EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 24 June 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Draft Summary Report

Chair: Stefan Schreck, European Commission, DG SANTE C ADV01

Audio participants: AT, BE, BG, CZ, DE, DK, EL, FI, FR, HR, HU, IE, IT, LU, MT, NL, PL, PT, RO, SE, SI, SK, NO, CH, UK, AD, AL, XK, DG SANT, DG ECHO, DG MOVE, DG HR, RTD, COUNCIL, ECDC, WHO

Key Messages

1. Update on the common list of Rapid Antigen Tests (RAT) – outcomes of the technical working group (TWG)

The HSC TWG on **COVID-19 diagnostic tests** met for the third time on 22 June to discuss **50+ submissions by manufacturers** and **new proposals** by Member States. No agreement was put forward for inclusion in the RAT common list. The outcomes of the TWG meeting included:

- 15 tests were either already included or data was missing so as to evaluate whether the RAT met the criteria or not
- Most of the proposed tests will be further discussed during future TWG meetings.
- 5 proposed tests use **saliva specimen** and further discussions are required to reach a consensus on whether these tests should also be included on the common RAT list agreed by the HSC.

While the criteria as defined in the Council Recommendation provide a helpful framework, further criteria and definitions need to be agreed upon for independent validation studies. Therefore, a **dedicated meeting** will be organised on **29 June** to agree on a first set of additional criteria, to discuss the **type of eligible samples** (e.g. saliva) and whether there is a need to keep the selection in place for **mutually recognised tests**.

The TWG will also continue to **review country and manufacturer proposals** for new tests to be included. Further proposals for updates of the RAT common list for the HSC to agree on are expected on **7 July and 21 July 2021**.

Moreover, the Commission will soon be launching a **new web page** on the DG SANTE website, setting out details for the general public (and manufacturers) on the procedure in place for the updating of the RAT common list, as well as the role played by the Commission, JRC, the TWG and the HSC.

Furthermore, the COM asked whether MS found the overview table on *"testing strategies and approaches by EU MS concerning the use of rapid antigen tests (RAT)"* useful and whether the exercise should be continued.

FR uses the common RAT list, but also has its own RAT list. FR asked if the additional information of the RATs on the common list could be translated into French. The **COM** will reflect whether it is possible to translate the additional information, and if possible the document should be translated into all official EU languages.

AT commented that it would be helpful if the overview table document could be distributed. In addition, AT would appreciate the introduction of a transition period with a minimum of 6 weeks when a test is removed from the common RAT list. In this way, countries can still use the previously purchased tests. The **COM** will consider Austria's comment.

DK asked when the new RAT list will be circulated. In addition, there have been recent discussions about the criteria of RATs. DK noticed some issues around these criteria already in February. DK wanted to know if some of the inputs have been taken into account. The **COM** expects to provide an update on the RAT list on 7 and 21 July. Regarding additional criteria for the RATs, many discussions have been held on this topic. A dedicated meeting on the criteria will be organised on 29 June.

2. EU Digital COVID Certificate (EUDCC) – towards a common approach to implementation

The EUDCC Regulation was formally adopted and will enter into force on 1 July 2021. It only concerns the issuance and verification of certificates. MS are responsible for the decisions on their acceptance. MS reported that coordination between countries and coherence between national response measures **would be welcome**.

3. Update by ECDC on Delta variant

By 21 June 2021, the Delta variant was identified in 23 EU/EEA countries and globally in more than 80 countries. In week 21-22, the variant accounted for 0-66% of sequenced samples in the EU/EEA. The Delta variant is more transmissible than the Alpha variant and can escape partial vaccination (VE after one dose is in the order of 20-45%) regardless of vaccine type. The Delta variant can **rapidly become dominant in the EU/EEA**. ECDC's top options for response include: to achieve vaccination as early as possible for all groups at increased risk of severe COVID-19; continue the rollout of vaccines at current levels; and non-pharmaceutical interventions should be maintained to contain community transmission of the Delta variant.

MT asked for evidence regarding immunity of the AZ vaccine with a 4 weeks interval between the first and second dose. **ECDC** responded that the evidence comes from the previously published clinical studies. For the AZ vaccine, a longer interval (6-7 weeks) between the first and second dose results in better protection. Nevertheless, since full vaccination protects against severe disease for the Delta variant, it is recommended to have an interval of 4 weeks, to protect a larger population against it.

MT also asked for evidence regarding the need for a third dose. **ECDC** has no evidence of the need for a third dose against severe COVID-19 disease so far. However, the need for a boost will most likely be needed.

4. Update on EU-wide clinical trial networks for COVID-19 therapeutics and vaccines

RTD observed fragmentations of study initiatives and the use of potential therapeutics outside of a study/trial context. Strong coordination between EU-funded COVID-19 therapeutic trials is in place. However, several aspects contribute to barriers: geographic spread (complex governance), trial design, regulatory approval (duplication, different requirements, languages, etc.), and legal administrations (different legal frameworks, languages, etc.). To overcome and anticipate identified barriers, it is important to organise regular meetings of trial coordinators with the Clinical Trial Facilitation Group. Closer interaction between health and research is needed. RTD called on members of the HSC to engage.

No input was received by the MS.

5. AOB – State of play of vaccination of adolescents in EU MS Survey

The COM has almost completed the state of play of adolescent vaccination for the 27 EU MS. COM reminded MS that have not yet submitted their comments on adolescent vaccination plans to do so. Once all input is received, the COM will share the state play with the HSC.

AOB – Special HSC meeting

The COM will organise a special HSC meeting that does not include urgent political matters, but will be a 'market place' for new ideas, new tools, best practices and long term improvements. The COM welcomes proposals from MS to be discussed during the meeting.

AOB – outbreak of infection with SARS-CoV-2 in minks in Poland

The Polish competent authorities confirmed on 22 June that an outbreak of SARS-CoV-2 was detected in a mink farm in Poland. Non-pharmaceutical measures (culling) are being taken by the competent authorities.