



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 01 December 2021

Special Health Security Committee 10h00-11h00– EU/EEA countries only

Audio meeting on the outbreak of COVID-19

Summary Report

Chair: Head of Unit, European Commission, DG SANTE C3

Audio participants: AT, CZ, DE, EE, ES, FR, HU, IE, LT, LU, PT, SE, SK, NO, IS, DG SANTE, DG HOME, DG JUST, ECDC

1. Council Recommendations – presentation by DG HOME and DG JUST

DG JUST and **DG HOME** gave an overview regarding the proposals for revising Council recommendations 2020/1475 and 2020/912 regarding intra-EU travel as well as travel from 3rd countries to the EU.

DG JUST: In October 2021 the European Council called for further coordination to facilitate free movement within, and into, the EU. As a response, COM proposed a revised version in order to replace Council recommendation 2020/1475. The proposal was for the first time presented during the IPCR meeting in late November 2021. Key points of the proposal include a “person-based approach” (instead of a country-based approach) and a standard validity of 9-months acceptance period for vaccination certificates based on the completion of the primary vaccination series. The Commission also proposed to include booster vaccines to the EU DCC, but without a validity period, and a streamlined “emergency brake” procedure. In addition, it is proposed to adapt the EU traffic light map. The vaccination uptake will be added as a new criterion, in addition to the number of new cases/100 000 population in a given region. The traffic light map will mainly serve for information purposes. , It will also be an important tool if it comes to coordinate measures for areas with particularly low or high levels of circulation of the virus. The COM proposes that the updates to the common approach should apply as of 10 January 2022.

IE expressed its concerns regarding vaccine efficacy and mentioned that it might be necessary to consider the need of pre-testing travellers rather than only looking at their vaccination status. The COM agreed that once the emergency brake is put in place, testing should be added as a condition for travellers.

ES also expressed its concerns regarding vaccine efficacy. ES is not sure if the booster dose will solve the issue for variants. ES already vaccinated a large part the population more than 9 months ago. If the regulation of vaccine validity will change within the coming weeks, ES would not be able to vaccinate everyone to keep their vaccine status valid. The **COM** responded that this would be from January onwards, and will note down the concerns from Member States who would require more time.

SE agreed with **ES**, as most people have been vaccinated during spring. The **COM** responded that the booster will not have an expiry date (for now). **SE** responded that there still is lack of information about the vaccines and especially about the new variant. The **COM** responded that citizens are still able to do a test in case they have not received the booster dose.

DG HOME its proposal put forward to amend Council Recommendation 2020/912. While some MS have requested in the Council to wait with these negotiations in the light of the rapidly spreading Omicron variant, **DG HOME** stressed that the proposal provides a framework in which MS can define the relevant measures for third country travellers, including in the context of the Omicron variant. As of March 2022, it is proposed that Annex I will no longer be used and that a full person-based approach will be implemented for third country travellers. The proposal does not result in a relaxation of travel; instead, it serves as a restriction since travellers will need to be vaccinated before they can enter the EU. The **COM** proposes that COVID-19 vaccines listed on the WHO Emergency Use Listing should be accepted for entering the EU in addition to the vaccines authorized in the EU. Travelers vaccinated with a WHO accepted vaccine or a recovery certificate would still require a PCR-test.

IE is concerned about vaccine efficacy and suggested putting forward pre-travel testing measures. It is important to understand the characteristics of the variant before the proposal for third country travel measures can be agreed by Member States.

DE mentioned that the new proposal will foresee that travellers vaccinated with a WHO listed vaccine would be in need of a PCR-test, but wanted to know about the EMA equivalent vaccines listed by the WHO and if it is possible to register EMA equivalent vaccines under the EU Digital COVID Certificate.

EE would be in favour of having a validity for the booster vaccines concerning the national regulation, where the validity date should be mentioned.

The **COM** provided the HSC with an update regarding the meeting of an ad hoc expert group that discussed validity of vaccination certificates. There is enormous variety of vaccine validity periods and several specific issues to be clarified e.g. combination of two different vaccines, combination of recovery plus one or two doses of vaccines with the possibility that recover can also happen after the vaccination due to break-through infections. This is why the **COM** launched a survey among HSC members to gather their national practice on these topics. This information is needed in order to advance discussions in the eHealth Network regarding coding of the EU DCC. Discussions on the validity of certificates will continue and the Commission may still convene further dedicated meetings to discuss a future delegated act.

Luxembourg, 01 December 2021

Health Security Committee 11h00-13h00 - EU/EEA countries and observers

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Agenda points:

1. Latest updates on the Omicron variant - presentation by ECDC, UK, and CH
2. Paediatric vaccination – presentation by EMA, ECDC, discussion with Member States
3. World Health Organization on Covaxin – presentation by WHO

Key messages:

1. Latest updates on the Omicron variant

Since 26 November 2021, the variant Omicron has been characterized as a Variant of Concern and some Member States have applied travel restrictions from selected African countries. The ECDC provided the HSC with a daily update on what is known about the variant, its current spread worldwide and in the EU, as well as the possible implications on transmissibility, severity and vaccine coverage. So far, 135 cases have been detected in the EU/EEA, of which 57 cases have been confirmed and 78 are considered probable case. More data is needed regarding vaccination efficacy and severity among confirmed and probable Omicron cases.

The UK and CH were invited to give an update on their latest state of play on measures related to the Omicron variant.

UK: As of 30 November, 22 cases with Omicron have been confirmed in the UK. Following the confirmation of cases, the UK updated the briefing on variants to include Omicron. The national Incident Management Team meets now on a daily basis; they introduced targeted case finding and new measures for all international arrivals (travellers are required to take a PCR test at day 2 and self-isolate until they receive a result); and established quarantine facilities for international travellers arriving from “red list” countries.

COM asked if the confirmed cases with Omicron were vaccinated and whether they could provide information on the severity of the cases. UK had no clarity about the severity of the cases or the vaccination status of the patients now. UK will come back to this.

In **CH**, the epidemiological situation shows a high incidence rate and CH intends to implement new measures. Regarding the Omicron variant, three cases have been confirmed and one case is suspected. Two with a travelling history from South Africa, and two without contact tracing data yet. Cases were detected in routine analysis and confirmed using Sanger and Whole Genome Sequencing.

SE mentioned that the country updated their restrictions for incoming travellers from southern African countries. All travellers coming from countries outside the Nordic countries should do a PCR- test on the day one of arrival and self-isolate until they receive a test results (no exemption for vaccinated/recovery status).

IE mentioned the introduction of pre- and post- travel testing and home quarantine (testing on day two and eight). After two negative tests, quarantine can be lifted, otherwise quarantine is extended to 14 days.

ES has no direct flights from Southern African countries, travellers from there come through air transport hubs (Dubai/Amsterdam). **ES** informed that so far 2 cases have been identified in a rugby team coming from S. Africa via Amsterdam. **ES** also reported about on-going wastewater surveillance in Barcelona, awaiting genomic sequencing confirmation.

The **COM** highlighted that it would be important to discuss enhanced testing, quarantine and contact tracing over the next two weeks.

2. World Health Organization (WHO) on Covaxin

The WHO has recently included another COVID-19 vaccine for Emergency Use Listing: the Bharat Biotech BBV152 COVAXIN® vaccine. The HSC discussed in the past the question of acceptance of WHO vaccines, and Member States mentioned interest in hearing from the WHO on the process of acceptance. The **COM** has been gathering information about the vaccines being accepted in the different Member States (outside of the EU-authorized vaccines). The aim is to publish this information for the public, as each country is responsible for its own rules regarding acceptance. Some information is already available on ReOpen EU. In light of Covaxin, the COM sent an email this week (week 48) asking Member States where they stand on the acceptance of this vaccine. Answers are expected by 2 December 2021.

WHO provided the HSC with an overview of the features of prequalification and the Emergency Use Listing, non-clinical and clinical studies carried out for the approval of the COVID-19 vaccines, as well as an overview on the COVAXIN quality review, vaccine efficacy, Immunogenicity, vaccine safety and a benefit/risk assessment. A background [document](#) on the Bharat Biotech BBV151 COVAXIN vaccine is available in public domain. The document provides granular data from clinical studies on vaccine efficacy and safety.

3. Paediatric vaccination

On 25 November, **EMA** [published](#) their position on children vaccination, granting an extension of indication for Comirnaty to include use in **children aged 5-11 years**. EMA informed the HSC about the study population, immunogenicity, vaccine efficacy and the safety database. So far, the benefit risk analysis is positive, the reactogenicity is acceptable, there are no new safety concerns, and no cases of myocarditis. The study size did not allow detection of rare adverse events, but rarer risks differ compared to adolescents and adult populations.

In line with the EMA, the **ECDC** has published its latest [report](#) on COVID-19 vaccination for children 5-11 years old. The report gives an overview of vaccination implementation in the EU/EEA, an assessment of the burden of COVID-19 in children aged 5-11 years, the role of children in COVID transmission and the available data on COVID-19 vaccines in children.

Children aged 5-11 years who are at risk of severe COVID-19 should be considered as a priority group for vaccination against COVID-19, as in other age groups. COVID-19 vaccine safety data in children in this age group is currently limited. Before taking policy decisions on COVID vaccination for children, potential harms and benefits should be considered alongside the vaccine uptake and epidemiological situation in a particular region.

ECDC did an analysis on the reported TESSy data. Very few deaths or hospitalisation was reported in this age group. Most children experienced an asymptomatic disease or mild symptoms. Children that had COVID-19 have a higher risk of myocarditis compared to children who did not have the disease.

IE is still discussing vaccination for children. **IE** highlight that children already have been vaccinated in the US and no alarming messages have been sent out.

IT is not planning to vaccinate children aged 0-4 years. The decision about the extension of recommending Comirnaty to children aged 5-11 is expected from the Italian national regulatory agency for the beginning of December. The national immunization campaign will be consequently adapted following this decision. Priority will be given to vulnerable children. The structures used for routine vaccination of children is currently under discussion. **IT** plans to involve territorial paediatricians, paediatricians' scientific societies and specialized national centres so that they could play an active role in identifying, reaching and vaccinating vulnerable children.

In **SE**, vaccination of children is under discussion, including the vaccination of children aged 5-11 with an underlying condition.

AT recommends vaccination for children, with special focus on children with risk factors and children who are in close contact with high-risk persons. A structure for vaccinating children is in place. School vaccination plans are also starting. Information is available for patients and carers in different languages. The **COM** asked **AT** to share the available materials with the HSC.

FR intends to launch a vaccination campaign in early January 2022. Vaccination for children at high risk will start in December 2021. So far, **FR** has no intention to vaccinate children 0-4 years old. **FR** is still working on the implementation of communication to parents and carers. **COM** highlighted that the HSC's communicators network will probably discuss communication for parents and carers.

EE mentioned that the Estonian NITAG decided to recommend vaccination for children 5-11 years old, starting by the end of 2021.

In **NO**, children 5-11 years old with severe underlying disease will be offered vaccines as soon as they are available. Evaluation of vaccination of all children 5-11 years has started, conclusions are not ready until January 2022.

PT informed that vaccination of children 5-11 years old is under discussion by the Portuguese NITAG, supported by a group of paediatricians.

In **DE**, the Standing Committee on Vaccination (STIKO) is reviewing the topic of vaccinating children 5-11 years; a position will be published in the coming weeks. In **DE**, most children are vaccinated by paediatricians in private office, this will probably also be the main delivery structure for COVID-19

vaccines. Information materials are already available for families and are currently being updated for the 5-11 year age-group.

The **COM** closed the meeting and thanked all HSC members for their contribution.