, under investigation. Several companies are running clinical trials in various stages with monoclonal antibodies, either a single one or as a combination of two. Some companies are more advanced than others and EMA may start a rolling review on some of them soon. Monoclonal antibodies are studied in outpatient and inpatient groups as well as in specific

population groups e.g. immunocompromised persons. The interplay between monoclonal antibodies is another issue that needs to be studied.

The Commission has been in discussion with several companies having monoclonal antibodies in phase 3 clinical trials, for a possible joint procurement, a call for tender has been launched.

Follow-up:

- *The HSC continues to be updated on the topic of COVID-19 therapeutics.*

4. Use of rapid antigen tests (RAT)

The Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU was adopted on 21 January.

Compared to the Commission proposal, some of the changes introduced include:

- The minimum performance requirements have been changed to at least 90% sensitivity and at least 97% specificity
- The commonly agreed list of validated RATs should also taken into account how mutations of the SARS-CoV-2 virus may affect the efficacy of any particular test.
- Self-testing with or without professional guidance could also be considered, in case research proves that this is indeed possible.
- MS should mutually recognise the results of RT-PCR tests for COVID-19 infection carried out in other Member States by certified health bodies
- MS should agree on a common standardised set of data to be included in the form for test result certificates, which will facilitate mutual recognition of RAT and RT PCR test results.

The Commission Communication of 19 January stresses the importance of testing and the use of RATs. It calls on MS to ensure the swift implementation of all relevant Commission Recommendations as well as the new Council Recommendation, and includes the following key actions:

- MS should update testing strategies to incorporate the use of RAT and develop guidance on the use of these tests;
- MS should update testing strategies to reflect the new variants during February 2021
- MS should agree on a common list of RAT by end January
- Commission and MS should establish a standard set of data to be included on the results form of COVID-19 tests

In light of these recommendations, the Chair stressed the importance of the regular update of the overview circulated among the HSC on the use of RAT.

Follow-up:

- *The HSC to review the information included in the overview file on RTA and make any necessary changes, as well as add any relevant information concerning the possible use of RAT for COVID-19 diagnosis among people from areas with higher incidence of the new SARS-CoV-2 variants.*

5. Expanding viral genome sequencing

The need to rapidly expand genome sequencing was discussed at the last HSC meetings to better understand the epidemic in Member States and as a basis for adjusting control measures.

The Commission Communication of 19 January called on Member States to increase genome sequencing to 5-10% of positive test results and to share genome sequences at EU level. The Commission undertook to support Member States to increase capacity for sequencing in the near future.

The **ECDC** is carrying out a survey of Member States on detection and characterisation capability and capacity for SARS-CoV-2 variants, and informed on the preliminary results based on the responses from 29 countries. ECDC expects to have the full analysis and report at the beginning of February. ECDC noted that there is no significant increase in the level of sequences being submitted by countries and the capacity to access these variants is not sufficient currently. Countries need to increase the level of surveillance and the sequencing of representative samples of COVID-19 cases. From among 29 countries, 26 are actively investigating the emerge of new variants. Three countries sequence more than 10% of positive cases, 5 countries between 1-5%, other countries less than 1%. Ten countries replied to have sufficient capacity in place to reach the recommendation to sequence 5%.

The ECDC supports Member States, on request, to have genome sequencing carried out. Member States pay for the cost of the transport and ECDC covers the cost of the processing. The ECDC and the JRC are analysing results of COVID-19 sequences uploaded on GISAID.

At the last HSC meeting, the Commission asked Member States to indicate via EWRS if they had any needs for support for sequencing. Currently very few countries have indicated that they have a need for such support. The Commission is exploring how to assist e.g. by laboratory support, directly purchasing sequencing services or equipment for use by Member States – Commission is waiting on the results of the ECDC survey and the requests from countries.

ECDC has published estimates of the weekly sequencing capacity required by Member States under various scenarios. Countries should refer to the ECDC guidance to establish what is recommended by ECDC depending on their situation. The ECDC has capacity to assist Member States with up to approximately 2.500/week viral genome sequences carried out over 4 years. The maximum number of sequences, which could be supported per week or month under this contract remains to be determined as it requires negotiation with the laboratories participating in the framework contract. The ECDC is also investigating on how to improve their services and asks countries to keep them informed in this regard. The ECDC will expand their survey on this topic. Information on the process to access this support and contact details were circulated to the HSC.

WHO EURO has also capacity to support sequencing, however, WHO Balkan/Asia has a low sequencing capacity to focus on. WHO asked if ECDC can support the Western Balkan countries. The question will be further discussed between ECDC and WHO.

DG ECHO will check and provide a reply regarding the potential transport support under the Union Civil Protection Mechanism.

DE noted that the more genome sequencing the more variants we will find - a coordinated approach on the evaluation about the clinical and public health consequences as the virus naturally mutes is important.

Follow-up:

- *The full report from the survey on detection and characterisation capability and capacity for SARS-CoV-2 will be published in February.*
- *Countries to inform the Commission on strategies to reach the sequencing target, and information on needs.*
- *Countries should reach out to ECDC with requests for sequencing support, the Commission is exploring further possibilities.*

6. Vaccine deployment monitoring - ECDC

ECDC has been updating the TESSy surveillance system to include the option for Member States to report on the vaccination rollout e.g. number of persons vaccinated by age. A first report from has been shared with the HSC. 16 countries reported weekly data on the vaccine roll-out. The report includes information regarding the administration of the first vaccine, population target groups, estimation updated target groups.
The ECDC will update the report with information regarding the administration of the second dose once available.

Follow-up:

- *Countries to upload data on the vaccination rollout as soon as possible.*

7. AOB Emergency Support Instrument – Rapid Antigen Tests

A revised allocation key rapid antigen tests was circulated for comments for Member States, with a deadline of 22 January. The finalised allocation key, donation contract and further details will be shared with the HSC and focal points. Considerations related to VAT are currently being addressed.