



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

Luxembourg, 18 December 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, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PT, RO, SE, NO, CH, UK, AL, ME, RS, XK, MD, AD, DG SANTE, DG SG, DG ECHO, DG HR, EMA, ECDC, EMA, Council Secretariat, WHO

#### **Key Conclusions**

##### **1. Marketing authorization of vaccines and therapeutics for COVID-19**

DG SANTE updated on the ongoing work with EMA, including on the conditional marketing authorization for the BioNTech /Pfizer, and Moderna vaccines and discussions related to monoclonal antibodies.

Regarding the authorisation of vaccines, the aim for BioNTech/Pfizer is to receive a conditional market authorization by 22 December. Another meeting will be organised by EMA beginning of January 2021 on the Moderna vaccine in order to accelerate further the issuing of the CHMP opinion and the subsequent granting of the marketing authorisation. Regarding the vaccines developed by AstraZeneca/Oxford University and Janssen, rolling reviews are in progress. An EU market authorization could be expected for the first quarter of 2021.

Remdesivir (Veklury) received in July a conditional marketing authorisation as a COVID-19 treatment. On 10 December, the Committee for Medicinal Products for Human Use (CHMP) adopted a change to the indication of the drug (i.e inclusion of additional text specifying low- or high-flow oxygen or other non-invasive ventilation at start of treatment).

Currently, no monoclonal antibody treatments are authorised in the EU (nine products have received scientific advice by EMA so far including the monoclonal antibodies by Eli Lilly and Regeneron that received Emergency Use Authorisation by the US FDA in November 2020). Currently EMA has not received any application for a conditional marketing authorisation for monoclonal antibodies. However, these products are also eligible for compassionate use (Article 83 of Regulation (EC) No 726/2004), which allows MS to make unauthorised medicines available following an opinion by the Agency on how the medicine should be used and the type of patient who may benefit from the treatment. The request for a compassionate

use opinion has to be made to the Agency by national competent authorities and is not open to companies. Remdesivir was recommended for compassionate use in April 2020 before receiving a conditional marketing authorisation in July 2020.

Follow-up:

- *The HSC will continue to be updated on this topic.*

**2. The European Semester and support under the Recovery and Resilience Facility**

DG SANTE and SG informed about ongoing work related to the Recovery and Resilience Facility (RRF). This is the centrepiece of the Next Generation EU recovery instrument, which will be implemented between 2021 and 2027. The Facility provides loans and grants available to support reforms and investments undertaken by Member States, including mitigating the economic and social impact of the coronavirus pandemic. COVID19 health systems challenges are mainly related to critical equipment, medicine supply chains, and a lack of infrastructure. Support for reforms towards resilient, effective and accessible health systems, in line with the Country Specific Recommendations stemming from the European Semester process, is also eligible under the facility. Access to the Facility is based on National Plans that Member States draw up and submit. The strategic orientation/preparation is set out in the Commission's 2021 Annual Sustainable Growth Strategy. Member States may submit their Recovery and Resilience Plans at the latest by 30 April 2021. The Commission created a website<sup>1</sup> with FAQ. HSC Members are invited to liaise with their Member States contact point during the preparation of the Recovery and Resilience Plans.

Follow-up:

- *The HSC will continue to be updated on the work under RRF and the way these funds can be used for preparedness and response to cross-border health threats.*

**3. Progress on COVID-19 vaccination certificates**

DG SANTE and CNECT informed that discussions are ongoing within semantic/technical subgroups and with ECDC and WHO. Different data sets on vaccinations and vaccination certificates were reviewed, in order to identify which type of data will be useful for immunisation information systems and for the vaccination certificate. In addition, work is needed on trust-governance. The discussion on this topic will be continued in January 2021.

SE proposed to have continuing HSC conversations on the introduction/experiences of a vaccination certificate before the establishment of a unified system.

Follow-up:

- *The HSC will continue to be informed on the progress related to the vaccination certificates.*

**4. Update on response measures, mid-term strategy for the months after lockdowns**

The Chair asked the countries to provide an update on response measures and planning for the next months, in particular on national approaches or mid-term strategies on how to deal with

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<sup>1</sup><https://webgate.ec.europa.eu/fpfis/wikis/pages/viewpage.action?spaceKey=recover&title=RRF+-+Frequently+asked+questions>

the resurgence of cases (e.g., forecasts, scenario planning, preparedness regarding hospital capacities and medical countermeasures, roadmaps or blueprints for response)

FR has introduced a curfew between 8 pm and 6 am. More data on the effects of the taken measures will be available after Christmas.

IE introduced a 6-week lockdown; but schools remain open and construction work ongoing. As the cases are raising, new strict recommendations are expected to be introduced. IE has the priority to keep schools open but also to reduce work pressure on hospitals.

Follow-up:

- *The update on response measures, mid-term strategy for the months after lockdowns will be further discussed with the HSC. Countries are asked to share their strategies and mid-term plans.*

## **5. Quarantine and isolation**

After the last HSC meeting, Member States provided comments that are reflected in the revised version of the draft “Recommendations for a common EU approach regarding isolation for COVID-19 patients and quarantine for contacts and travellers”.

Generally, more references to national rules have been added to leave a maximum of flexibility in the recommended actions e.g. when it comes to defining the end of the isolation period for mild or moderate cases.

There are also several other edits e.g. referring only to quarantine and not “self-isolation” in the part on travel related quarantine.

The revised version was circulated to the HSC members before the meeting.

AT, DE, IT mentioned to send their comments in writing. SE expressed concerns regarding the need of such document.

DK explained that they have a good experience with their national guidelines; nonetheless, the Commission document will be taken into account.

Follow-up:

- *Member States to send all remaining comments in writing by 18 December by 18:00.*

## **6. Proposal for a Council Recommendation on a common framework for the use, validation and mutual recognition of COVID-19 rapid antigen tests in the EU**

The Chair informed that the Commission adopted a proposal for a Council Recommendation on rapid antigen tests (RAT) on 18 December. This document was adopted in response to a specific request by the Council for the Commission to put forward a common framework on RAT, addressing in particular the issue of mutual recognition of RAT test results.

The proposal builds on the two Commission Recommendations published on 28 October and 18 November on COVID-19 testing and in particular RAT, as well as the ECDC technical guidance published on RAT.

Moreover, Member States were asked to provide comments and further suggestions on the points included in the draft proposal. We received feedback from 15 Member States (AT, BE,

CZ, DE, DK, EE, FI, FR, HU, IE, IT, MT, NL, PL, SE) of which the majority has been addressed and included in the final proposal.

The Chair informed that the Commission signed today two contracts; with the companies Abbott and Roche for the supply of rapid-antigen tests for up to €100 million, financed by the Emergency Support Instrument. The rapid-antigen tests will be distributed to MS as of early January onwards. The Commission will coordinate the distribution based on an allocation key.

Follow-up:

- *Member States to inform the Commission that they would like to receive a donation of rapid-antigen tests. Additional information to be provided by Member States: focal point, contact details, delivery location.*

## **7. ECDC/EASA Guidelines for COVID-19 testing and quarantine of air travellers**

The HSC discussed the recent ECDC/EASA guidelines in previous meetings. The ECDC received the written feedback from the MS. The ECDC produced an amended version, which is currently under revision and discussion with EASA. This includes among others the recommendation of the ECDC to avoid unnecessary travelling. A revised version is expected in the following days.

## **8. Case definition for COVID-19**

The ECDC has consulted with the Member States on the update of the case definition to include rapid-antigen testing, which has been published on 3 December<sup>2</sup>. All criteria stayed the same with the exception of the laboratory criteria, to which “*detection of SARS-CoV-2 nucleic acid or antigen in a clinical specimen*”<sup>3</sup> was added. The ECDC closely cooperates with WHO, therefore, there will be no conflicts with their case definition.

## **9. AOB - Update on the SARS CoV2 variant reported by UK and their forthcoming threat assessment**

ECDC informed that following large-scale sequencing efforts the UK has reported a rapid increase of a new COVID19 variant, characterised by spike protein mutations and deletions, in South East England. The ECDC is closely monitoring the situation and preparing a Threat Assessment Brief. There are no indications for increased severity so far. Colleagues of the UK note that one of the mutations of this variant causes a negative result from S-gene RT-PCR assays. Assays targeting the S-gene are not widely used for primary detection, but other countries should be aware of this. The UK recommends to increase monitoring, sequencing of samples, and to investigate this new COVID-19 variant. Investigations on the new variant and the spread across the UK are ongoing.

## **10. AOB – Western Balkan countries – availability of supplies for mass vaccination**

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<sup>2</sup> <https://www.ecdc.europa.eu/en/covid-19/surveillance/case-definition>

<sup>3</sup> Rapid antigen test should be performed within 5 days from symptom onset or within 7 days from time of exposure. If the exposure time is unknown, the rapid antigen test should be performed as soon as possible. Refer to the ECDC rapid antigen test technical document for guidance on the settings rapid antigen tests should be used in, and for further details on confirmation of rapid antigen test results among asymptomatic persons.

The Chair reminded WB countries to make use of EU instruments to support ensuring capacities for the upcoming vaccination campaigns.