EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Luxembourg, 19 November 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, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PT, RO, SE, SI, NO, CH, UK, AL, MK, XK, MD, AD, DG SANTE, DG ECHO, DG HR, EMA, ECDC, JRC, COUNCIL, WHO

Key Conclusions

1. Update on response measures

The Commission asked the HSC to provide important updates on response and mitigation measures, especially related to health system's resilience, as the increase in hospital/ICU occupancy and new admissions due to COVID-19 is of major concern for most countries.

Follow-up

- *Countries to continue to report on new measures via the EWRS.*

2. Commission proposals - Building a European Health Union: Stronger crisis preparedness and response for Europe – Commission, HSC

The Commission presented a summary of the Commission proposals on building a European Health Union: Stronger preparedness and response for Europe. The proposals include:

- Communication: Building a European Health Union - preparedness and resilience;
- Proposal for a Regulation on serious cross-border threats to health
- Proposal to extend the mandate of the European Medicines Agency
- Proposal to extend the mandate of the European Centre for Disease Prevention and Control

The reinforced framework on cross-border threats aims to:

- Strengthen preparedness: EU health crisis and pandemic preparedness plan will be developed, together with recommendations for national preparedness plans, coupled with comprehensive and transparent frameworks for reporting and auditing.

- Increase capacity of the EU and its Member States for accurate risk assessment and targeted response;
- Reinforce surveillance: A strengthened, integrated surveillance system will be created at EU level, using artificial intelligence and other advanced technological means.
- Improve data reporting, including the reporting of health systems indicators.
- Ensure a stronger role for the Health Security Committee to allow the triggering of a common EU-level response.
- Allow for the recognition of an EU emergency situation that would trigger increased coordination and allow for the development, stockpiling and procurement of crisis relevant products.

The extension of the mandate of ECDC aims to:

- reinforce recommendations on measures to control outbreaks;
- strengthen preparedness support and capacities (e.g. on analysis and modelling) to support Member States in the control of outbreak;
- collect and process data on outbreaks through rapid digitization and integrated surveillance systems;
- reinforce capacity to mobilise and deploy the 'EU Health Task Force' to assist local response in Member States;
- build up the key competences for health protection in Member States through coordination of a new network of EU reference laboratories for public health;
- reinforce the prevention of communicable diseases and specific health issues, e.g., antimicrobial resistance, vaccination and biosecurity.

The Commission has also set out the main elements of the future Health Emergency Response Authority (HERA), to be proposed by the end of 2021. Such a structure would be an important new element to support a better EU level response to cross-border health threats.

DE asked what the role of the future HERA would be compared to the mandate of ECDC. The Commission informed that the establishment of the authority is foreseen by 2023. Currently, a complete impact assessment is planned and the Commission is preparing preparatory actions focusing on emerging biological threats to human health, announced for 2021. The role and interactions with the EU agencies will be defined.
BE asked when and how the legislative proposals will be discussed. The Commission informed that a first presentation of the package took place on 18 November in the Council Working Party on Pharmaceuticals and Medical Devices.

DE informed that the Presidency is still discussing which proposal should be discussed first.

Follow-up

- *Commission to update the HSC on the timeline for negotiations of the proposals, and on the planned webinar on the package.*

3. Commission Recommendation on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection

The Commission presented the Recommendation adopted on 18 October, on the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infection. The recommendation lays down

criteria for selection of rapid antigen tests, recommends specific setting for the use of antigen tests, informs on testing capacities and resources needed and shares the baselines for validation and mutual recognition of rapid antigen tests. It recommends Member States to conduct rapid antigen tests with an appropriate clinical performance by trained operators and in clearly defined settings, as further specified in the document. The tests should be CE-marked and undergone validation studies (other than those carried out by the manufacturer). The Recommendation also stresses the importance of sharing the results of such validation studies carried out within countries, and encourages Member States to share these results, as well as details on their testing strategies and how rapid antigen tests are used or intended to be used.

An **overview table** of all information collected up until this point, on the use, validation or considerations of rapid antigen tests in EU countries was circulated to the HSC. This overview table should be seen as a 'living document' that we intend to update on a continuous basis. We are planning to circulate it regularly, and strongly encourage you to ensure that the information for your country is up to date by sending the HSC Secretariat any new information or details on developments as soon as possible. Sharing of information on testing strategies, use of rapid antigen tests and results of validations studies are elements that are included in the Recommendation that was published yesterday, as well as the testing document that the Commission adopted on 28 October. Moreover, as laid out in the Recommendation, the Commission will extend the existing COVID-19 diagnostic test database ('COVID-19 In Vitro Diagnostic Devices and Test Methods Database') with information on rapid antigen tests and validation studies results and keep the database updated with the latest information.

Finally, in addition to the Commission Recommendation on rapid antigen tests, **ECDC has** published a technical guidance document that intends to facilitate further discussions between Member States on criteria to be used for the selection of RATs, as well as scenarios and settings during which rapid antigen tests are appropriate to be used. The document from the ECDC will also present key elements to take into account for the validation of rapid antigen tests. These, if applied, will ensure reliability and comparability of tests between Member States. The Commission Recommendation stresses that ECDC, in cooperation with the Commission and Member States, will prioritise and coordinate the validation of existing and upcoming types of rapid tests – not only rapid antigen tests but also other ones such as, for example, saliva tests.

BE informed that they are positive towards this recommendation, notably on the criteria for use of rapid antigen tests. Nevertheless, BE noted a minor comment on the mention of the use of rapid antigen tests in local communities, to not be interpreted as elderly care homes, as for said setting the risk linked to the use of rapid antigen tests is too high.

DE supported the comments and suggested that it might be of interest to have Member States consulted on such documents beforehand.

The Commission noted the comments and informed that, evidence and advice from ECDC are being considered for such documents, as well as discussions with Member States in the HSC and other fora. Rapid antigen tests are used in most countries. Limits of performance and appropriate use of these tests are known. As an additional measure to check symptomatic people, rapid antigen tests make sense to be used. But different strategies and applications are in discretion of each Member States. It is necessary to be flexible, also in context of upcoming new, other, methodologies for rapid tests.

CH informed that rapid antigen tests have been validated in Geneva and validated rapid antigen tests are being used for diagnostic purposes. They should be used in the first 96 hours after symptoms or within 5 days after contact with positive case. Abbott and Roche tests have been validated in CH.

Follow-up

- *MS to share results from studies with scientific evidence.*

4. Surveillance for severe acute respiratory infections (SARI) – ECDC

ECDC presented to HSC members an up-date on its work on surveillance of severe acute respiratory infections (SARI)

ECDC work aims to monitor trends of respiratory diseases over time. It is of particular importance in preparation with dealing with several waves of COVID-19 over time.

ECDC explained that part of the joint initiative with the WHO office in EU includes the use of a common protocol and common database, which will be TESSy. In the coming year, this work will fit into a larger project of the ECDC. It will allow to measures vaccine effectiveness for COVID-19, but there is a need to rely on results from surveillance systems.

In May, ECDC director consulted with national competent bodies to see how many countries wanted to join this project and to commit to strengthen the surveillance system. A contract was established with a company to help manage the project when it comes to subcontracting budget to Member States to acquire necessary resources to do data collection. At the moment, 11 countries have confirmed that they are joining this project.

This presentation is to raise attention to the project. Member States intending to join are invited to email ECDC.

Follow-up

- *MS to present their interest to be part of the project to ECDC.*

5. Vaccination plans – HSC

The Commission gave an update on the Advance Purchase Agreement for COVID-19 vaccines being signed. The Commission has now approved a fifth contract, this time with the company CureVac, for the purchase of COVID-19 vaccines on behalf of Member States. It is essential that Member States continue their preparation plans for the arrival and deployment of these vaccines. Key elements for consideration when developing deployment and vaccination plans can be found in the Commission Communication of 15 October, and elsewhere. The WHO has also issued guidelines for countries, including detailed guidance published this week with useful checklists *(WHO/UNICEF Guidance on developing a national deployment and vaccination plan).*

The Commission announced that it would like to maintain discussion on this topic in the HSC and monitor preparedness states on the various elements (e.g. logistics of deployment, prioritisation, registration systems, communication, etc.). A survey was sent out to all HSC Members, with deadline 20 November.

The HSC was also asked to note that the Steering Board on COVID-19 Vaccines has set up an informal subgroup on Vaccination campaigns and logistics.

BE asked the Commission to provide an update on the Joint Procurement of Vaccine Supplies and suggested the organisation of a meeting to discuss more in detail vaccination campaigns.

The Commission will table a more in depth discussion on vaccination campaigns in the HSC. The Commission reminded that ECDC is collecting information on vaccination plans as well, and organises the NITAG meetings on COVID-19 vaccines. WHO also has a group of national

representatives discussing COVID-19 vaccination. Ideally, country representatives taking decisions in this regard should participate in the discussion.

SE updated on their vaccination strategy for COVID-19 vaccines. Preparedness work to implement vaccination plans is ongoing. Currently, priority groups are designated as the elderly and healthcare workers, then followed by the rest of the population. SE noted that national plans are discussed but it is also up to regions to put regional plans in place.

Follow-up

- Commission to organise a meeting to discuss vaccination campaigns
- Member States to further share preparedness plans for vaccination strategies

6. Update on Joint Procurement, emerging needs

The Commission updated on the launch the joint procurement for rapid antigen tests on 19 November, inviting more than 80 manufacturers and distributors. Products covered include rapid antigen test with sensitivity and specificity higher than 90%, using visual and device read technologies. 31 countries (26 EU Member States), EEA and acceding countries are involved in this procedure.

A first virtual meeting was held at technical level with the Specific Procurement Procedure Steering Committee (SPPSC) on 3 November and countries approved specifications of the call on 16 November. The deadline of the call is 3 December and following the evaluation, contract signatures are anticipated before the end of the year, with placing of orders and first deliveries in January 2021.

The Commission further pursues the procurement of Rapid antigen tests through the ESI.

Follow-up

- *Commission to update details on the joint procurement for vaccine supplies at the next HSC.*

7. AOB quarantine

The HSC has discussed the issue of isolation of COVID-19 cases and of quarantine for contacts or related to travel already at several occasions.

Countries have gradually built a number of practices on isolation and quarantine measures. However, the circumstances and duration of such measures vary greatly between countries: while in some Member States the isolation and/or quarantine measures are implemented on a voluntary basis, in others these are mandatory. Moreover, the duration of isolation and quarantine for contacts varies from 4 to 14 days.

On 13 October 2020, the Council adopted a Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, which provides a common framework as regards possible measures for travellers coming from higher-risk areas. As mentioned earlier, the Commission also issued a recommendation suggesting to Member States to conduct rapid antigen tests in addition to RT-PCR tests in clearly defined settings to detect SARS-CoV-2 infections and to limit isolation and quarantine measures.

On 20 November, the new advisory committee bringing together all chief scientific advisors from EU countries discuss the issue of quarantine and isolation as well.

The Commission proposed to the HSC to discuss isolation and quarantine more in-depth in the next meeting with the aim to agree on a joint statement on isolation and quarantine.

Follow-up

- *HSC to further discuss quarantine and isolation in the next meeting with the aim to agree on a joint statement.*

8. AOB – measures related to minks UK update

The UK provided an update on the measures put in place in relation to the detection of new strains of SARS-CoV-2 in mink farms in Denmark.

- On 6 November, DK was removed from the travel corridor list. Travellers from DK are therefore required to self-isolate for 14 days.
- On 7 November, the UK clarified specific exceptions to these measures applied in all sectors.
- On 8 November, the UK prohibited vessels coming from DK to land on territory.
- On 12 November, as no additional epidemiological information was shared, the measures have been extended for 14 days.
- In the meantime, Scotland and Wales have banned direct travel from DK, North Ireland included restrictions on vessels.

9. AOB on testing strategies (requested by Czech Republic).

CZ asked countries if they have changed testing strategies in the last weeks and about the rational behind changes.

DE informed that the testing strategy was developed to be more specific concerning only people with respiratory symptoms, with or without contact.

FR informed that they changed their testing strategy to include rapid antigen tests.

Testing with rapid antigen tests is in place for asymptomatic close contacts, and symptomatic under 65 years old, with no risk of developing severe forms of the disease. It can also be used for large scale testing operation in university and schools.

EL informed that the testing strategy has not been changed but adapted to current regional lockdowns. Drive-through are still available and testing rates have increased with the use of rapid antigen tests.