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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

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Health Security Committee

Audio meeting on the outbreak of COVID-19

Draft Summary Report

Chair: Ingrid Keller, European Commission, DG SANTE C

Audio participants: AT, BE, CZ, DE, DK, EE, EL, ES, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, IS, NO, CH, UK, AD, AL, DG SANTE, DG MOVE, DG ECHO, DG HR, SG, COUNCIL, EMA, ECDC, JRC, WHO

Key Messages

1. **New ECDC rapid risk assessment (presentation by ECDC) – information point**

On 10 June, the ECDC published the 15th update of the Rapid risk assessment (RRA) which assesses the circulation of SARS-CoV-2, variants of concern, non-pharmaceutical interventions and vaccine rollout in the EU/EEA. The RRA is available online from the ECDC website. Colleagues from the ECDC gave a short introduction on the major updates. The RRA addresses non-pharmaceutical intervention measures, summer travel and considerations for the ongoing UEFA Euro Cup, and the possible options for response.

2. **Relaxation of non-pharmaceutical interventions (NPIs) (presentation by ECDC)– information/discussion point**

The ECDC gave a short presentation on the relaxation of non-pharmaceutical interventions (NPIs). In the light of lowering incidence rates across the European Union, Member States are lifting or changing their NPIs, especially on stay-at-home measures and public gatherings. The ECDC gave a summary on these changes, concluding that many Member States have now reduced and relaxed many of the NPIs. The ECDC reminded Member States that no country situation is the same and that decisions to ease measures need to be consider the local situation, the prevalence of variants of concern and the vaccination coverage. The COMM invited Member States to share their current measures and considerations.
The COMM invited Member States to share their current measures and considerations, especially on what their plans were on loosening the requirements for mask wearing, measures for schools and children and the opening of the cultural sector.

DE commented that there is political pressure to relax the NPIs in Germany and that this is ultimately the decision of each federal state in Germany. Some states have now removed face mask measures, and public gathering measures. **DE** asked about the 'fourth wave' and what considerations should be made

to the unvaccinated groups (young adults, adolescents, children, etc.) especially in regards to the severity of infections.

IS commented that the plan is to have no restrictive measures as of July 2021. They asked the ECDC whether there is an estimate on herd immunity. The ECDC addressed the questions by saying that herd immunity depends on a number of factors, such as how transmissible new variants become, and the duration of immunity of the vaccines. It is also important to consider the increased transmissibility or variants (as seen with the Delta variant) which will require higher number of population coverage to reach herd immunity. The ECDC also clarified that herd immunity is a moving target, and that it is very context specific, citing the example of Israel, where Israel came out of a very strict lockdown and had rapid vaccination rollout with an mRNA vaccine which had indirect effects in the rest of the unvaccinated population.

The **COMM** mentioned that it is planning on taking up the topic of immunity in a future HSC meeting, and it also plans on discussing the rapid rollout of vaccines.

The **UK** gave an update on their epidemiological situation, where cases are rising dramatically, but it is mostly regional. Hospital admissions are increasing but it is clear that the rate of cases to hospitalisations is much lower than pre-vaccine cases and deaths are low. Studies demonstrate that there is good vaccine effectiveness over the Delta variant. The government has decided to postpone the final relaxation of social distancing measures (step 4) until 19 July. The UK is anticipating a resurgence of cases in the autumn, and if there are no NPIs in the winter, it is likely that there will be flu and other respiratory viruses in the mix.

3. Heterologous Vaccination ("mix and match") experiences of MS – information/discussion point

Under this agenda point the mixing and matching[1] of vaccinations was discussed. ES and the UK were invited to present their work on heterologous vaccination. ES presented a summary of the results of their clinical trial study, for which the peer-reviewed study has now been accepted for publication. The United Kingdom presented three different studies that investigate the mixing and matching of vaccines, including: COV-BOOST; COM-COV; and COMFLUCOV. The COMCOV trial is the most advanced and studies the mixing and matching of vaccines. The COMBOOST study evaluates the COVID-19 vaccine platform combinations for administration of a third dose to people immunized with two doses. Lastly, the third study COMFLUCOV, which is planned to take place later this year, will help establish the safety, reactogenicity and tolerability of COVID-19 vaccination administered concomitantly with the influenza vaccine.

FR asked whether it was possible to receive the slides from the presentations and whether the UK studies were integrating the Sanofi-GSK vaccine. To which the **UK** replied that the slides belong to the coordinators of the studies, and would consult them for distribution of the slides and clarified that the Sanofi-GSK vaccine would be included in the COVBOOST study.

DE asked what the considerations are in relation to waning immunity and a fourth wave and what the current evidence is on the need for booster vaccines. To which the UK replied that there is no certainty about a 'fourth wave' and that it should be considered as a plausible scenario in which there will be a resurgence of cases in the autumn and winter. The **UK** also commented that there are some signs of waning immunity in relation to the vaccines, and the emergence of new variants could change the effectiveness of vaccines, therefore, booster jabs will be an important defence against the variants in the absence of variant specific vaccines.

IT shared their experience with heterologous vaccination, whereas of 14 June IT approved heterologous vaccination for people vaccinated with first dose of the AstraZeneca vaccine to be

[1] Refers to when a person received two doses from two different vaccines

vaccinated with the BioNTech-Pfizer or Moderna vaccines for their second dose in people who are less than 60 years of age. The second dose is administered 8-12 weeks after the first dose.

In **DE**, there was an update on heterologous vaccination, where people vaccinated with the AstraZeneca vaccine and under 60 years of age, since April, are recommended to do the 2nd dose with either the BioNTech-Pfizer or the Moderna vaccine. They have conducted three studies which they will share with the HSC, but they show the same results as the ES study, where the immune response increased and there were more side effects after vaccination.

DK asked the COMM whether they are considering including heterologous vaccination to the document that was circulated to the HSC on different issues related to tests, and vaccination in the context of the Digital COVID Certificate. The **COMM** welcomed any comments and would reflect how this could be included in the paper.

The **JRC** asked whether the use of heterologous vaccines would become a normal practice, to which the UK replied that there is not enough data at the moment, but the results of the COMCOV will be helpful for countries that are starting their vaccination campaigns.

The **UK** also took the opportunity to raise the question on how people who have participated in vaccine trials and studies would fit into the issues related to the Digital COVID Certificate. The **COMM** clarified that the Digital COVID Certificate included the number of doses and the name of the dose for each individual, therefore, issuing a certificate to a vaccinated individual should not be hampered with authorised vaccines. In relation to unauthorised vaccines, it will be up to each individual country to accept the certificates and it is up to each country to issue certificates to the participants in the trials.

4. Update of common list of RAT (outcomes technical working group) – for agreement

Last month, the HSC technical working group (TWG) on COVID-19 diagnostic tests was set up, consisting of technical experts of all 27 MS and Norway, as well as representatives from the ECDC, the JRC and different Commission services. The group met for the first time on 10 June, and on 15 June for a second time.

The COMM gave an update on the state of play of the discussion of the TWG. During the first meetings of the TWG, the importance of ensuring that the HSC agreed on an RAT common list which is up to date and reflects the current use of RATs across the EU, particularly in the context of the EU Digital COVID Certificate. Expectations at both the political level and on the side of manufacturers is high, and as a first objective it was agreed that the group would work towards a proposal for a next update as soon as possible.

From the start, it was clear that, while the criteria as defined in the Council Recommendation provide a helpful framework, further criteria and definitions need to be agreed on for independent validation studies. This will be addressed by the technical working group during the next weeks to assess whether tests should be included or not. Until such additional criteria have been agreed upon, the RAT common list is evaluated against the current criteria in place.

Over 50 submissions by manufacturers were reviewed and over 100 proposals by countries were put forward, including proposals from countries and manufacturers. Of these, the majority were either already included or data was missing to evaluate whether the RATs met the criteria. Around half of the tests put forward need further discussion and five new RATs have been put forward for inclusion in the EU common list.

In the coming weeks, the TWG will further discuss and agree on additional criteria, particularly related to the independent validation studies. Once the additional criteria has been agreed, a thorough review of the overall list will be carried out, and several tests that are currently ‘on hold’ will be reviewed again. Based on the ongoing discussions concerning the definition and criteria to be linked

to the independent validation studies, the TGW suggests that, at this stage, none of the tests already included be removed. To address these points, additional text was included to the main body of the document presenting the RAT common list. Moreover, a disclaimer was added to the top of the list, stressing that the tests included represent eligibility based on the information and available data, but that discussions will continue on defining further criteria. Furthermore, it was agreed that an addendum should be published to the RAT common list, setting out which tests proposed by manufacturers and countries have been reviewed but not included and which tests are still under discussion.

As next steps, the group will review again new submissions by manufacturers (>50) and continue discussions on the common framework for independent validation studies. The TWG will meet on the week of 21 June, with the aim to put forward a next proposal for tests to be included in the RAT common list at the next HSC meeting on 24 June. After this, the TWG is working towards putting further proposals forward to the HSC on 7 July and 21 July. The updating process will thus become a regular exercise.

The **COMM** then asked the HSC whether they agreed with what was proposed by the TWG, including: the five tests put forward to be included in the list, the disclaimer and additional text and the addendum.

FR stated they saw no major difficulties with the proposed text in the list. FR is in the process of implementing the Digital COVID Certificate and is currently liaising with pharmacies and health professionals on the RAT list that is validated at EU level. FR asked if the list would be published in a recognised website for pharmacies and health professionals to access it.

AT wanted clarification on the tests removed from list, because tests were procured in large numbers in AT and wanted to make sure these tests were included.

DE agreed with the five tests and the disclaimer and expressed it was problematic that there are tests on the list that were negatively evaluated in DE and would therefore only welcome the list if they were deleted. DE agreed with keeping them temporarily, but on condition that the TWG discusses deleting these tests in the coming weeks.

The **COMM** commented that the group will continue discussing and agreeing on the criteria for validation studies and have a thorough review of all tests. The COMM concluded the discussion with agreement from the HSC on the five additional tests included, the disclaimer and additional test and on the addendum. Both documents will be published in the website and the link will be shared with the Members.

5. AOB – Handling of sublicensed vaccines and recognition of paper vaccination certificates

The COMM received a question from **DE** regarding the recognition of vaccines approved by the European Medicines Agency (EMA) and sublicensed in third countries, as these vaccines may have different names. DE would like the creation of a list of sublicensed vaccines, so they can be easily recognised. DE also wanted to have more information on the paper vaccination certificates and proposed that it would be useful to find a common approach to avoid doubling the work within the EU. The **COMM** commented that these topics would be included in the discussion paper circulated to the HSC and asked the HSC Members to send their comments on these issues to find a common stance.

AOB - State of play of vaccination of adolescents in EU MS

As a follow-up to the discussion from the previous HSC Meeting on vaccination of adolescents (12-15 years), the secretariat circulated a question about Member States' plans. The COMM reminded Member States to send their feedback on the state of play of vaccination of adolescents.

AOB – COVID outbreaks –EWRS

The COMM asked BE to provide information on the recent COVID-19 outbreak in a retirement home. BE provided an update by reporting that the retirement home had been affected by both the Alpha (B.1.1.7) and Delta (B1.617.2) variants and both residents and staff had been affected. The first case was notified on 18 May. Eleven people died among the residents during the last four weeks, and the current vaccination status (2nd dose >88% on 19 February 2021), other variants involved and possible other underlying causes are now being examined in detail to confirm a linkage with the delta variant. Samples for serology are currently collected and processed (University KULeuven), after which a booster vaccination will be considered. The presence of SARS-cov2 variants among the staff is ongoing and confirmed so far the presence of the Alpha variant. Infection prevention measures (including cohorting and isolation) as well as additional training and encouragement to increase the vaccination coverage among staff (approximately 40% in February 2021) were organised. The Walloon Ministry of Public Health and regional Health authority AVIQ, university laboratories and Sciensano are working together with the dedicated direction and staff, to further analyse this in detail after which we will communicate of our findings.

Conclusions

The COMM concluded the meeting and reminded the Member States to send their comments on the RAT list by 14h00 on **16 June**, to send written input on national recommendations for vaccination of adolescents, and to send comments on the paper on topics of vaccination and tests in the context of the Digital COVID Certificate with deadline of **18 June**.