EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 12 May 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, CZ, DE, DK, EE, EL, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, SE, NO, CH, UK, AL, BA, XK, UA, MD, AD, DG SANTE, DG ECHO, DG HR, DG MOVE, COUNCIL, ECDC, WHO, OSHA

Key Messages

1. **EU Strategy on Therapeutics – information point**

The EU Strategy on Therapeutics was published last week. Although there are now four authorised vaccines in the EU, there is only one authorised medicine, Remdesivir. The COM Strategy on COVID-19 Therapeutics intends to change this. It is crucial that alongside vaccines, the EU intensifies its work in the field of therapeutics and brings together the different strands of work to speed up recovery, reduce hospital admissions and save lives, and help those who are experiencing more long-term effects of this disease.

The EU Strategy on COVID-19 therapeutics:

- Is a building block for the European Health Union
- Is complementary to the successful EU strategy for COVID-19 on vaccines
- Builds an EU portfolio of therapeutics to enhance the response to COVID-19
- Increases Member States' capacity to meet the demand for therapeutics during the pandemic

Key deliverable actions of the strategy:

- Investing on research and development on therapeutics and scanning for candidates
- Ensuring access to large scale clinical trials in the EU
- Reinforce financing and procurement capacities
- Securing supply chains and delivery of therapeutics
- Allowing for a rapid while secure regulatory process
- Accelerating international cooperation and distribution

Further details can be found in the EU strategy on COVID-19 therapeutics PowerPoint presentation.

FR and **DE** welcomed the EU Strategy on Therapeutics.

FR would like to know how the DGs, the respecting funding programs and the agencies will collaborate, how the existing/novel therapeutics will be prioritised, and how the COM will work together with the private sector and pharmaceutical industry. The **COM** responded that several DGs were involved in the processes of establishing the EU strategy. It can be seen as a collaborative platform that also includes other stakeholders. The private sector is providing information to EMA. The COM will continue to collaborate with the private sector. Regarding the prioritisation of therapeutics, HERA will be involved

in scanning the therapeutics, there will be a platform to collect information/tools where many different actors will be involved.

CH mentioned the lack of oral paediatric COVID-19 therapeutics. The COM explained that the strategy is taking in a wide perspective. However, oral paediatric therapeutics will be taken into account.

2. **Rapid Antigen Tests (RAT) – information point**

The HSC has **agreed** by written procedure to update the RAT common list. As a result of this update, 83 RATs are now included in the common list, of which the results of 35 tests are being mutually recognised. The updated document, together with a short press release, was published by the Commission yesterday and circulated to the HSC.

The common list of rapid antigen tests agreed by the HSC is the list of RATs as referred to by the draft Regulation on the **Digital Green Certificate**, which is currently being negotiated in the European Parliament and the Council. Member States shall issue and accept Digital Green Certificates based on this list (and subsequent updates). As the Digital Green Certificate will be based on the information encoded in the JRC database, it is key that all the RATs included in the HSC agreed document are also included in the JRC database. If this is not the case, manufacturers should submit details on their test to the JRC, via the JRC website of the COVID-19 in Vitro Diagnostic Devices and Test Methods Database. Furthermore, as part of the new updating procedure put in place for the RAT common list, it is now possible for RAT manufacturers to submit information and data for RATs that are not yet included in the common list and that they believe is relevant for the HSC to consider. They can do so on the website of the JRC COVID-19 in Vitro Diagnostic Devices and Test Methods Database.

- *The COM still has to receive the nominations of **BG, CY** and **LU** for the technical working group on RAT before the end of this week.*
- *A first meeting of the technical working group, chaired by the JRC, will be organised before the end of the month.*

AT asked how often the common RAT list will be updated. The **COM** replied that this depends on the number of tests that come in and how often it will be necessary to update the list.

IT asked if tests based on saliva will be included. The **COM** responded that from a scientific perspective, it is not certain whether these tests give reliable results. The discussion on this matter will be part of the agenda for the first HSC Technical Working group meeting.

PT asked whether it is planned to add other types of tests to the Common list. The **COM** responded that this is also a good example for a discussion point for the HSC technical working group. The date for the first meeting of the HSC technical working group is not yet agreed. The agenda will be shared with the HSC committee.

The **COM** underlined that members of the HSC can also provide suggestions for topics that should be discussed in the HSC technical working group.

3. **COVID-19 testing in the occupational environment – ECDC-OSHA technical document – information point**

On 6 May, ECDC and EU-OSHA published a technical report on the considerations on the use of rapid antigen detection (including self-) tests for COVID-19 in occupational setting. The use of rapid antigen detection tests (RADTs) and/or self-test RADTs in occupational settings can complement, but not replace, occupational safety and health measures and existing non-pharmaceutical interventions at the workplace aimed at preventing the introduction and spread of COVID-19. There are different legal frameworks and requirements in the different EU/EEA countries concerning testing in the workplace. Several EU/EEA countries have introduced the use of RADTs in the workplace. However, a recent EU-OSHA survey indicates that the use of self-test RADTs is limited in occupational settings in most EU/EEA countries. When considering the use of RADTs and/or self-test RADTs in occupational settings, having a clear testing strategy promotes occupational safety and health and facilitates meeting

the public health objectives of testing. Within the strategy, the test performance must be considered as well as the prevalence of COVID-19 and the transmission dynamics in the occupational setting at hand. Further details of the document can be found here.

DE welcomed the technical document and mentioned that DE has already taken notice of the important points and implemented in laws to oblige companies to offer RAT (including also self-tests) twice a week to their employees.

4. **Use of antibody tests – information from JRC and ECDC – information / discussion point**

The Digital Green Certificate will include the option of a recovery certificate for certificates for persons that have recovered from a COVID-19 infection, if they have proof of an initial positive Nucleic Acid Amplification Tests (NAAT) and that sufficient time (=10 days) has passed since that test. To respond to suggestions that antibody tests should be allowed as proof of immunity for the issuance of recovery certificates, as part of the ongoing negotiations, ECDC has produced a technical note on considerations for the use of antibody tests for COVID-19. Key notes include:

- A positive antibody test result can be a proof of a past infection but is not an absolute proof that a person is not infectious and/or protected against a new infection and cannot transmit the virus further
- There is a risk that the antibodies detected by currently used commercial tests do not prevent infection from newly emerging SARS-CoV-2 variants
- The tests that target the spike protein will be unable to distinguish between people who have been previously infected and those who have received at least one dose of the vaccine

Further details can be found in the PowerPoint presentation from the ECDC: Summary of ECDC Technical Note on the Use of Antibody Tests in the Context of Digital Green Certificate

DE welcomed the technical note from the ECDC. With the current scientific evidence, DE strongly advises against introducing antibody tests in the Digital Green Certificate.

5. **AOB - 'Indian' variant update**

India is currently experiencing a COVID-19 wave with close to 400 000 cases and nearly 4 000 reported deaths per day. The UK observed last week that this particular variant started increasing and there is a possibility that it competes against the current so called 'British variant'. If this is the case, the same may be seen in the EU in two or three weeks. That is why the UK define it as a "variant of concern" and the WHO is proposing the same as a precaution. Further details can be found in the PowerPoint presentation from the ECDC on Threat Assessment Brief: Emergence of SARS-CoV-2 B.1.617 variants in India and situation in the EU/EEA.

WHO mentioned that the Indian COVID-19 variant B.1.617 has been classified as variant of concern since yesterday (11/05/2021).

BE wanted to know the current position of the ECDC on travel bans introduced by several MS towards India. **ECDC** responded that ECDC is giving guidance on non-pharmaceutical measures, and that these NPIs are important to enhance. ECDC continues to evaluate the transferability of the variant and the possible evolving risks.