EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
**Health Security**

Luxembourg, 06 July 2022

**Health Security Committee**

**Audio meeting COVID-19 and Monkeypox**

**Summary Report**

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

**Audio participants:** AT, BE, CZ, CY, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LV, MT, NL, PL, PT, RO, SE, SI, SK, NO, IS, LI, UK, DG SANTE, DG EMPL, DG HR, HERA, SG, COUNCIL, ECDC, EMA, WHO

**Agenda points:**

**COVID-19**

1. Overview on the current COVID-19 pandemic situation – presentation by ECDC
2. ECDC testing/vaccination document – presentation by ECDC
3. COVID-19 measures and testing strategies for the autumn – discussion point
4. Follow-up of communication on COVID-19 strategy in autumn/winter – presentation of survey results by DG SANTE and discussion

**Monkeypox**

5. Epidemiological update on the monkeypox outbreak + summary NITAG meeting – presentation by ECDC
6. Update on availability of vaccines and antivirals – presentation by HERA
7. Use of smallpox vaccines against monkeypox – discussion/sharing experiences among Member States

**AOB**

8. AOB: HSC letter - Reporting Regulation Article 7
9. AOB: AMR workshop on 11 October

**Key messages**

**COVID-19**

**1. Overview on the current COVID-19 pandemic situation – presentation by ECDC**

ECDC gave an overview on the current COVID-19 pandemic situation. **Transmission continues to increase** in the EU/EEA. Overall, hospital and intensive care unit occupancy increased, but remains lower compared to previous waves. **Variants of concern** BA.4/BA.5 are now the predominant variant in 12 EU/EEA countries. BA.2 +L452x variant (Omicron) reached the 5% threshold and increasing trend in 16 EU/EEA countries. BA.2.75 is a starting to be considered a "**variant under monitoring"** due to mutational profile (48 cases in India, 6 cases in UK, 2 cases in Germany). In the total EU/EEA population (18+) received 72.7% a primary **vaccination** course and 52.7% a booster/additional dose.

**DE** asked if clinical data is available on the BA.2.75 variant. **ECDC** responded that information on this variant is still limited. It seems to have an increased transmissibility compared to other circulating viruses, however, this still has to be confirmed. ECDC is monitoring the variant closely.

**EE** asked if ECDC has a prognosis for the upcoming week with regards to the increase of hospital admissions. **ECDC** expects an increase of notification rates in hospital admissions during the next two weeks. More information on forecasts can be found on the ECDC website.

**2. ECDC testing/vaccination document – presentation by ECDC**

**ECDC** gave a presentation on the operational considerations for respiratory virus surveillance in Europe. **Common objectives for integrated surveillance of respiratory viruses** include:

1. Monitor the intensity, geographical spread and seasonal activity of influenza, SARS-CoV-2 and other respiratory viruses to inform mitigation measures.
2. Monitor severity, risk factors for severe disease and assess the impact on health care systems of influenza, SARS-CoV-2 and other respiratory viruses to inform mitigation measures.
3. Monitor characteristics of circulating and emerging viruses as well as viral changes of influenza, SARS-CoV-2 and other respiratory viruses to inform treatment, drug and vaccine development.
4. Assess vaccine effectiveness against influenza, SARS-CoV-2 and other respiratory viruses
5. Describe the burden of disease associated with influenza, SARS-CoV-2 and other respiratory viruses

To monitor acute respiratory infection surveillance, **sentinel surveillance systems** could play a major role (installed at primary care/hospitals). The sentinel surveillance systems should be fit for purpose, well designed, and able to expand in order for the system to be sustainable. ECDC also highlighted the importance to continue to collect data from **non-sentinel sources**. Countries should plan for a potential upscaling of testing for influenza and SARS-CoV-2 if required in response to the emergence of a new variant of concern. Virological testing and characterisation should be implemented and investigated.

The **Commission**, together with ECDC, will explore how to support those countries that indicated the need for more support to strengthening their sentinel surveillance system.

Regarding the **autumn/winter vaccination strategy** against COVID-19, ECDC presented several public health considerations, including:

- To improve vaccine uptake of the primary course and first booster in eligible individuals;
- Second booster roll-out for adults of 60 and above and medically vulnerable individuals;

- Continued monitoring of protection against severe disease in those population groups that have received a second booster dose;
- Communication initiatives to promote uptake of additional vaccine doses in the autumn and winter;
- Updated Omicron-updated vaccines will likely to be authorised for use in the EU and possibility available from September 2022.

Some **Member States** asked if ECDC could establish thresholds for the testing/vaccination strategies. **ECDC** responded that an EU wide threshold is not feasible due to the differences among the Member States. ECDC does recommend the Member States to reintroduce non-pharmaceutical interventions in public places and public transport when cases are rising.

The draft versions of the **Surveillance strategy document** and the V**accination strategy document** will be shared with the HSC for comments this week (27).

**3. <u>COVID-19 measures and testing strategies for the autumn – discussion point</u>**

Several countries shared their national plans regarding COVID-19 surveillance, testing and sequencing for the coming months. Some countries are still discussing/preparing the recommendations for the autumn/winter period, while others already started a campaign for a second booster dose for specific groups (e.g. residents of long-term care facilities, older persons 60+/75+ (age range differs between countries)). Some countries mentioned that they plan upscale their testing methods or to increase their water surveillance system.

**DK** offers booster doses to specific groups (vulnerable groups, individuals with risk of severe illness). No boosters are recommended for children. DK is closely monitoring the epidemiological situation.

**AT** is preparing for the autumn period. Four strategies have been prepared in order to be ready for different scenarios. COVID-19 testing will be up-scaled.

In the **NL**, the testing strategy consists of self-testing in combination with practical, easy to find isolation and self-care advice. This is the strategy now and for the future. In the event of a new variant that does not respond to antigen tests and which puts a strain on the Dutch healthcare system, PCR-capacity could be scaled up. The municipal health care services are preparing for this scenario.

**IE** is currently preparing the autumn/winter recommendation. IE wants to know if ECDC is planning to provide guidance on the new vaccines and if ECDC will help to prepare guidance on who to give the new vaccines first. **ECDC** responded that they can certainly help with assessing the new vaccines and guidance. However, the current vaccine also helps against hospitalisation.

**PT** follows the international guidance from ECDC and WHO and adjusts the national strategy with the most suitable recommendations. PT has developed a new COVID-19 surveillance strategy, which includes vaccination. A fourth dose is recommended for those aged 80+ and to individuals (12+) with medical conditions/immune immunocompromised.

**NO** started a campaign for a second booster (fourth dose) for nursing homes residents and everyone of age 75+ on 1 July.

**SI** is preparing for the next wave. SI is increasing their waste monitoring, their sentinel system in hospitals and primary care. The testing strategy is currently under discussion. As for the vaccination strategy, SI is awaiting the updated ECDC guidelines for a second booster dose. SI will most likely recommend a second booster to the population aged 60+. Simultaneously, SI is preparing a strategy for prepare entire population in cases something arises.

**EE** has started to provide vaccination with second booster in elderly/nursing houses.

**FR** is continuing its second booster dose campaign (60+ and people living in care homes). The objective is to protect them the best as possible regarding the epidemic context. The objective is also to articulate this campaign and the communication with the fall campaign (in particular to prevent vaccine hesitancy).

**IT** is recommending a second booster dose for those aged 60+ with medical conditions, in people aged 80+ and individuals staying in long-term care facilities. At this stage, no changes have been made regarding contact tracing and surveillance strategies: high risk contacts are traced and tested. If symptomatic, cases are isolated and tested at day 7 or 10 to discontinue isolation.

**SE** only has contact tracing in sensitive environments such as hospitals.

**4. Follow-up of communication on COVID-19 strategy in autumn/winter – presentation of survey results by DG SANTE and discussion**

On 27 April, the Commission published the Communication on COVID-19 - Sustaining EU Preparedness and Response: Looking ahead laying out key actions that Member States should implement. In late June SANTE sent a survey to the HSC to follow-up on these key actions, in preparation for the autumn/winter months. 20 EU/EEA countries responded, main observations include among others:

- **Vaccination:** in the majority of the countries, the current strategy to increase primary vaccination and first booster dose uptake in autumn/winter is currently under discussion. The inclusion of younger children to be included in the autumn/winter strategy is also under discussion in the majority of the responding countries. A strategy for a fourth dose, is either under discussion, planned, or implemented.
- Target groups for scaling up vaccination mainly include immunocompromised/ immunosuppressed individuals and older persons (65+).
- Plans to incorporate COVID-19 vaccination into the national vaccination programme in under discussion in 15 countries.
- **Testing and whole genome sequencing**: in the majority of the Member States that responded, an integrated year-round surveillance system for acute respiratory illness is in place. Most countries share this information with ECDC's integrated surveillance system. The majority of the responding countries has a complementary surveillance system in place, such as wastewater monitoring.
- **Preparedness planning**: contingency plans to re-induce public health measures is under discussion in 15 countries. The majority of the responding countries has published updated recommendations on the use of face mask.
- **Communication**: 14 countries publish continued, consistent and repeated messaging to reduce mis- and dis- information. 13 countries have prepared clear messages on balanced non-pharmaceutical interventions, the need for vaccination, and the possible re-introduction of measures based on the best available science.

Countries that did not respond to the survey so far are encouraged to do so.

**Monkeypox**

**5. Epidemiological update on the monkeypox outbreak + summary NITAG meeting – presentation by ECDC**

As of 5 July, 3989 confirmed cases of monkeypox have been reported in 26 EU/EEA countries. ECDC and HERA did a **modelling exercise** on the monkeypox situation, which included isolation, contact tracing as control measures and the use of potential vaccination strategies. Some main modelling results include:

- Effective isolation of cases and tracing of contacts increase the chance of outbreak control.
- **Pre-exposure prophylaxis vaccination** is efficient in settings with less effective tracing (and highly efficient in settings with more effective tracing). Pre-exposure prophylaxis vaccination is more efficient targeting those at-risk or with highly risky behaviour.
- **Post-exposure prophylaxis vaccination** is effective with more effective tracing and higher vaccine uptake levels.

In ECDC's forthcoming up-dated risk assessment, it still predicts a moderate overall risk for persons with multiple sexual partners, including some MSM (men who have sex with men).

**PT** highlighted the need for clear advantages of pre-exposure vaccination for monkeypox. PT hopes that the new rapid risk assessment of ECDC will focus on the evidence for pre-exposure vaccination. An ECDC/WHO protocol on the use of smallpox vaccine against monkeypox would be appreciated. **ECDC** explained that the modelling focussed on the ones with highest at risk behaviour. With regards to the development of a protocol, ECDC will continue to closely cooperate with WHO.

**FI** would like to hear more about the safety data of vaccinations, and if the use of vaccination is crucial, as most cases are mild. **ECDC** mentioned that most data is based on the data used for smallpox. With regards to the severity of cases, it often does not lead to hospitalisation, however, the symptoms can be very unpleasant.

**ECDC** gave a short summary on the **EU/EEA Network of national immunisation contact points Webinar** held on 28 June 2022. Topics of the webinar include an up-date on the monkeypox multi-country outbreak and response measures, including immunisation strategies, and sharing experiences among countries. 18 EU/EEA countries, UK, USA, ECDC, EMA, HERA, EC, WHO participated. Main conclusions are:

- Countries are observing outbreaks with similar epidemiological characteristics (e.g. transmission predominately within MSM community and sexual networks; mild disease).
- Contact tracing is challenging in the context of MSM sexual networks.
- EU/EEA countries have adopted (7 countries) or are discussing (6 countries) immunisation strategies against monkeypox with the aim of interrupting transmission, but approaches are still heterogeneous across countries (post-exposure: 7 countries; pre-exposure: 2). No strategies: 8; missing information: 9.
- Few countries are combining post- and pre-exposure prophylaxis strategies according to a focused or phased approach, as additional vaccine supplies become available and vaccination strategies expand (e.g. UK, USA, Germany).
- Adapted immunisation schedules: single dose in case of previous smallpox vaccination; time interval for second dose is 28 days apart, longer in the context of limited supplies, or administered only if exposure persists).

- Vaccine supply still limited (from joint procurement; or direct purchase) increasing in Q3.
- Very few countries have started rolling out vaccination against monkeypox.
- Evidence is lacking on effectiveness of different monkeypox immunisation strategies in different target groups.
- Some countries have developed research projects: focusing on post-exposure vaccination/prophylaxis (Low intervention clinical trial in France); pre-exposure vaccination/prophylaxis (prospective cohort study among MSM in Germany), sero-epi studies (UK).
- Sharing of protocols should be facilitated and opportunities for implementation of multi-country studies explored.

**IE** mentioned that restrictions are imposed on clinical samples due to the bio-safety level categorisation of monkeypox. Consequently, limited laboratories are able to collect/analyse monkeypox samples. IE asked for possible change of the bio-safety levels so more laboratories could work on monkeypox samples. The **Commission**, together with ECDC, will come back to IE in writing.

**6. Update on availability of vaccines and antivirals – presentation by HERA**

The smallpox vaccines Jynneos (Bavarian Nordic) has been distributed among the first three Member States (ES, DE, PT). Three more deliveries are planned for this/next week. So far, 14 out of 26 donation agreement documents have been signed. It is expected that all countries should have received their doses by the end of July. A joint procurement for the vaccines has to be decided with the HERA Board. Deliveries resulting from that joint procurement are not expected before 2023.
Regarding the antiviral Tecovirimat (SIGA), 27 countries expressed their interest in a joint procurement. The draft contract and call for tender documents are ready, HERA is currently waiting for the last information form the manufactures.

**7. Use of smallpox vaccines against monkeypox – discussion/sharing experiences among Member States**

Member States up-dated on their current recommendations on using the smallpox vaccine against monkeypox. A few countries published their guidance recently, while other countries are still in need of more information about the vaccine. One of the main issues is to define a vaccination strategy in the light of the very limited number of vaccine doses available.

**PT** received a limited amount of doses smallpox vaccines.

**DE** recommends the smallpox vaccine for post-exposure prophylaxes after monkeypox exposure and for people with an increased risk of exposure and infection. As the availability of the vaccine is currently limited, the vaccine should be offered as a priority to exposed contacts.

The **UK** still counts a large number of monkeypox cases. Contact tracing is complicated and a limited stock of smallpox vaccines are available. Recommendations can be find on the website.

**DK** asked how the UK is managing the demand issue and if certain groups are prioritised within the high risk groups. The **UK** responded to use health data sets on sexually transmitted diseases, vaccines are allocated in proportion to this available data.

**AOB**

**8. AOB: HSC letter - Reporting Regulation Article 7**

In June, the Commission, the European Parliament and the Council reached a political agreement on the new Regulation for serious cross border threats to health. The Commission expects the final version to be adopted in October/November 2022. The HSC will start preparing for the implementation of the Regulation, pending its final adoption. One of the areas of this **preparatory work relates to reporting requirements**, which previously fell under Article 4 of Decision 1082/2013/EU and now under Article 7, where countries will have to report every three years on their preparedness. Countries can nominate a representative to participate in the **Preparedness Working Group by email (deadline: 15 July).**

**9. AOB: AMR workshop on 11 October**

Regarding the preparatory work for the new Joint Action on antimicrobial resistance, the Commission is planning a workshop to facilitate the drafting of the joint action proposal. This workshop is due to take place in Brussels on the **11th of October**. Emails with 'Save the date' notification have already been sent to the HSC and the One-Health-Network.