EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 05 May 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, CZ,CY, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, CH, LI, UK, AL, BA, XK, AD, MD, DG SANTE, DG ECHO, DG EAC, COUNCIL, ECDC, WHO

Key Conclusions

1. A new Emergency Support Instrument (ESI) on Mobility Package – information point by DG ECHO

DG ECHO gave a presentation on the new invitation to submit applications under the Emergency Support Instrument Mobility Package. Key actions under the new invitation to submit applications include: **cargo transport of COVID-19 vaccination related equipment and therapeutics** (opened as of 05 May 2021), **transfer of patients, transport of medical personnel and teams** (ongoing).

- MS can apply by filling out the application documents. MS Focal Point confirms it is of public benefit and fits into the national response plan.
- MS Focal Points sends the application to DG ECHO via email and enters a short summary in CECIS
- The COM ensures the application meets the conditions
- Option 1: the COM organises transport for the MS via a broker
- Option 2: the COM and beneficiary sign the Grant Agreement
- Operation takes place, visibility obligations
- Beneficiary is reimbursed if option 1 Grant Agreement

Questions can be sent to DG ECHO:ECHO-ESI@ec.europa.eu

2. Testing on children – information/discussion point – ECDC presentation – HSC tour de table

The HSC meeting focused today on the issue of testing children. The **ECDC** provided a presentation regarding the age after which children may/should be safely tested. The ECDC mentioned that if sampling instructions are strictly followed, good quality samples for SARS-CoV-2 detection can be safely obtained from children of any age. Children can be included in testing strategies if the performance of the diagnostic test is similar to adults, using the same sampling type and sampling time.

The following question were sent to the MS before the meeting:

a. Do you have any approaches, experiences, or guidelines on testing children, including self-testing (where, when (including at what age) and how are they (systematically) tested?)
b. Do you have a specific strategy for testing children under age of 4 or pre-school children; are they included in these guidelines?
c. Do you test children at schools at national level? If yes how it is organized and which tests do you use (nasal swab, gargling, saliva etc.)?
d. Are you collecting information on accidents with self- testing in children and if so have any of such accidents been reported so far at the national level?
e. If you carry out mass testing in your country: are children included in mass testing? If yes, from what age on?

AT includes children in its mass testing campaigns.

BE mentioned that teachers are part of the testing strategy, children are excluded. In case of symptoms: for children under 6 years old (= child not yet in primary school), a PCR test is only recommended if the child meets the definition of a possible case of COVID-19 AND the clinical condition requires hospitalisation OR if the result implies that measures should be taken to protect close contacts. In case of a high risk contact: children <6 years old do not have to be tested after a high-risk contact within the family but are tested with a PCR test if the high-risk contact took place outside the family. In kindergarten classes and nurseries: in case of 2 confirmed cases within a group or class, all other children and the teacher/caretaker are considered high risk contacts and are to be placed in quarantine and tested with PCR.

In **CZ**, people from any age can be tested. For travelling and attending school, children of 5 years and older should be tested. CZ has a testing strategy in schools: mandatory testing for children and teachers, self-tested and professional testing is accepted, vaccinated persons have an exception. Testing is implemented twice a week.

DE has different testing routes for children, there are no age limits. For travelling, children of 7 years and older should be tested. DE recommends regular testing in educational institutions. There is a testing policy for children and teachers to be tested twice a week (different tests are used).

DK has guidelines for testing children. Children 12 years and older are tested twice a week in order to attend school. Children younger than 12 years old are only tested when there are indications of COVID-19.

In **EL,** according to the current legislation, published today (05/05/2021), all students aged 5 years old and above should undergo a self-test at least once a week and strictly 24 hours prior to return to class. The self-test is performed at home via nasal swab. There is no guidance for the time being for children age of 4 or in pre-school. EL does not collect information systematically about accidents and no such events have been reported. In cases of mass testing in certain settings such as airports children aged 5 years old and above can undergo test according to current national guidelines.

In **ES** all ages can be tested. ES tests only symptomatic cases and people who have been in contact with a confirmed COVID-19 case. Although some trials have been carried out for self-testing and routine screening in schools, the application of such activities were discarded. Mass testing was performed in the educational settings, but only for teachers, children are not involved in mass screening whenever it is carried out in the community.

FI does not conduct mass screening tests, except for the exposed ones in school. No self-testing is accepted.

FR recommends the use of antigenic tests on nasal swabs, which have the advantage of combining rapid results and possible repeated use in a large public (asymptomatic children and adults). It stated that the self-tests can also be used as a screening tool in children under the age of 15. In all schools, screening operations are in place: RT-PCR on saliva samples are performed since 9 April and soon self-tests or antigenic tests on nasal swabs will be deployed. In France, children are included in mass screening organised by the Regional Health Agencies (ARS) or by the national education system in nurseries, preschools, primary schools, secondary schools and, since 3 May, in high schools, so starting at early age, below one year old).

In **HU**, children follow similar test guidelines for adults, but are tested less frequently and always in the presence of a parent. HU has not conducted regular test screening in schools.

IT approaches and guidelines on testing are the same for adults and children. Self-testing is not recommended in children at this stage. No mass testing is carried out at the moment.

LT mentioned that from this week, children in schools can perform self-tests under the supervision of a school employee. Saliva will be used as a sample material for COVID-19 testing. An amendment to the legislation is currently being drafted, which will allow all children to test themselves in educational institutions. Currently surface sample testing of SARS-CoV-2 (2019-nCoV) RNA by real-time PCR is being performed in preschools. LT is using rapid antigen tests, pooled PCR method and self-testing. The use of self-testing in educational institutions was legalised only this week. Tracking such reports is not currently planned. LT does not apply age restrictions to testing.

NL has a less invasive testing approach for children of 12 years and younger. Self-testing among children started recently. NL has several pilots studies in place regarding mass testing, which include children of 6 years and older.

PT mentioned that with regard to children, the priority has been to test children who have a strong suspicion of COVID-19 symptoms, who are high-risk contact of a confirmed case, or in an outbreak context. Due to the importance of protecting children and generating confidence in the education system, a screening strategy was implemented in kindergartens and pre-school, targeting teachers and other professionals who are in direct contact with children and from secondary school children are included in these screenings. The SARS-CoV-2 recommended tests are TAAN and RAT. For this testing PT considers naso-/oropharyngeal for TAAN and RAT and saliva just for the TAAN. Self-testing can be used at national level but so far without a specific recommendation for children..

SE is testing children with symptoms or who have been in close contact with a confirmed COVID-19 case.

SI is testing children with symptoms or who have been in close contact with a confirmed COVID-19 case. Testing children in school is currently under discussion. Self-testing is considered to be implemented for high schools/universities.

SK mentioned that in case a test shall be carried out in case of a child less than 10 years old, the decision is to be made by a GP or a pediatrician. Testing in schools: 1st – 5th graders: mandatory proof of a negative test (RAT, RT-PCR) of at least one parent and a declaration of no infectivity of the child. The rest of grades (elementary schools, secondary schools): mandatory proof of a negative test (RAT, RT-PCR) of at least one parent and also a negative test (RAT, RT-PCR) from the student. From 3 May, 2021, some schools carry out gargling tests of students. SK is currently carrying out mass testing, only children older than 10 year old are included.

CH recommends to start testing among children in the first year of school (6 years and older – if the school is mixed with the kindergarten, kids starting at 4 years of age are also included). CH recommends using a mouth wash with saline solution. As for the sample collection, CH advises to do it at home under the control of the parents or in school supervised by the teacher. In the latter case CH advises against gargling as this might lead to aerosol and droplet formation.CH is currently carrying out mass testing, only children of 6 year and older are included.

NO recommends testing in children with symptoms or who have been in close contact with a confirmed COVID-19 case. In case parents refuse their child to be tested, the parents can do a test instead. Regarding travelling, children are not excluded from testing. NO recommends test screening in children aged 13-19 years old (pupils), students attending university, and teachers (mostly rapid antigen tests). Testing is recommended twice a week.

In the **UK**, as with adults any child who presents symptoms should undertake a PCR self-test. Children 12-17 should undertake this with adult supervision. Tests for children 11 and under should be undertaken by adults. There is guidance on how to test a child on the UK Government's website. On mass testing, all households with children of school age are advised to take two RAT self-tests per week. This is for children aged 11 and over. Children in primary school do not need to be tested.

3. Reopening of the cultural sector – discussion point

During the HSC meeting, **DG EAC** mentioned the importance of culture during COVID-19, especially for mental health. The cultural sector lost 30% of income, 90% for performing arts and 70% for music. The cultural sector is clearly in a bad position and is looking to reopen. There is a transnational dimension: artists and people travel to cultural events. Therefore, EAC is investigating whether a coordinated approach is possible. EAC is considering developing guidance and would like to know if MS see a place at EU level to discuss the experiments / tests for conducting live concerts, and to exchange best practices.

The **ECDC** mentioned that the COVID-19 risk associated with people gathering in cultural settings and events depends on a **variety of factors**. The decision to proceed with a specific event, or to allow for certain types of events to happen, should be based on a **careful assessment** of the risk, on the basis of the indicators described before. The **residual risk** associated to an event where people come from a low incidence area, where at least all risk groups have been vaccinated, that takes place in an outdoor environment, and where physical distancing is possible, could be further mitigated by implementing measures such as testing at entrance, use of face masks, and implementing hygiene measures. Furthermore, before deciding to hold an event, **ECDC recommends** doing so in a controlled manner to find out which measures have worked and which have led to further infections and require adjustments.

The following questions were sent by the COM to the HSC before the meeting:

1. What are the national plans for the re-opening of the cultural sector? Are there specific measures for different sectors or settings (e.g. cinemas/theatres vs. festivals) that are already in place or that you plan to issue?
2. Would you support a coordinate approach for the safe re-opening of the cultural sector across the EU?
3. Are you considering the use of the Digital Green Certificate for accessing cultural places?

Of the 16 countries that responded, 4 MS (+ Liechtenstein) reported that they have already started to **gradually open cultural institutions**, 3 countries have such plans from the beginning of May and 2 countries are still considering this. Only five countries say "yes" to a **coordinated approach** to safe reopening of the cultural sector across the EU, and few propose other solutions. So far, only one country is considering using the **Digital Green Certificate** for access to cultural places. Discussions about the use of the Digital Green Certificate are still taking place in most countries.

FR asked whether the Ministries of Culture have been contacted. FR suggested collecting the information in the context of the ISAA report. **EAC** replied that they chose to consult the health authorities first. EAC plans to consult the Ministries of Culture as well.

DE noted that it is difficult to take a clear position and it is unlikely that there will be a coordinated approach in the different German Laender as it is a complex topic. DE appreciates ECDC guidance and the reminder to take into account all the different factors.

- *The COM invites MS to send examples of their experiences.*

4. COVID-19 testing:

a. Agreement on update of the common RAT list

Based on further feedback received from AT, BE, DE, DK, EE, LT, NL, and SI and additional details from CH, the COM has sent a revised proposal to the HSC for an update to the RAT common list. In short, changes proposed based on new info received from countries includes:

- Addition of 54 new RATs to the common list that meet the inclusion criteria. Of these, the results of 17 additional RATs will be mutually recognised.
- Removal of 2 RATs, based on new validation data from Germany (showing a sensitivity of less than 80%)*****
- The results of 1 RAT are no longer mutually recognised (as DE is no longer using this test in practice) **
- This overall change results in a proposal for a common list that includes **78 RATs in total** (compared to 26 RATs in Feb) **of which the results of 32 RATs will be mutually recognised** (compared to 16 RATs in Feb).

Other main changes include are:

- For ease of reference, the RATs of which their results are mutually recognised have now been highlighted in Annex I instead of listing them separately in the text of the HSC agreed document.
- The tests included in the RAT common list only concern those tests for which their clinical performance was measured based on samples collected from nasal, oropharyngeal or nasopharyngeal specimens. RATs that have been validated in EU MS based on alternative samples, such as saliva, sputum and/or faeces, are not included. The new HSC technical Working Group will look into this issue and further discuss whether these tests should be included in future updates of the RAT common list.

AT does not agree with the current version, since there are still 4 tests proposed by AT, which are not included in the list. AT will agree as soon as these tests are include. If necessary they will provide further information to allow inclusion to the list.

COM announces that there is no agreement on the RAT common list and that actions to reach agreement will be taken.

b. Use of new gargle/mouthwash test in Member States – Information point and discussion

The **COM** has been informed that new gargle / mouthwash tests have come into the market. In addition, the use of rapid antigen tests based on salivation seem to be increasing. The **ECDC** explained that nasopharyngeal specimens remain the gold standard for COVID-19 testing for use with RT-PCR and rapid antigen diagnostic tests. The current **limited evidence** does not support the use of saliva as alternative sample material for rapid antigen or antibody tests. Further clinical validation studies on the different available tests are needed.

AT reported on the advantages of the new gargle/mouthwash tests. Gargle/mouthwash tests are less invasive and faster in general. According to AT, the test procedure is very easy. Instructions are clear and a straw is used to facilitate the process. Once the sample is transferred to a tube and put back into packaging, the user can drop it off at a supermarkets, gas stations (long opening hours) and other places.

If the sample is dropped off before 9 am the result will be available within 24 hours. The sample is sent to laboratories, where 10 sample are tested at the same time, only if at least one of the samples is positive then all samples are tested individually. These type of tests are more sensitive than usual RATs, and sequencing is also possible. Right now this is only a pilot project in Vienna. AT goal is to offer this type of test and procedure to people in rural areas (where delivery is more difficult). If the pilot is successful, AT plans to expand this type of testing and procedure to all regions in Austria.

5. AOB - Up-date on the JP of monoclonal antibodies & new therapeutics

Since early 2020, 12 joint procurements with up to 36 countries have been carried out. A number of contracts were concluded following the first four joint procurements on PPE, ventilators and laboratory equipment have already expired or are about to expire. To this end, the COM has launched a survey to hear from countries about their experiences and suggestions for the future. Countries have until **Friday, 7 May** COB to reply. Nonetheless, the remaining contracts still allow countries for countries to order:

- Personal protective equipment,
- 30 types of laboratory equipment (tests, reagents, swabs, etc.)
- remdesivir
- Intensive Care Unit medicines
- rapid antigen tests and reading devices
- syringes and needles and other supplies needed in the vaccination campaigns – the contracts also include a large number of low-dead volume syringes and needles.

These essential medical supplies can be ordered by MS and countries over the course of one year. It is paramount that countries inform the COM about the orders placed in a timely manner. So far, more than 10 countries have ordered millions of gloves, masks, remdesivir vials, needles and syringes, millions of rapid antigen tests, thousands of coveralls and goggles, as well as hundreds of ventilators. The quality of deliveries has so far been 100% compliant. Sizeable quantities remain available and can be ordered in case of need. Moreover, the COM is working to ensure access to several future therapeutics:

- The fist main achievement is a recently signed contract for **monoclonal antibodies** with Hoffmann-La Roche. Countries can place orders, as soon as a conditional EU marketing authorisation is available or upon respective national emergency authorisations. According to Hoffmann- La Roche the EU marketing authorization is expected between August and October 2021.

More such products will be made accessible following the conclusion of the respective processes with two other companies. Depending on the advancement of development and performance of the medicines, as well as of the needs of countries, new joint procurements might be carried out. Lastly, the COM will carry out an in-depth assessment of the Joint Procurement Agreement, with special attention to the practical implications of using the mechanism for emergency response, as well as for medicines for human use.

- *The COM would like to **remind countries** to:*

- *Provide timely information about firm orders and the quality and quantity of supplies.*
- *Communicate more proactively on the availability of these contracts at national level, so that all potentially concerned authorities at national and regional levels are fully aware.*
- *Consider appointing several alternates to Specific Steering Committees, possibly involving different national authorities in Joint Procurement processes.*

5. AOB – Passenger Locator Form (PLF)

The COM confirms the organisation of the Cross-Border Health Threats Committee meeting on **Tuesday 11 May.** So far, **only 17 countries** have provided their nomination and two countries have provided specific comments to the implementing act draft text, comments are welcome until the **07 May 2021**.

5. AOB - EWRS (reminder/ action point)

An EWRS EU survey was shared on 14 April as a selective message, on the use of the EWRS modules during the COVID-19 epidemics and possible future developments in line with the EU Health Union proposal, the MS and EEA countries are invited to provide their input. So far, **only 15 countries** have provided their input. After a discussion with the ECDC, it was agreed to extend the deadline for one additional week: the **new deadline** is **12 May 2021.** Any questions can be sent to the SANTE EWRS <SANTE-EWRS@ec.europa.eu>

[Prepared by: D. Pietersz, DG SANTE]