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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

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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, EL, ES, FI, FR, HR, HU, IE, IT, MT, NL, PL PT, SE, SI, SK, NO, CH, UK, AD, DG SANTE, DG MOVE, DG HOME, DG JUST, DG ECHO, DG HR, Council Secretariat, EMA, ECDC, WHO

Key Conclusions

1. Commission Communication on preparedness for the increased threat of SARS-CoV variants

Later this year the Commission will come forward with a proposal for a Health Emergency Preparedness and Response Authority (HERA). HERA will help to anticipate serious cross-border threats to health and identify effective responses. The aim is to have HERA operational by 2023 at the latest. The Inception Impact Assessment of HERA was published end of January and is open until 24 February.

In the interim, the Commission has put forward a specific strategy for EU prevention, mitigation and response to the potential impact of SARS CoV-2 variants. In line with this, the Commission aims to establish and operate a new bio-defence preparedness plan – the HERA Incubator – as set out in the Communication *'HERA Incubator: Anticipating together the threat of COVID-19 variants'* put forth on 17 February, for discussion in the upcoming European Heads of State and Government meeting on 25 February to endorse and mandate the proposed bio-preparedness work.

The Communication outlines five key areas, with a view to better equip the EU to deal with the threats posed by new variants of COVID-19 and to support efforts to develop and significantly increase production of COVID-19 vaccines.
The first of these actions aims to ensure rapid detection and characterisation of SARS CoV-2 variants. The second action area will focus on providing support for the swift adaptation of vaccines by boosting related research, in terms of identification of relevant strains and guidance on vaccine changes that may be needed. The third area covers the setting up of a European

Clinical trials network. As such, a new clinical trial network called VACCELERATE COVID-19 is launched on the 17 February. If needed, the Commission will then stand ready to use the existing Advance Purchase Agreements (APAs) to support companies in necessary investments to ensure rapid access and delivery of these next generation vaccines. The fourth action area aims to ensure a fast tracking regulatory approval of updated vaccines and new or repurposed manufacturing infrastructures. Under the final heading, support will be made available for enabling the upscaling of production of existing, adapted or novel COVID-19 vaccines.

HERA Incubator will ensure continuous exchanges and operational cooperation between regulators, public authorities and industry involved in the value and supply chain. It will be operated and driven by the Commission and form the backbone of a cooperation between researchers, technological companies, developers, manufacturers and regulators and public authorities. This plan serves as the building blocks for the upcoming HERA.

Follow-up:

- *The HSC continues to be updated on this topic.*

2. Progress with vaccination certificate

On 21 January, the European Council agreed to work on a standardised and interoperable form of proof of vaccination for medical purposes. The certificates would allow people to use their medical records in other Member States; other possible use of such certificates will be determined at a later stage.

On 27 January, the eHealth Network adopted Guidelines on proof of vaccination for medical purposes[1]. The guidelines define the central interoperability elements: a minimum dataset for vaccination certificates and a unique identifier, and set out the basis for a trust framework. This work is ongoing in the eHealth Network, in collaboration with the World Health Organization. A short survey was launched on the possible use of vaccination certificates with the HSC. So far, 8 EU/EEA countries have replied (BE, BG, CZ, DE, IT, LV, SK, and NO). The current use of the certificates is for medical purposes. Most of the countries reported they do not have plans yet for future areas and are still discussing this question.

DE is working on digital vaccination certificates. Currently, both paper and digital certifications are being issued. According to the law, documentation must be done on paper making the digital certificate complementary. Discussion is ongoing regarding the use of vaccination proof for other than medical purposes, as no scientific evidence is available yet about vaccination and the infectivity of a vaccinated person.

Follow-up:

- *Results of the survey on the possible use of vaccination certificates will be shared with the HSC.*

3. Rapid risk assessment

While most countries are currently seeing a decline in overall infections in response to non-pharmaceutical interventions, the introduction and increased spread of new SARS-CoV-2

[1] https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

variants has raised concerns. The variant B.1.351 has also been increasingly reported in EU/EEA countries, often but not only linked to travel, and it has been associated with outbreaks. The variant P.1 is so far reported at lower levels, which may mainly be linked to travel exchange with Brazil, where this variant appears to be spreading.

The B.1.1.7 variant appears to be more transmissible and may cause more severe infection; several countries where the variant has become dominant have seen rapid increases in incidence. B.1.351 is also associated with increased transmissibility; in addition, there is evidence pointing to the potential for reduced effectiveness for some of the COVID-19 vaccines and this variant. Ireland reports B.1.1.7 to be the dominant circulating SARS-CoV-2 strain and, based on growth trajectories observed, several other countries expect the same in the coming weeks**.**

Based on the current epidemiological situation immediate, strong and decisive public health interventions are essential to control transmission and safeguard healthcare capacity, including proactive strengthening and maintaining of layered non-pharmaceutical interventions in the coming months. A rapid vaccine deployment among priority groups is needed to reduce hospitalisations and intensive care unit admissions due to COVID-19. ECDC recommends that non-essential travel should be avoided as part of general physical distancing measures in the community. Moreover, increasing levels of pandemic fatigue need to be addressed.

IE asked about the new advice in the risk assessment regarding quarantine measures for travellers. Previously 14 days and testing on day 7 was recommended, when negative, quarantine measures could be released. In the latest publication, some of these measures have been relaxed. The **ECDC** noted that according to the latest evidence, the risk of transmission by introducing less quarantine days does not justify more days of quarantine, which has a higher impact on the overall population. The new recommendations are in line with the recommendations of the Council.

4. Response to COVID-19 including new variants, exit from lockdowns

The Commission asked for updates from the Member States on new measures implemented, as well as on planning exit from lockdowns and criteria for decision making. **DE** has 16 autonomous states deciding on COVID-19 measures. Not all decision taken on federal level are automatically binding in the single states. Currently, more than 20% of newly identified cases on a daily basis are of variants of concern, mainly B.1.1.7. In addition, there are concerns about increased dramatic developments in neighbouring countries

BE is reflecting on measures for nursing homes once reached vaccination coverage. Non-medical contact professions (hairdressers etc.) are operating again.

Follow-up:

- *Member States to notify response measures through EWRS.*
- *The Commission is developing a discussion paper on the elements and experience with implementing elimination strategies to be shared with the HSC.*

5. Use of rapid antigen tests, for agreement

Since the adoption of the HSC document on *'Recommendations for a common EU testing approach for COVID-19'* on 17 September 2020, the HSC has been actively discussing and sharing information on national testing strategies, in particular with regards to the use of rapid antigen tests.

Several countries provided feedback (AT, CY, DE, DK, ES, NL, PL, PT); mostly to complete details in the common list of RAT, but some were more substantial and referred to specific points where further discussion in the HSC is required.

Specific points raised by countries were set out in the document, including issues around the quality of data collected through national validation studies, sensitivity levels reported and the context in which mutual recognition should be applied. These are thus points that the HSC will further focus on when continuing its discussions on RAT. The Joint Research Centre will play a key role in the continuation of the work on RAT, and is currently updating its COVID-19 diagnostic medical devices database.

The Chair stresses that the document should be seen as a *living document*, and that discussions on RAT will continue in the HSC and updates will be made to the document. Moreover, regarding the common the common dataset for COVID-19 test results, the HSC will continue discussions to explore whether there is a need to create a digital platform in this context. The eHealth network is involved in these discussions, including on specific recommendations on the common dataset for COVID-19 test results.

Follow-up:

- *The HSC agreed on the 'Common list of COVID-19 rapid antigen tests and standardised set of data to be included in COVID-19 test result certificates'. The document will be published.*
- *JRC will give a presentation before the end of the month on how they are planning to restructure the database and other next steps.*

6. Using face masks in the community

The ECDC introduced guidance on mask wearing. The evidence for the use of medical face masks in the community to prevent COVID-19 is limited; face masks should be considered as a non-pharmaceutical intervention in combination with other measures to control the COVID-19 pandemic, considering the following options:

- Wearing a face mask is recommended in confined public spaces and can be considered in crowded outdoor settings.
- For people vulnerable to severe COVID-19, such as the elderly or persons with underlying medical conditions, the use of medical face masks is recommended as a means of personal protection in the above mentioned settings.
- In households, the use of medical face masks is recommended for persons with symptoms of COVID-19 or confirmed COVID-19 and for the people who share their household.
- Based on the assessment of the available scientific evidence, no recommendation can be made on the preferred use of medical or non-medical face masks in the community.
- When non-medical face masks are used, it is advisable that masks that comply with available guidelines for filtration efficacy and breathability are preferred.

DE mentioned there is a strong tendency to withhold use of non-medical masks, strong recommendations for medical masks. Bavaria only recommends FFP2 masks in public transport.
FR does not recommend homemade facemasks. FFP2 is mainly recommended for medical staff, not for general population.

7. Certificate for recovered persons of COVID-19

The opinion from HSC members were asked on a common approach for an EU medical certificate to attest the full recovery of confirmed patients. From the responding 12 countries, 8 countries showed support or interest (AT, BG, CZ, DE, ES, LT, ES, NO). NL is still investigating and SE sees limited possibilities in arriving at a common position on an EU medical certificate to attest the full recovery of confirmed patients.

Based on the feedback provided, the Commission will prepare a background document and circulate to the HSC for discussion at the next meeting towards a common approach on this topic.

FR considers people who have a positive laboratory test result older than 15 days and less than 60 days, does not ask for a doctor certificate.

Follow-up:

- *Remaining Member States to send their feedback in writing.*
- *The Commission will prepare a background document on certificate for recovered persons of COVID-19.*
- *The topic will be further discussed in the next HSC meeting.*

8. Vaccination recommendations for children and adolescents, clinical trials

Three COVID-19 vaccines are currently authorised by EMA for use in the EU. The BioNTech/Pfizer vaccine is authorised for use in individuals **16 years** of age and older and the COVID-19 vaccines from Moderna and AstraZeneca respectively are authorised for use in individuals aged **18 years** of age and over. The safety and efficacy of the various COVID-19 vaccines in children and adolescents younger than specified age groups have not yet been established and no data are available.

There are currently two clinical trials in children **aged 12** and over, one with the COVID-19 vaccine developed by BioNTech/Pfizer4 and one with the COVID-19 vaccine Moderna. Results are not expected to be available before mid-year 2021. Oxford/AstraZeneca are planning a new trial starting this month assessing safety and immune response in children aged 6-17 years old. According to lead investigators in the study, the main rationale for vaccinating children would be to have an impact on transmission of the virus. Some children may also benefit from vaccination due to other health risks. The other vaccine developers have not started trials in children yet. To conclude**, there are no data on safety and efficacy of the COVID-19 vaccines in children at this stage**. **WHO SAGE is currently not recommending vaccinating children under the ages for which the vaccine products have been licensed**.

Furthermore, evidence of safety and efficacy, or immune responses indicating efficacy, in children is necessary in order to expand the age indication for COVID-19 vaccines. The current COVID-19 vaccination strategy focused on the vaccination of those most at risk (i.e. elderly

and those with certain underlying conditions) until there is insufficient number of vaccine doses available.

DE does not expect to have specific recommendations for this age group available before 2022. Moreover, it would be extremely helpful to know more about the role of children and adolescents in terms of the dynamics of the pandemic. This would help to understand the urgency of having specific vaccination strategies in these age groups.

Follow up:

- *The Commission asks the Member States to provide their vaccination plans and approaches regarding children and adolescents.*

9. Common position for the quarantine measures for fully vaccinated persons

Malta raised concerns regarding the implementation of travel restrictions, noting that several European countries are restricting travel; however, people transiting through European airports are not being stopped. This is posing a problem, as they are not be identified on arrival at final destination, also in view of the new variants especially from South Africa. Another point raised was that the US CDC recommends not to quarantine persons who have had two doses of vaccine. This already presented challenges with travellers refusing quarantine.

Regarding the mechanisms for travellers into the EU, the Council Recommendation on this topic has recently been updated: Council Recommendation (EU) 2021/89 of 28 January 2021 amending Recommendation (EU) 2020/912 on the temporary restriction on non-essential travel into the EU and the possible lifting of such restriction[2]. The Commission (DG HOME) and IPCR are working to assist Member States to coordinate and to come to a common position regarding the responsibility for travel related measures and border controls, including for transiting passengers rests.

Currently there is a consensus, also at political level, that vaccination certificated should be used for health reasons and not be part of travel related measures, including on quarantine provisions. This needs to be further considered when more information is available on the effectiveness of vaccines in preventing transmission.

ECDC's opinion is that at the moment, there is no evidence that a vaccinated person (with any of the existing vaccines licensed in EU or outside the EU) would not be able to transmit to other susceptible individuals. It is considered likely that vaccination will reduce the chance of a vaccinated person to transmit to a susceptible person, however this has not been yet demonstrated, and even then it is quite unlikely that this protection will be full in all vaccinated individuals. Vaccine effectiveness and impact studies are ongoing focusing on the role of vaccinated individuals in contributing to SARS-CoV-2 transmission.

The current priority of COVID-19 vaccination roll-out is to reduce hospitalizations and deaths, i.e. targeting those most at risk (elderly and those with certain underlying conditions) of severe disease and death. There is currently very limited scope in considering vaccines against COVID-19 as an international travel related measure.

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32021H0089

Given the uncertainty about the potential role of vaccinated individuals in contributing to transmission, there is currently not sufficient evidence to justify any exemption from existing measures for fully vaccinated individuals.

IE noted that in nursing homes, data remains unknown regarding immunity and reduced risk of transmission once vaccinated. Therefore, non-pharmaceutical measure should not be lifted too early.

DG HOME emphasised that within the EU, there are currently no exemptions from non-pharmaceutical measures for vaccinated people.

DG JUST highlighted that transit travellers are considered to be travel passengers with a functional need, and they are not required to undergo quarantine (point 19 of the Recommendation). Member States can nevertheless impose a testing requirement. Passengers with a functional need travelling from a dark red area should fulfil testing requirements and undergo quarantine, if this has not a disproportional impact on their functional need (point 19a).

Follow up:

- *Member States to provide written feedback to the question from Malta.*

10. AOB: Update on passenger locator forms (PLF) and proposal

The Commission has previously updated the HSC on the development of the PLF projects – both the EASA and Healthy Gateways strands of the projects. A meeting dedicated to the PLF projects will be organised **next week**. The projects will be entirely presented; the status of the developments, the roles of the different parties and how Member States' involvement could be strengthened.

Follow up:

- *Meeting dedicated to the PLF projects will be organised next week.*

11. AOB on minks

The EFSA report on Monitoring of SARS-CoV-2 infection in mink is published[3]. Amongst other options for action, it calls for: **strict and frequent monitoring** of farm personnel and all people in contact with the animals and their household members, since humans are expected to be the most likely introduction of virus into the farm.

Follow up:

- *Countries having mink farms to revert to the Commission on current practices and any additional measures planned.*
- *The EFSA report will be discussed during the next HSC meeting.*

[3] https://www.efsa.europa.eu/sites/default/files/scientific_output/6459.pdf