



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 9 June 2021

Health Security Committee

Audio meeting on the outbreak of COVID-19

Summary Report

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

Audio participants: AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LV, MT, NL, PL, PT, SE, SK, IS, LI, NO, CH, UK, AD, DG SANTE, DG EAC, DG ECHO, DG MOVE, COUNCIL, EMA, EASA, ECDC, WHO, CA, US.

Key Messages

1. Vaccination for adolescents (presentation by EMA, ECDC, DE, IT, USA and Canada)

On 28 May, the European Medicines Agency (EMA) approved the use of the COVID-19 vaccine from BioNTech-Pfizer for use in adolescents 12-15 years old. This vaccine has also been authorised for use in adolescents in the United States and Canada. According to recent information collected via the weekly Integrated Situational Awareness and Analysis (ISAA) reports, some Member States have already started vaccinating individuals under 18 years of age, and some are planning to start vaccinating adolescents 12-15 years old. On 1 June, the European Centre for Disease Prevention and Control (ECDC) published guidance on vaccination of adolescents in the EU/EEA.

EMA provided details on the Comirnaty clinical trials for adolescents 12-15 years old on which it based its recommendation for authorisation. EMA is also monitoring the cases of myocarditis.

ECDC shared their recommendations for COVID-19 vaccination of adolescents aged 12-18 years. The **direct potential objectives** for vaccinating adolescents include protecting the adolescent's health and normalising their lives. The **indirect objective** of vaccinating adolescents is to reduce viral circulation in the overall population. ECDC recommends to vaccinate **adolescents at high risk** of severe COVID-19 to be considered as priority, as with other age groups. Given the anticipated reduced individual benefit-risk ratio from COVID-19 vaccination of adolescents compared to older age groups, careful consideration of the epidemiological situation and of **vaccine uptake in older age groups should be given before targeting this age group**.

Germany has the intention to reach a final recommendation for vaccinating adolescents aged 12-17 years by the end of this week. At the time of the meeting only preliminary

recommendations exist with pre-existing or underlying conditions (obesity, severe heart failure, chronic lung disease, cancer, etc.). [This recommendation was adopted after the HSC meeting]

Italy shared their experience regarding vaccination of adolescents. On 31 May, the Technical Scientific Committee of the Italian Medicine Agency (AIFA) approved the extension of indications of the (BioNTech/Pfizer) Comirnaty vaccine for the age group between 12-15 years. The target population of adolescents is 12-19 years (Comirnaty starting from 12 years of age; Vaxzevria, Moderna, Janssen starting from 18 years of age). As of 9 June, the first dose was administered to 240,000 adolescents (5.17% of the target population) and the full cycle (2 doses or single dose) to around 71,000 adolescent (about 1.5%). One of the key factors in the increase in administration lies in the **increase in vaccination points**. In addition, **open days** are very effective for vaccinating adolescents.

The United States (Centers for Disease Control and Prevention (CDC)) was invited to give an overview on vaccination of adolescents. On 12 May, the Advisory Committee on Immunization Practices (ACIP) voted to recommend Pfizer-BioNTech COVID-19 Vaccine for persons aged 12–15 years old under the FDA’s Emergency Use Authorization. The CDC follows a stepwise approach to increasing vaccine access to adolescents (existing infrastructure, adding providers that can reach adolescents, school-focused strategies). The federal government does not have specific requirements for medical consent for vaccination. States/jurisdictions have medical consent laws that address the circumstances that require consent and the process for obtaining it. COVID-19 vaccines and other vaccines may now be administered without regard to timing with other vaccines. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days.

Canada (Health Canada and the Public Health Agency of Canada) was invited to give an overview on vaccination of adolescents. As of 5 May, **Health Canada** authorised the use of the Pfizer-BioNTech COVID-19 mRNA vaccine for adolescents 12-15 years of age. As of 18 May, the **National Advisory Committee on Immunization (NACI)** released a statement recommending that a complete series of the Pfizer-BioNTech COVID-19 vaccine be offered to individuals 12-18 years of age. As of 21 May, the **Canadian Paediatric Society** advocated that all children and adolescents aged 12 years and above get vaccinated as soon as supply allows. As of 29 May, 1% of youth nationally have been vaccinated with their first dose. Canada will implement a **Federal Vaccine Confidence Communications Strategy** to target youth as well as their parents and caregivers, in order to increase vaccine confidence and trust among vaccine hesitant parents and caregivers.

DE asked when the first safety data from the post-approval phase in the US and Canada become publicly available (e.g. from passive surveillance). The **US** and **Canada** have both indicated that this data will be made available on their government websites.

FR mentioned that the Health Authorities published a report on the vaccination strategy on adolescents on 3 June. It is recommended that priority be given to vaccination of adolescents with co-morbidities or immunocompromised individuals, followed by healthy adolescents. In order to speed up the vaccination campaign before summer, the French government has decided that from 15 June, the Comirnaty vaccine will be made available on a voluntary basis and with parental consent to all adolescents aged 12-15 years.

2. Preparations and hygiene concepts of EU countries that host football marches in the frame of the European Football Championship June-July 2021 – information/discussion point

The European football championship will start this week, and several EU Member States will be hosting matches (NL, RO, HU, DK, DE, IT, ES). Due to the COVID-19 pandemic and the risk that these competitions and related activities may pose to the spread of the virus, the Commission was interested in knowing the host countries' preparations in this respect.

All hosting countries have a **testing strategy** in place for players/support staff and spectators. Players and support staff will be tested regularly by the hosting countries. Spectators can only enter the stadium with proof of a negative test (NL, DE: use of national CoranaCheck App, IT: EU Digital COCIVD Certificate, DE and HU: valid antigen test/ recovery certificate/ vaccination certificate).

General **precautionary measures** in the stadium to limit the spread of COVID-19 will be in place (e.g. wearing masks, authorised hand sanitizer, physical distance, measuring temperature). Some countries also mentioned they will assign seats to control movement (IT, DE) and disinfect the stadium after a match (ES, DE).

The **percentage of spectators allowed in the stadium** compared to normal capacity is 25% in most of the hosting countries (20% in DE, 30% in DK, 33% in the NL).

The host countries stressed that the **regulations for the championship** are in line with the country's general approach to organising cultural events during the COVID-19 pandemic.

WHO is not too concerned about the event itself, but expressed concern about small gatherings after the football matches.

3. EASA/ECDC guideline document – information point

EASA updated the COVID-19 Aviation Health Safety Protocol - *Operational Guidelines for the management of air passengers and aviation personnel*, together with the ECDC. The updated document will take into account new variants of concern, vaccination roll-out, natural immunity/ recovered persons, Digital COVID Certificate and Digital Passenger Locator Form, new scientific evidence and implementation data, and new technologies. The next meeting between EASA and ECDC is scheduled for Friday 11 June. The document will be shared with the Member States before publication.

4. AOB - two important upcoming meetings on 10 June: technical working group on RATs and the set-up of the PLF Joint controllers working group – Information point

Technical working group on RATs - meeting on 10 June

On **Thursday 10 June**, the first meeting of the HSC technical working group on COVID-19 diagnostic tests will take place. The technical working group will be focusing, as a first task, on the next update of the RAT common list. This will be based on two sources of information:

- **Input received from RAT manufacturers** via submission of forms that are available on the website of the JRC database on COVID-19 medical devices. For information, over 50 proposals for RATs to be considered for the next update have been put forward.
- **Suggestions by countries** – to be put forward with specific details on the tests by the technical expert participating in the working group.

The technical working group will meet for the second time next week, on **Tuesday 15 June**. The purpose of this second meeting is to **agree on a proposal for a next update**. Once the technical working group has agreed on the proposal, it will be sent to the HSC for final review

and agreement. The Commission hopes that agreement on the next update of the RAT common list can be reached by the HSC during the meeting next week.

DE stressed the importance of regularly updating the RAT list as DE was still in the process of contacting all relevant manufacturers since the last HSC meeting. The **Commission** replied that there will be regular updates. After the holidays, the RAT list will probably be updated once a month.

Passenger locator form (PLF) - meeting on 10 June

The Commission Implementing Decision (EU) 2021/858 adopted on 27 May 2021 amending Implementing Decision (EU) 2017/253 as regards alerts triggered by serious cross-border threats to health and for the contact tracing of passengers identified through PLF article 2b (5) defines the Early Warning and Response System (EWRS) competent authorities as **joint controllers** for the entry and transmission of data through the PLF exchange platform, in line with the Regulation on General Data Protection. On **Thursday 10 June**, the Member States EWRS – PLF joint controllers will meet for the first time to discuss responsibilities and decision making processes of this group.

AOB - up-date on the process for the EC to provide grants to EU MS to purchase SARS-CoV2 tests (NAAT or RAT)

Last week there was an information point on the grants for supporting accessibility of tests for delivery of EU Digital COVID Certificates. An **invitation for express of interest and nomination of** a designated national authority was sent on Monday 7 June with **deadline of Thursday 10 June**. The Commission is currently finalising the administrative steps for this project, the ESI Steering Committee Decision and the Financial Decision. The Commission will contact the designated authorities next week. The financial support will be distributed among the MS that have expressed interest by 10 June.