EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 20 July 2022

Health Security Committee

Audio meeting COVID-19, Monkeypox and AMR

Summary Report

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

Audio participants: AT, BG, CY, DE, DK, EE, EL, ES, FI, FR, HR, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK, LI, CH, UK, DG SANTE, DG HR, HERA, EMA, ECDC, WHO

Agenda points:

COVID-19

1. Overview on the current COVID-19 pandemic situation – presentation by ECDC
2. Update on the Vaccine Steering Board meeting and adapted COVID-19 vaccines – presentation by HERA
3. "Protecting the vulnerable with agility, efficiency, and trust: Strategy considerations for SARS-CoV-2 and other respiratory viruses in the WHO European Region during Autumn and Winter 2022/2023" - Presentation by WHO/EURO
4. Discussion point among Member States:

Monkeypox

5. Epidemiological update on the monkeypox outbreak – presentation by ECDC
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8. WHO MPX Emergency Committee Members on 29 June
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AOB

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Key Messages:

COVID-19

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

The ECDC gave their regular update on the COVID-19 pandemic situation and on the Omicron sub-lineages. Transmission is increasing in all age groups. In persons >65 years-of-age it increased in 23 out of 27 countries in the EU/EEA, by 23% compared to previous week. Transmission remains high in this group (reached 78% of the pandemic maximum) and has led to increasing rates of severe disease. The 14-day COVID-19 death rate has been stable for five weeks (8.3 deaths per million population), increasing in seven countries. Overall, hospital and ICU occupancy are increasing in 12 out of 30 countries, although remaining lower than in previous surges. BA.4-5 (combined) are the dominant SARS-CoV-2 variants in the majority of the EU/EEA countries, however, BA.5 was detected more frequently than BA.4. There are many new sub-lineages defined for BA.4 and BA.5. The detection of BA.1 is very low and that of BA.2 is decreasing, while BA3 is not existing anymore. BA.2.75 was escalated to a variant of interest on 14 July 2022. This change was made due to increasing number of detections in India and world-wide as well as the concerning mutation profile of this variant. Such profile might potentially be associated with a change in the antigenic properties of the virus, which could ultimately lead to a new surge in COVID-19 cases. However, no solid scientific evidence on the transmissibility, disease severity or immune escape of BA.2.75 is currently available. The WHO designated BA.2.75 as a variant of concern/lineage under monitoring. It was mainly detected in India so far, where it is quickly increasing in proportion. However, cases were also detected in Australia, Canada, Denmark (1), Germany (2), Indonesia, Japan, Luxembourg (1), Martinique, Nepal, Netherlands (1), New Zealand, Turkey, USA and United Kingdom. Its genomic properties contain spike changes, if compared to the index virus lineage B. BA.2.75 is often incorrectly referred to in the media as “Centaurus”. However, this variant has not officially received yet a name in the WHO SARS-CoV-2 variant nomenclature. On 18 July, ECDC published a statement on BA.2.75, where it asks countries to enhance surveillance and sequencing efforts to better understand circulating SARS-CoV-2 variants and to timely submit complete genome sequences and associated metadata to a publicly available database (e.g.) GISAID. Furthermore, if available, raw data should be deposited in the COVID-19 data portal through the European Nucleotide Archive (ENA). Countries should also perform and share results of field investigations and laboratory assessments to improve the understanding of the potential impacts of BA.2.75 on COVID-19 epidemiology, severity, effectiveness of public health and social measures, diagnostic methods, transmissibility, immune responses, antibody neutralization, or other relevant characteristics. Countries of the EU/EEA may use the EpiPulse event (2022-IRV-00003) on BA.2.75 to informally discuss and share such information, including partial and preliminary data. On vaccination coverage in the EU/EEA, as of 14 July 2022 72, 8% of the total population have completed the primary course, while 52, 9% of the total population have had their first booster or an additional dose.

SANTE asked on the possible spreading of BA2.75 in the EU and whether there already are any studies or forecasts, also taking into account the difference of the baseline of the variants in India and the EU. **ECDC** replied there is no specific data on B2.75 yet as the data from India is not clear. The variant was escalated exactly for the purpose of retrieving more information. As far as predictions are concerned, there is no solid data on that yet.

2. Update on the Vaccine Steering Board meeting and adapted COVID-19 vaccines – presentation by HERA

DG HERA gave an update on the adapted COVID-19 and the Vaccine Steering Board discussions, asking that any information shared in the context of this meeting remains confidential. They recalled that the availability of adapted vaccines depend on the approval for marketing authorisation from EMA and its position regarding approval of further adapted vaccines, namely BA.4/5 vaccines, with or without clinical trials. Also, the FDA position to approve the BA.4/5 adapted vaccine without clinical data end of June has drastically changed the context for discussions about which adapted vaccines to use, and how to deal with approval of vaccines. On Moderna, the current scenario assumes the approval of a bivalent BA.1/Wuhan vaccine end of summer 2022 and deliveries of that vaccine could start as early as first week of September. HERA is specifically working on an amendment of the purchase agreement to ensure the deferral of July and August doses to September onward, therefore ensuring access to the adapted vaccine as required. In the event that a marketing authorisation would not require additional clinical data, a BA.4/5 vaccine could be supplied in November. Member States of the Steering Board have this week already indicated an interest in a BA.4/5 Vaccine in November and December if the Marketing Authorisation allows. However, in the event that additional clinical data is required, Moderna would likely not be able to get Marketing Authorisation in 2022 for a BA.4/5 vaccine. On BioNTech Pfizer, with a marketing authorisation end of August, the company could deliver a BA.1/Wuhan bivalent vaccine already in September, while a BA.4/5 vaccine could come as early as end of September/October, if no additional clinical data is required for marketing authorisation. If that is not the case, an approval for a BA.4/5 vaccine could come only later in 2022. HERA would overall receive about 400M doses of adapted vaccine in the autumn/winter season, which should be more than enough to vaccinate the targeted populations. The approach to Member States would currently be to give enough BA.1 and BA.4/5 doses, and to later on make a decision on whether earlier vaccination with BA.1 or later vaccination with BA.4/5 is the best approach. It has to be kept in mind that the ECDC and EMA have recommended the rapid deployment of a second booster dose for people over the age of 60 years and medically vulnerable populations at high risk of severe disease.

3. "Protecting the vulnerable with agility, efficiency, and trust: Strategy considerations for SARS-CoV-2 and other respiratory viruses in the WHO European Region during Autumn and Winter 2022/2023" - Presentation by WHO/EURO

WHO EURO gave a presentation on their new publication on its autumn strategy for COVID-19 and other respiratory viruses. The strategy provides guidance to decision makers to calibrate interventions in preparing for the autumn and winter of 2022/23. The rationale behind the need for interventions is based on the recent upsurge in COVID-19 cases during the summer; the likelihood of another COVID-19 surge in the autumn and winter; and increased risk of other respiratory virus infections as we enter the autumn season and their co-circulation with COVID-19. A critical component of the response to COVID-19 and other respiratory viruses is the need to protect vulnerable populations. WHO recalled the joint publication with the ECDC on 18 July on Operational Considerations for respiratory virus surveillance in Europe. They outlined that despite the good protection vaccines provide against severe disease, significant morbidity and mortality is still seen in older persons. Also, the acute impact of increased prevalence of long- COVID is now becoming more relevant, considering there is still substantial and continued lack of understanding on long COVID and its consequences. WHO stressed the need to act now and to increases laboratory and surveillance capacities in preparation for autumn, especially as several countries currently have low laboratory capacities. On risk communication and community engagement, pandemic fatigue and the lifting of public health measures are big challenges that have to be tackled and WHO encouraged MS to

rigorously promote and emphasize the need to wear protective measures, both for individual protection but also as an act of social responsibility.

4. Discussion point among Member States

In preparation for today's meeting MS received the following question on non-pharmaceutical measures: *Is your country considering to (re)implement/already implementing non-pharmaceutical measures in the light of the current COVID-19 wave? (e.g. improvement of ventilation at schools?).*A survey was launched as a follow up to the Commission's Communication on COVID-19 published in April, and the results showed that few Member States have re-introduced the use of facemasks and some have put in place general recommendations. The Commission encouraged Member States to exchange information about applied measures.

IT: recommends to wear masks on public transport. Workers and visitors of social and health care facilities are obliged to use FFP2 masks (this obligation does not apply to children < age of 5 or to people who cannot wear a mask due to disability). From 13 June FFP2 masks should be considered for employees, if the distance of 1 m cannot be kept. The employer should guarantee the availability of FFP2 masks at the workplace.

EE: reported that the 5th COVID -19 wave in EE started end of June and cases are still increasing. Last week, a total of 500 new cases were registered and this week, about 100 people are expected to be hospitalised. Currently there are no strict measures in place and the health boards has issued the following recommendations: self-isolation for 5 days for everybody with either a positive RAT or a real time PCR test and for anybody diagnosed with COVID-19 by a health care provider. The recommendation to self-isolate for a close contact does not apply to people who are fully vaccinated or were infected in the past 180 days. Currently there is on rule of quarantine, which is an individual's responsibility. Asymptomatic people are recommended to stay at home for 5 days or until the symptoms have disappeared for at least 24h. Wearing masks is recommended for risk groups (over 60 age and people with underlying conditions). Overall, EE is recommending to keep good hygiene practice (washing hands, keeping distance of 2 m). Furthermore, EE has recently changed its testing strategy, and PCR tests are only available for free for risk groups (60+, pre-conditions). People not belonging to these groups cannot take a PCR test for free, but are recommended to either pay for it or take a RAT at home and isolate until symptoms have cleared. At the end of July the 2nd booster dose was made available for risk groups and technically everybody else who has justified reasons have one. For the year 2022/2023 there are strategies in place, which are similar to the WHO strategy to prevent the spread of infections and preparation of health care providers in case of high raise with 3 different scenarios.

ES: reported that currently the only intervention in place is the use of face masks in public transport. Moreover, there are mandatory instructions for personnel working in health care facilities. NPIs are recommended but not compulsory (ventilation, safe distance, masks, reduce visits that are not necessary). Case trends are not increasing in ES right now, and for the last 2 weeks a decrease in transmissions was registered. ES is preparing to modify the recommendation for the future. The current level of alert is 2, and should it change to level 3 or 4 (according to the national guide/risk assessment) stronger recommendations for the use of masks indoors etc. will be issued. This will include the use of masks in settings where vulnerable people gather (LTCF, hospitals) and increased ventilation indoors (and all measures to increase the quality of the air), as well as testing for those with symptoms and self-isolation

of confirmed cases, who currently are only recommended to wear masks. Moreover, the capacity for the health care facilities will be reinforced, to have enough resources to respond to the increase of cases in autumn/winter. However, the impact of the currents incidence in health care facilities and severe illness are low. This is considered to be due to the very high level of vaccination in the population (coverage of people 60+ with 1st booster is 98% and for people over 40 years is 85%).

SE: reported that no NPIs are implemented and they are only testing people who come to the hospital. They are however preparing for interventions, if needed in the coming months.

IE: reported that it has moved into a transition phase since February. Testing is only advised to close contacts or people 65 years + without booster, immunocompromised people, pregnant women and health care workers. Anyone who has symptoms should self-isolate for 48 hrs and not attend social events, work, colleges etc. Those diagnosed with COVID-19 should self-isolate for 7 days from the day of their first positive test/the day they started to be symptomatic. There is no general mask mandate in place, but masks wearing is advised in public transport. Moreover, health care works dealing with suspected or confirmed cases are required to wear ffp2 masks. IE is currently looking at the autumn/winter planning regarding ventilation and testing, surveillance and masks.

Monkeypox

5. Epidemiological update on the monkeypox outbreak– presentation by ECDC

As monkeypox cases continue to raise in Europe and globally, the ECDC gave an epidemiological update on the outbreak. As of 19 July, there are 8 164 confirmed cases in 27 EU/EEA countries. In the western Balkans & Turkey, there are 7 confirmed cases in 3 countries. The epidemiological curve is still increasing when looking at week 28. ECDC has stopped collecting worldwide data on 7 July and referred to the emergency situation report from WHO. The ECDC also gave an overview of their latest Rapid Risk Assessment published on July. Most of the cases occurred in males between 18-50 years, and primarily among MSM. Particular sexual practices have facilitated the transmission of MPX among MSM groups with multiple partners. However, there is potential for further transmission in other population groups. No documented evidence of human-to-animal or animal-to-human transmission in the EU/EEA to date.
The main conclusions from modelling were that effective isolation of cases and tracing of contacts increase the chance of outbreak control by week 12 of the outbreak to more than 50%. On PrEP vaccination, if the vaccine uptake is high (of 80%), it considerably increases the probability of outbreak control by week 12. PrEP vaccination would be most efficient in settings with less effective tracing and highly efficient in settings with more effective tracing, while with more effective tracing and higher vaccine uptake levels, PEP vaccination of contacts of cases would be the most efficient vaccination strategy. Moreover, PrEP vaccination is more efficient when targeting those at-risk or with highly risky behaviour. The risk for transmission from SoHO (substances of human origin) – is considered low, as is the risk for animal transmission. However, little is known about the susceptibility of animal species endemic to Europe.

Regarding options for response, the current priorities for countries should be the identification, isolation, contact tracing and vaccination of MPX cases. This means countries should review and strength laboratory diagnostic capacity and increase availability for orthopoxviruses. They should continue activities to increase awareness of health professionals around the ongoing outbreak and develop, review and

implement vaccination strategies. Also, continue monitoring of antiviral use for the treatment for severe cases as well as a strong risk communication and engagement with at risk groups, as well as the broader public. Currently, mass vaccination for MPX is not required nor recommended. Effective contact tracing is needed, according to modelling, to help control the outbreak but many challenges exist. It was stressed that there are still many knowledge gaps and limitations, and therefore it is important to work on producing more evidence. ECDC recently published a Joint ECDC-WHO Regional Office for Europe Monkeypox Surveillance Bulletin (europa.eu) and a Risk communication and community engagement approaches during the monkeypox outbreak in Europe, 2022 (europa.eu), as well as a resource toolkit for event organizers.

PT: asked whether there is evidence for transmission via fomites, considering that the current experience tells the virus is behaving very differently from clade 2 and not much evidence on transmission ways is available yet. The **ECDC** replied they are currently looking into data from countries, as well as continuously reviewing literature (including grey literature), as this is one of the most important research questions to be investigated. ECDC launched a survey from local focal points, which will include ongoing studies to summarize some of the evidence gathered. So far, there is no information on transmission through fomites.

FI asked what specific recommendations are given to contacts, especially whether a strict quarantine should followed, including the avoiding close and/or sexual contacts. **ECDC** currently does not recommend quarantine of close contacts but stressed the need to avoid sex and contact with vulnerable persons at risk of severe disease (pregnant women, children, and immunocompromised people). Moreover, medical personnel who screens/takes samples should be sensitized to communicate to contacts/suspected cases that if they are being tested for MPX, they are highly recommended to self-isolate until they receive their results back as a precaution.

IS askes on the number of people with severe symptoms, to which **ECDC** replied that only few cases have been fully reported by the countries so far, and among others, secondary skin infections were recorded.

6. Vaccination policies as part of the response to the monkeypox outbreak– survey results – presentation by DG SANTE

Given that some Member States have already started to receive smallpox vaccines for the current monkeypox outbreak, a survey was launched on Tuesday 12 July to understand vaccination policies as part of the response to the monkeypox outbreak. There were 26 replies so far. With thanks to all those who have replied, those who have not were encouraged to submit a reply.
DG SANTE presented the preliminary results. These show that 15 countries have issued national policy/ guidelines for monkexypox that includes the use of a smallpox vaccine for monkeypox. This is under discussion in 5 countries, while 1 country has not issued any policies. The target groups considered are close contacts at risk of serious disease, people working in laboratories, all close contacts that are health care workers, all health care workers at risk of exposure, close contacts affected by immunocompromising diseases, close contacts living with HIV, close contacts that are pregnant, close contacts that are children, close contacts of MPX cases aged 18+, close contacts and at-risk of exposure population groups nationwide. Most countries recommend 2 doses. So far, only 1 country is carrying out a study on the use of the vaccine, while a few are planning (2) or discussing (2) the option and most countries have no study

planned. The regulatory mechanisms for national use of a vaccine are either the approval by national medicine authorities, the issuing of a national exemption or compassionate use. Some countries (3) use consent forms before administration. Overall, high levels of contact tracing are performed in most countries (17), however, information about contacts is not easy to obtain.

EE commented that vaccination is included in their strategy, however, this was not published yet.

7. National policies for the monkeypox outbreak control including vaccination

The United Kingdom and Switzerland were invited to give an overview on their current strategies to manage the monkeypox outbreak, including their vaccination strategies **UK** reported that the latest update registered 2137 cases in the UK, with the majority of those in London. 99.3% cases are male and the adult medium age is of 37 years. The control strategy is similar to what has been presented by other EU countries. UK is focusing on case finding, contact tracing, prevention, risk communication and vaccination. Currently, sexual health clinics are predominantly used. On case finding, this is predominantly focused on sexual health clinics ensuring there is supporting laboratory capacity. On contact tracing, UK just published changes in their contact guidance, no longer recommending the isolation of contacts, because contact tracing has been challenging, especially in the difficulty identifying particularly sexual contacts. The focus currently is on prevention with community engagement, engaging with 3rd sector organisations. On Vaccination, UK published a strategy to interrupt transmission in subgroups at increased risk. Post exposure prophylaxis is recommended to cases predominantly within 4 days of the contact, however, groups with high risk of complications are recommended to take it up to 14 days. Furthermore, UK started the distribution of PrEP both occupationally for health care workers and gay, bisexual and other MSM using same criteria for PrEP for HIV. They are predominantly using sexual health clinics to deliver PrEP, exploring though at other possibilities.

CH reported that the situation and measurements in place are very similar to what has been presented so far. Currently, CH has 216 - laboratory confirmed cases, all men, most occurring within the MSM community. Only few cases were hospitalised mainly for pain. The assumption is that cases will significantly increase in the future and spread to other population groups. Ongoing work is closely cooperating with NGOs, while the main challenge is to convince people to get tested, as there is some resistance in this regard because people wish to avoid self-isolation. Close contacts are informed and recommended to avoid all sexual contacts 21 days after their contact. On vaccination, currently none of the vaccines are authorized in CH, and the vaccine strategy is under discussion. At the moment, a PrEP (pre exposure prophylaxis) strategy is considered by targeting the population at risk.

8. WHO MPX Emergency Committee Members on 29 June

WHO MPX Emergency Committee Members met the first time on 29 June 2022. At that time, based on information provided by committee members and member states, it was not recommend to determine the monkey pox outbreak as a public health emergency of international concern. However, it was noted that there was a great amount of uncertainty and that remaining knowledge gaps needed to be filled in. The committee offered a set of indicators based on which they would evaluate the ongoing transmission. The committee will reconvene tomorrow (21.07.22) at midday and will make new recommendations. Announcements can be expected for either Friday or during the weekend.

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

During the last HSC meetings, HERA presented their latest work on monkeypox. Today HERA provided another update of their current work related to the availability of vaccines and antivirals for monkeypox, and about the first vaccines delivered to the Member States. Update on the joint procurement on Tecovirimat: progressing in the procedure to launch the joint procurement, some discussions are ongoing with the company on the renewal of the first purchase. Vaccine from Bavarian Nordic: distributions are ongoing, 8 countries were delivered. Another 8 countries have not provided the necessary documents to organise the delivery yet. As soon as this issue is resolved, HERA hopes to deliver all purchases done by August. There has been the opportunity to increase the number of doses by 50% -, additionally purchasing 54 000 doses, which however, will only be available in December. For these doses, it will have to be decided in November who are those in the most need. On the joint procurement with Bavarian Nordic, HERA is currently discussing the details. The company has been very clear that doses and the procurement will not be available before 2023. Decision will have to be made whether to purchase Imvanex or Jynneos. Bavarian Nordic made clear that the purchase of Imvanex will depend on how many doses are requested, as production sites will have to be reopened.

AMR

10. New Joint Action on Antimicrobial Resistance (AMR) – discussion point among the Member States

As discussed in previous HSC meetings, the preparatory work for the new joint action on AMR is already on-going and informal discussions with the French leader (who have so far expressed willingness to lead again as they did for the previous AMR joint action EU-JAMRAI) regarding the possible structure and activities of the new joint action have started. SANTEs understanding is that they aim to have a first structure for discussion already at the HaDEA-organised workshop on 13-14-15 September, which can further be developed also at the SANTE-organised workshop on 11 October. A save the date email has been sent for the latter and invitations will be sent out in due course in September. The deadline for the nomination of competent authorities to HaDEA is 1 September so as soon as it is known who has been nominated, invitations can be sent out. Questions had been sent to the HSC in advance of the meeting and Member States were asked if they foresaw any limitations regarding their participation in the upcoming Joint Action. This is particularly in the light of a significantly larger budget now planned and due to the co-funding structures, which would also require for Member States to ensure adequate co-funding. AT informed that they are looking forward to participating and are clarifying further steps internally. NO informed that they have identified the most suitable competent authority and affiliated bodies, as well as clarified their co-funding question. HU are preparing for the Joint Action and have asked to be sent the letter from HaDEA again.

AT commented that they already participated in one joint action and wish to participate in the new one. They have been working with an organisation called *Health Austria*. They have not encountered any problems, but are in the process to make the nomination and are looking forward to participate in this joint action.

NO mentioned it is prepared for affiliated buddies, the co-funding seems to be partly taken care of.

HU commented it is preparing for the joint action, but asked whether any official letter was sent to the MS about this nomination. Should this be the case, they wish to receive it again.

SANTE confirmed that a letter was sent in March. This information will be checked with HADEA colleagues and they will be asked to resend this letter. In the interest of time, SANTE would welcome anybody else, particularly those who feel they struggle in the requirement of the co-funding, to please reach out to SANTE by email and it can be taken from there.

AOB

11. HSC Plenary meeting 04/05 October 2022

Following the political agreement on the Serious Cross-Border Threats to Health Regulation and hoping that epidemiological situation will allow this, the Commission is planning to organise on 04/05 October the physical meeting of the Health security committee under the new regulation. The meeting will be held in Luxemburg. Save the date information and more detailed arrangements for the meeting will follow.

12. EU preparedness

As part of DG SANTE efforts to strengthen preparedness capacity DG SANTE is launching the Tender for "EU preparedness: planning, reporting and training programmes for health specialists" that will be published on TED website **next Monday, 25/07**.

Conclusions and follow-up

- HSC will continue discussion on non-pharmaceutical measures in the light of the current COVID-19 wave and preparation for autumn and winter.
- HSC will continue exchange on the response to the monkeypox outbreak.
- Preparatory steps for the HSC Plenary meeting 04/05 October 2022.