EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 07 September 2022

Health Security Committee

Audio meeting on Monkeypox and COVID-19

Summary Report

The meeting brought over 80 participants together

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

Audio participants: AT, BE, CZ, CY, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LV, MT, NL, PL, PT, SE, SI, SK, NO, LI, DG SANTE, DG ECHO, DG JUST, DG CNECT, DG HR, HERA, HADEA, RTD, SG, COUNCIL, ECDC, EMA, WHO

Agenda points:

Covid-19
1. Update on the current epidemiological situation – presentation by ECDC
2. Update on adapted vaccines – presentation by EMA
3. COVID-19 communication – EU response to COVID-19: preparing for autumn and winter 2023 – presentation by DG SANTE
4. COVID-19 preparations for autumn/winter – survey results – presentation by DG SANTE
5. Newly authorised adapted COVID-19 vaccines encoding in EU DCC – survey results – presentation by DG SANTE

Monkeypox
6. Epidemiological update on monkeypox – presentation by ECDC
7. HSC document on "Recommendations for a common EU approach regarding vaccination policies for Monkeypox outbreak response" – discussion point among Member States
8. Possible case of monkeypox human-to animal transmission - presentation by France
9. Circulated communication visuals – Feedback from Member States
10. Update on monkeypox treatments– presentation by RTD
11. Update on vaccine procurement – presentation by HERA

AOB
12. Antimicrobial resistance (AMR) – study/ interviews with Member States – information point
13. EWRS meeting on 15 September
14. UA: Medical hub opening in Poland – intervention by the Polish Ministry of Health

Key messages

Covid-19

1. Update on the current epidemiological situation – presentation by ECDC

ECDC provided its regular epidemiological situation update on COVID-19 in the EU/EEA. The overall notification rate of COVID-19 cases has been decreasing for six weeks. The wave driven largely by variant BA.5 appears to have passed its peak in all EU/EEA countries, with no countries reporting increases in in their case notification rates. Current levels of hospital and ICU admissions/occupancy remain low (and at between 1-23% of the maximum values observed during the pandemic maximum) and continue to decrease.

2. Update on adapted vaccines – presentation by the European Medicines Agency (EMA)

EMA provided the HSC with an update on adapted vaccines. EMA and ECDC issued a statement on the use of the newly authorized adapted COVID-19 vaccines to support the planning of the autumn and winter vaccination campaigns.

EMA has recommended authorising two adapted vaccines to provide broader protection against COVID-19. Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1 are for use in people aged 12 years and above who have received at least primary vaccination against COVID-19. These vaccines are adapted versions of the original vaccines Comirnaty (Pfizer/BioNTech) and Spikevax (Moderna) to target the Omicron BA.1 subvariant in addition to the original strain of SARS-CoV-2. The adapted vaccines are authorized currently to be used as a booster vaccine. EMA is still analysing if the adapted vaccines can be used for primary series as well.

Other adapted vaccines such as those adapted to the Omicron subvariants BA.4 and BA.5, are currently under review by EMA or will be submitted soon, and, if authorised, will further extend the arsenal of available vaccines. The clinical data generated with the original/BA.1 bivalent vaccines will support the evaluation and authorisation of further adapted vaccines, making the authorisation process go faster.

Vaccines for booster doses are currently only authorised for persons of 12 years and above. EMA expects to approve both booster vaccines (Pfizer and Moderna) for younger children (6+) in October.

The **NL** asked for the benefit-risk ratio for administering adapted vaccines for people at a younger age. **EMA** responded that the booster dose is currently only authorised for people aged 12 years and older, but expects to approve the vaccines for a booster dose for the age of 6+ in October.

3. COVID-19 communication – EU response to COVID-19: preparing for autumn/winter 2023 – presentation by DG SANTE

The Commission Communication on EU response to COVID-19 adopted on 2 September 2022 puts forward proposals for actions to be taken by Member States to prepare for the upcoming autumn and winter months. This communication builds on the Commission Communication adopted on 27 April, which stresses the importance of continued coordination, integrated strategies and measures to respond to future outbreaks, and collaboration on real differences and strengthen the EU's capacity to prevent, prepare and respond to health crises. The Commission Communication has a strong focus on vaccination strategies and essential areas for increased efforts in the EU (e.g. integrated surveillance

systems, non-pharmaceutical interventions, healthcare systems and capacity, COVID-19 therapeutics, clinical trials, etc.).

4. COVID-19 preparations for autumn/winter – survey results – presentation by DG SANTE

The Commission sent out a survey to the HSC in late August with the aim to follow-up on the survey from July 2022. This assesses if and how countries are preparing for the upcoming autumn/winter months and building on actions put forward in its Communication from 27 April 2022. 25 EU/EEA countries responded to the survey, covering several topics: communication regarding the upcoming autumn/winter, vaccination strategies, surveillance systems, testing and sequencing, preparedness and planning.

Some main conclusions are that the majority of countries started to sensitise the public that the next wave is likely and that people/certain population groups will need to be vaccinated again. Co-circulation of COVID-19 and influenza is likely, and that certain non-pharmaceutical measures (e.g. masks) may need to be reintroduced again. A third of the responding countries are discussing/will soon agree on how to communicate to the public about COVID-19 and the upcoming months.

The majority of countries aims to prioritise the rollout of additional booster vaccines for older people and population groups of any age at risk of severe disease, and to close the vaccination gap. Seven countries are planning the rollout of a population-wide vaccination campaign (boosters for everybody interested). The majority of countries does not foresee any difficulties in ensuring sufficient capacities for vaccination in the upcoming months.

The Commission will share the full results with the HSC. Countries that have not completed in the survey yet are encouraged to do so.

ES mentioned to have established four levels, which are mainly based on the functioning/pressure on the healthcare system. Non-pharmaceutical interventions will be re-introduced based on thresholds, which will be mainly assessed at local and regional level. ES is aiming to adapt to local situations instead of national decisions, more information can be found here.

In **LT**, criteria of incidence (aggregated incidence of COVID-19, influenza and ARV – 1500 cases / 100 000 population) and bed occupancy have been set, which could lead to the declaration of an epidemic at municipal or national level. After declaration of an epidemic, enhanced measures in health care and social care settings would be applied, as well as mass gathering restrictions. Possibility to organise distance learning would be available at the school setting, based on certain criteria. Recommendations regarding other preventive measures, including mask wearing, would be strengthened.

In **EE**, there have been few scenarios under consideration, with three main scenarios: mild, severe and new pandemic. Some indicators that will be looked at, such as higher infection rate, when WHO classifies a variant of concern, hospitalisation for COVID-19 and mortality, burden on the healthcare system exceeds its capacity, and planned treatment becoming significantly limited.

5. Newly authorised adapted COVID-19 vaccines encoding in EU DCC – survey results – presentation by DG SANTE

On 1 September, EMA recommended the first adapted COVID-19 booster vaccines for approval in the EU. Subsequently, the Commission has authorised the first two variant-adapted COVID-19 booster vaccines: Comirnaty Original/Omicron BA.1 and Spikevax bivalent Original/Omicron BA.1, by BioNTech-

Pfizer and Moderna after a positive opinion from EMA. The Commission sent out a short survey to assess current/or planned practices of Member States to record the adapted COVID-19 vaccines, also in relation to the EC Digital COVID Certificate (DCC). 20 EU/EEA Member States responded. Topics addressed in the survey are: the use of adapted vaccines and coding needs and the EU DCC. The responses show that many countries plan to record the adapted vaccines as such in their vaccination registries, but do not see the necessity to make such distinction for the EU DCC. The Commission will share a more detailed document with all survey results to the HSC. Countries that have not completed in the survey yet are encouraged to do so.

Monkeypox

6. Epidemiological update on monkeypox – presentation by ECDC

ECDC provided an epidemiological update on the current monkeypox situation in the EU/EEA. So far, 18 736 confirmed cases were registered in 29 EU/EEA countries. Reported case numbers have been decreasing over the past weeks, possibly related to behavioural changes due to community engagement with risk groups and natural immunity acquired in the last months by part of the risk population. The number of vaccinations is probably still too low to have a significant impact on the reported case numbers as some countries only started to vaccinate very recently. The decline of cases still needs to be interpreted with some caution as delay in testing over the summer period could influence this.

7. HSC document on "Recommendations for a common EU approach regarding vaccination policies for Monkeypox outbreak response" – discussion point among Member States

The Commission gave a short update on the document: "Recommendations for a common EU approach regarding vaccinating for monkeypox". Vaccination strategies for monkeypox should be developed as part of the overall set of control measures. Continued community engagement efforts are needed to support and complement the monkeypox vaccination strategies. In the context of limited vaccine supply a suitable option would be to offer post-exposure preventive vaccination prioritising close contacts of cases and/or contact at high risk of severe disease. Systematic data collection on the effectiveness and safety of the vaccine, independently of the adopted vaccination strategy would be pivotal. An updated version of the document has been shared with the HSC for their comments. The document will be further discussed during the next HSC meeting.

8. Possible case of monkeypox human-to animal transmission - presentation by France

FR gave a short presentation on the evidence of human-to-dog transmission of the monkeypox virus. Two men that had been infected with the virus reported symptoms in their dog. The dog was tested positive for monkeypox by real-time PCR. Further exploration of this case (serological assays) is ongoing.

9. Circulated communication visuals – Feedback from Member States

The Commission has shared communication visuals on monkeypox with the HSC to support Member States with risk communication and raise awareness. Member States are welcome to provide any comments and suggestions. No comments were received during the meeting and therefore the visuals will be further discussed in the next HSC ComNet meeting later this month.

10. Overview on monkeypox treatment – presentation by RTD

RTD started several research actions since the World Health Organization declared monkeypox a public health emergency of international concern, which authorised RTD to mobilise funding from the Horizon Europe Framework. RTD is involved in several clinical studies: 1) on the effect of the antiviral Tecovirimat (focus on severe cases); 2) randomised controlled trial looking at the best treatment for

monkeypox (focus on mild cases); 3) global cohort study on the natural history of monkeypox disease, risk factors for severity, and management strategies.

11. Update on vaccine and Tecovirimat procurements – presentation by HERA

HERA provided the HSC with a short update on vaccine and Tecovirimat procurements. Regarding vaccines, HERA has purchased over 160 000 vaccine doses to donate to Member States. 22 Member States have already received vaccines, and two countries are still pending to authorise import and use. 20 countries have expressed an interest for the Jynneos/Imvanex vaccine Joint procurement. Evaluation has started. Negotiations will start quickly. Deliveries are planned for Q3 2023. Maximum amount is 1 million doses. EMA together with Member States ensures close monitoring for potential safety signals for both vaccines. HERA will collect data after 6-months of the signature of the contract on the actual use of the vaccines.

Regarding antiviral treatment, 26 countries have expressed an interest for the antiviral Tecovirimat joint procurement. Evaluation has started. The maximum amount of the tender is 100 080 treatment courses. Member States can reassess their quantities until any of the framework contracts are signed.

AT asked if HERA has an update on the possible Direct Purchase of Tecovirimat, which was mentioned in a previous HSC meeting. **HERA is** unfortunately not yet in the position to confirm direct purchase, HERA hopes to share (good) news with the HSC shortly. However, such a purchase would take place under the rescEU framework, which is a last resource mechanism. Member States would therefore only be able to request amounts that they urgently needed at that moment.

AOB

12. Antimicrobial resistance (AMR) – study/ interviews with Member States – information point

DG SANTE has commissioned a "Study on the barriers to effective development and implementation of national policies on antimicrobial resistance (AMR)". The 1 million EUR study has been contracted to an independent research consultancy, Tetra Tech International Development, and partners and will be running until June 2023. The study builds on the Council conclusions of 2019 and the main objective of the study is to look into existing barriers to the implementation of effective policies and measures to combat antimicrobial resistance across the European Union Member States, Norway and Iceland. The study will support the preparation of future policy initiatives on AMR and support the implementation of the EU One Health action plan against AMR.

13. Early Warning and Response System (EWRS) Joint Controllers meeting on 15 September

On 15 September 15:00-17:00 (CET), the EWRS Joint controllers meeting will be held, focusing on new developments of EWRS 2022 -2024, update on the ongoing EWRS related contracts, planning for the EWRS-related implementing decisions and delegated act preparation, EWRS – electronic Passenger Locator Form integration: discussion on the way forward. Member States are asked to confirm their participation by sending an email to the HSC functional mailbox.

14. UA: Medical hub opening in Poland - intervention by the Polish Ministry of Health

On 1 September, the Polish Medical hub in Jasionka was officially inaugurated. The European Commission (ECHO, HOME, SANTE), Ministries of Health from Poland and Ukraine as well as Norwegian representatives participated in opening a medical evacuation hub in Jasionka near Rzeszów airport to facilitate transfers of Ukrainian patients. The new Medevac Hub is financed through the EU Civil

Protection Mechanism, which is part of a broader medical evacuation scheme launched by the European Union in March 2022. A video from the inauguration is available.

The Chair announced that the physical HSC meeting will take place in Luxembourg on 4/5 Oct and that the next online meeting would be held on 21 September.