EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 28 July 2021

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, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, LI, NO, CH, UK, AD, AL, BA, DG SANTE, DG MOVE, DG ECHO, DG HR, COUNCIL, ECDC, WHO, HEALTHY GATEWAYS

Key Messages

1. Update on SARS-CoV-2 variants– presentation by ECDC

There has been an increase in the EU/EEA 14-day case rate for past three weeks, with an increase in all age groups, but it being highest in those 15-24 years old. Overall hospital admissions and deaths due to COVID-19 have been stable. The Delta variant is now dominant in the EU/EEA, while the Alpha variant is declining in nearly all countries. There is also low prevalence rate of the Beta and Gamma variant. As of 23 July, ECDC changed the classification of C.37 (Lambda) from variant under monitoring to variant of interest. Reporting of Lambda in TESSy (the ECDC data collection system), will be implemented during the coming week. ECDC also added a new category of variants, including de-escalated variants. Variants B.1.427/B.1.429 (Epsilon) and B.1.616 were moved from variants of interest to de-escalated variants.

2. Correspondence of COVID-19 vaccines for the purpose of travel

Following three specific HSC meetings on correspondence of COVID-19 vaccines for the purpose of travel, including interventions by EMA and WHO, and a survey where EU/EEA countries indicated their approach, the Commission will publish information on whether Member States accept complete vaccine correspondence regarding:

1) Vaccines produced outside the EU for which the marketing authorisation holder is the same as in the EU
2) Vaccines produced outside the EU for which the marking authorisation holder is not the same as in the EU but for which the company that provided the sublicense (e.g. AstraZeneca) assured that the composition and manufacturing processes are the same

This information is important to get a better overview of Member States' positions and to be transparent towards citizens from third countries and for travellers to the EU. Regarding third countries, Switzerland is connected to the EU gateway; work on equivalence decisions continues with microstates (with Vatican and San Marino in the pipeline for adoption). Contacts are ongoing with several other third countries. Additional questions to the technical check list on the acceptance of EU-DCC certificates and data protection have been sent to third countries.

NL: Third countries administer vaccines on the basis of their own approval or on the basis of WHO approval and not on EU approval; therefore, it is necessary to determine whether the COVID-19

vaccines administered by third countries correspond to an EU-authorised vaccine. NL expressed its concern, as the Dutch Medicines Evaluation Board noted the fact that two vaccines have the same marketing authorization holder does not necessarily mean they are alike. If vaccines are manufactured under different legislations, there might be differences in terms of quality, safety and effectiveness. The Commission responded that this topic would be better discussed in a more specialised Committee. In addition, the Commission has sent a request to ECDC for their scientific opinion.

FR has yet to consider their position regarding the correspondence of COVID-19 vaccines for the purpose of travel. **AT**, **DK** and **IT** do not have an official position yet.

The **HSC agreed** to publish the information on correspondence of COVID-19 vaccines for the purpose of travel (Points 1 and 2 mentioned above). Countries have until **30 July** COB for their final comments, before the information is published on the **Re-open EU website**.

3. Breakthrough infections in long-term care facilities – presentation by ECDC + DE

On 26 July, the ECDC published a new Rapid Risk Assessment on COVID-19 outbreaks in long-term care facilities (LCTF) in EU/EEA countries. Morbidity and mortality in LTCF residents have dramatically declined with the progressive increase of COVID-19 vaccine uptake. However, several outbreaks have continued to occur, coinciding with high levels of community transmission and incomplete vaccination of LTCF residents and staff. 81 % of the outbreaks occurred in LTCFs with less than 80 % full vaccination coverage among staff. ECDC recommends full vaccination coverage of LTCF residents and staff, together with countermeasures to reduce the risk of introducing the virus in LCTF communities, to ensure early identification of COVID-19 cases in LTCFs and to maintain non-pharmaceutical interventions.

DE gave an update on COVID-19 outbreaks in LCTF after vaccination in their country. Prioritising vaccination of LTCF residents and staff successfully reduced COVID-19 outbreaks and mortality at population-level. Nevertheless, outbreaks have occurred, including **breakthrough infections** in residents and staff. Vaccination reduces COVID-19 risk but severe COVID-19 cases have occurred in fully vaccinated LTCF residents. (Co-morbid) residents at an older age group with no **neutralising antibodies** after complete vaccination were identified.

PT referred to the ECDC's Rapid Risk Assessment and mentioned that it might be helpful to establish a testing policy in LCTFs – even with a high vaccination coverage rate. **ECDC** responded that tests could be conducted, especially among residents and staff with similar symptoms to COVID-19.

4. Document on partial vaccination (heterologous vaccination: "mix and match") – presentation by ECDC

On 22 July, the ECDC published a summary of available evidence on alternative COVID-19 vaccination schedules, to inform ongoing national decision-making on vaccination policies and strategies. Key messages include: 1) partially vaccinated vulnerable individuals may be significantly less protected against COVID-19; 2) among previously infected individuals, vaccination with one dose may provide comparable immunogenicity compared to fully vaccinated individuals. It is still unclear whether this will translate into comparable protection and long-term protection, in particular in the light of immune escape variants; 3) preliminary evidence from "mix and match" vaccination studies indicate that heterologous schedules induce a robust immune response with no relevant safety signal identified yet.

HR raised a question about the need for two-dose vaccination for people recovered from COVID-19. **ECDC** clarified that in the document, ECDC is not making a recommendation on this, but just highlights the lack of information so far on mix and match with recovery and one vaccine, as it is seen that the variants do not respond well to a single dose. Further information and evidence will be monitored over time.

IT mentioned that people who received AstraZeneca (AZ) as a first dose, can either receive AZ or an mRNA vaccine as a second dose. IT subscribes one dose of vaccine for COIVD-19 recovered patients at the moment, but is considering to review this recommendation.

5. Passenger Locator Form - presentation by DG MOVE, Healthy Gateways, ES, and MT

The digital Passenger Locator Forms (PLFs) are essential tools because they ensure that public health authorities can continue to perform contact tracing, in an effective way, when a person travels by plane, train, boat or bus, nationally or across borders. As such, they can contribute to safer mobility in the European Union.

DG MOVE gave an overview on the use of the ePLF so far: 22 MS have a PLF of some kind for different purposes, and 17 MS having expressed interest for the ePLF. Two MS (IT, MT) are already onboard, with four more (FR, LT, SI and ES) close to being onboard, and with EL to follow shortly. Two MS (DK, SE) are not planning to introduce an ePLF. The ePLF is also applicable for EEA counties, CH and IS already shared their interest in joining.

The **Implementing Decision 2021/858** has established the EU passenger locator form platform (ePLF), allowing the transmission of contact tracing of passengers and exposed persons identified in the context of the completion of Passenger Locator Forms. On 26 July, a new PLF Implementing Decision (OJ L 263, 23.7.2021, p. 32–35) entered into force: to include the exchange of data of exposed persons; to allow MS to exchange data provided by carriers in case of temporary malfunctioning of their PLF systems; and to introduce more flexibility in the PLF travel data to be collected and transmitted.

Healthy Gateways provided the HSC with information on the EU Digital Passenger Locator Form (EUdPLF). Mainly on the web portal of the platform, the characteristics of the app (multilingual, data to be shared, different user roles and user authentication), on transferring PLF data to ePLF, steps for using the EUdPLF (it takes approximately one month to go through all 10 steps), and challenges related to onboarding. Further detailed information on these topics can be found in the PowerPoint on the EU Digital Passenger Locator Form.

ECDC mentioned that there are guidelines available regarding contact tracing (COVID-19 Aviation Health Safety Protocol).

FR congratulated Healthy Gateways on their work and the importance to guarantee data protection. The COM mentioned that EU regulation regarding data protection is taken into account in the EUdPLF. The COM will come back on further details regarding data protection protocols.

MT is one of the Member States with national experience on the use of EUdPLF. MT mentioned it has been a smooth process, as well as from a legal point of view. MT started to use the EU platform as of 1 July 2021. To date, there are already over 50,000 submissions (paper PLF is still in use, but they are slowly reducing this process). It is currently discussed whether an additional function of using "accept" and "denied" boarding should be used. MT mentioned several benefits for using the platform (aligned and integrated with other national systems, support from EU Healthy Gateways, more efficient data analyses) and challenges (system needs to be aligned with other Member States, volatility of evolving situation – dPLF needs to adapt to rapid changes and policy decisions, integration with EWRS not yet clear – it is important that efforts are not duplicated). MT is not sure if the PLF is necessary after COVID times, however, it is good to keep the platform for long-term use in place. MT also emphasised the importance for contact points for the public while integrating the new system.

ES has its national ePLF, called the GECO Application. The GECO Application allows for searching of all inflight contacts of COVID-19 infected cases while travelling to Spain by plane. ES has been in close contact with DG MOVE while developing the application. The strengths of using ePLF include: the amortisation and relief of contact tracing and communication burden for countries and EWRS, sharing standardised information, the ePLF is secure, easy and fast to use, the platform improves the in-country contact management. The platform is adaptable for situations beyond COVID-19.

6. AOB points

AOB: COVID-19 Monoclonal antibody treatment

On 28 July, the COM signed its second joint procurement contract for a monoclonal antibody therapy for patients with COVID-19. The contract was signed with pharma company GlaxoSmithKline for sotrovimab. The treatment can now be purchased by the 16 EU Member States involved in the joint procurement. The therapy is currently under rolling review by the European Medicines Agency, but the agency has already issued guidance to national decision-makers to support its use.

AOB: request on prolongation of the COVID-19 recovery certificate

HR would like to revise the rule of validity of the digital certificate of recovery, in order to allow for validity for longer than six months, based on evolving scientific evidence. The Commission has sent a request to ECDC for their scientific opinion and will come back later on this topic.

AOB: FFP3 masks for HCW

During a previously HSC meeting, FR asked if other countries are considering the use of FFP3 masks for healthcare workers in hospitals to reduce the circulation of the Delta variant. Therefore, the Commission asked the HSC to send their answers in writing. From the responding countries, the use of FFP3 masks for healthcare workers in hospitals is not mandatory. Two Member States mentioned that FFP3 are being used by healthcare workers for the care of COVID-19 patients, if the handling involves **aerosol generating procedures**. One country mentioned that FFP3 respirators are currently used by healthcare workforce in specific units in hospitals (emergency, COVID-19 wards), mainly in order to protect the workers, not to reduce the circulation of the new variant. Two countries reported that there is no obligation for the use of FFP3 masks for healthcare workers at this moment.

AOB: Survey on vaccine acceptance and proof of vaccination for clinical trial participants

The COM reminded the Member States to complete the EU survey on vaccine acceptance and proof of vaccination for clinical trial participants. The deadline is **28 July**.

AOB - Vaccination for Adolescents

Following approval of two vaccines for vaccinating adolescents, the Commission would be interested in re-opening the discussion on the current state of play of Member States' vaccination plans for the age group 12-18 years of age. Some Member States have started vaccinating the entire group and some are only vaccinating adolescents at high risk. The Commission is planning a detailed discussing on this topic during next week's HSC Meeting. Member States are invited to send their current vaccination plans for this age group in writing.