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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 15 June 2022

Health Security Committee

Audio meeting on COVID-19, Monkeypox and Ukraine

Draft Summary Report

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

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

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Key messages

COVID-19

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

On 13 June, the European Centre for Disease Prevention and Control (ECDC) published an Epidemiological update on COVID-19: *"Implications of the emergence and spread of the SARS-CoV-2 variants of concern BA.4 and BA.5 for the EU/EEA".*

The BA.4 and BA.5 are two sub-lineages of the Omicron clade (B.1.1.529) variant. These variants have emerged in multiple countries and have become dominant in South Africa and Portugal. Their growth advantage over BA.2 appears to be driven by a greater ability to evade immune protection. Emergence in both South Africa and Portugal has led to increases in COVID-19 cases and hospital admissions. Sensitive, representative testing and genomic surveillance are required to accurately determine the variant distribution. Robust reporting via TESSy and EpiPulse is required. Regarding vaccination, for those aged 80 years and above, a second booster dose was found to be optimal in situations where viral circulation was high or increasing. Depending on the evolving epidemiology, data on vaccine effectiveness over time, and other factors such as seasonality, it will be necessary to re-assess recommendations on timing and the target groups that may benefit from additional booster doses.

2. Trilogue on the extension of the EU Digital COVID Certificate

Regarding the extension of Regulation (EU) 2021/953 on EU Digital COVID Certificate, a second trilogue meeting took place on 13 June. The co-legislators reached an agreement to extend the Regulation by one year. One of the outstanding points remained on whether the Commission should also report on the domestic use of the certificates. The co-legislators agreed that the report should contain '*an overview describing all the developments regarding the domestic and international uses of the certificates*'. In addition to the extension of the certificate, the new text includes some changes in two topics raised during past HSC meetings:

- On clinical trials, Member States may issue certificates of vaccination to all participants (irrespective of what vaccine they received), and these may be accepted by Member States. The HSC is expected to come up with a coherent approach regarding the acceptance of these certificates and we will bring this topic back shortly in another HSC meeting.
- Testing certificates will also be able to be issued following lab-based antigen tests (a list of these has been developed in the TWG on RAT).

The current expiry date of the Regulation is 30 June 2022. Next steps include a Coreper debrief (14 June), a Plenary vote, which will then be followed by a Council vote.

MONKEYPOX

3. Overview on the current monkeypox situation, vaccination, antivirals, and risk classification strategies – presentation by ECDC and EMA

The **ECDC** gave an update on the monkeypox situation. So far, 1 141 confirmed cases have been reported in the EU/EEA. Current EU/EEA priorities are the identification, isolation and contact tracing of monkepox cases, and to report these in the European Surveillance System (TESSy). ECDC established a dedicated website on monkeypox. ECDC emphasised that the response to this outbreak requires a high degree of community engagement to make any response measure work. To prevent stigmatisation to the MSM (men who have sex with men) community, it is important to clarify that monkeypox transmission is not related to sexual orientation. Preliminary modelling results underline the importance

of early diagnosis, isolation and contact tracing, risk communication and community engagement. Healthcare workers in specialised hospitals treating monkeypox patients may be targeted for vaccination.

FI expressed concerns regarding the possible use of the vaccine and questioned if enough research was done by ECDC. **PT** asked about the experience and vaccine effectiveness in other countries. **ECDC** responded to have collected information from countries who started with off-label use of the vaccine. However, ECDC is not in the position to recommend the use of the vaccine, as the vaccine is not EU-approved for monkeypox at this stage.

The **European Medicines Agency** (EMA) gave a short presentation on the use of vaccines and antiviral treatments in the context of the recent monkeypox outbreak. **Tecovirimat** is the first line candidate for the treatment of monkeypox and the only antiviral approved in the EU for that indication. Tecovirimat should be used for individuals at risk of complications or hospitalised patients with severe forms or potentially invalidating manifestations of the disease. The use of Tecovirimat could also provide benefits in terms of reducing the transmission of the virus or beneficial in the context of post-exposure prophylaxis either in individuals that may not respond well to the vaccines or in addition to vaccination in individuals at high risk for complications. Several clinical trials will take place in multiple EU/EEA countries.

Regarding vaccines against monkeypox, **Imvanex** is currently authorised in the EU for active immunisation against **smallpox** from the age of 18 years. This vaccine is the most suitable option for vaccination against monkeypox considering its favorable safety profile in comparison with older generation smallpox vaccines. Data on effectiveness and safety should be collected to refine benefits and risks in its use against monkeypox.

4. Update by HERA on their activities - presentation by HERA

HERA gave an update on their current work regarding antivirals and vaccines against monkeypox. On antivirals, 26 countries expressed interest for a Joint Procurement for the **antiviral Tecovirimat** (SIGA). Discussions on logistical aspects are ongoing. Once the tender document is finalised, the tender procedure can be launched.

Regarding vaccines, the Commission purchased Jynneos (Bavarian Nordic) vaccines using funding from the EU4health Annual Work Programme 2022. A call for tender was launched on 1 June by HaDEA. Signature of donation agreements between HERA and the countries have to be signed. The vaccine requires emergency authorisation from the national countries. First deliveries are expected by the end of June, and will be distributed to the countries most in need.

EE asked how fast the doses could reach the countries after signing the donation agreement. **HERA** clarified that the contract refers to a short delivery deadline. It would therefore be most important to be ready at national level to receive, stock and administer the doses.

FI asked which countries have experience with the use of the smallpox vaccines and how effective the vaccine are against monkeypox. **ECDC** is currently collecting data.

Regarding to the marketing authorization status of Imvanex for monkeypox, which is assessed only by the U.S. Food and Drug Administration, both **FI** and **PT** asked if there is any EMA assessment foreseen for a harmonised EU approach. **EMA** responded that the vaccine is only approved for smallpox, not for monkeypox. Discussions with the company are currently ongoing. However, an approval for monkeypox will not be given before July. To speed up the process, countries can decide to use the product off-label. To harmonise the use of the vaccine among the EU Member States, EMA could possibly give an emergency opinion on the use of the product.

5. Monkeypox: Risk classification strategy of contacts in social context or a health care setting – discussion point

Member States briefly discussed risk classification strategies for monkeypox in their own country, how this is implemented and which challenges are faced. Some Member States mentioned the introduction of 21 days of quarantine, the need for more information on the vaccines, and challenges around contact-tracing. In other countries a strategy still under discussion.

PT has no available vaccines against monkeypox and would need more information on the use of the smallpox vaccine for monkeypox. A rapid risk assessment from ECDC would be welcome. PT is providing information to close contacts to avoid further spread.

Discussions are ongoing in the **NL**, especially related to the consequences of a 21-day quarantine period. The long quarantine period would make individuals less willing to participate in trials. At the national level, NL has the vaccines, and the regional level does the contact tracing procedures and puts in the requests for vaccines from the national level.

FR mentioned that the contact tracing process is a challenge. FR divided risk classification in two categories: close contact (more than three hours) and respiratory contact. For high risk contact, the smallpox vaccine is offered together with a follow up for symptoms. No strategy is in place for low risk contacts.

DE is still discussing its strategy, especially on how to distribute the monkeypox vaccine, the vaccine schedule, and the quarantine period. DE would like to know how other Member States are distributing vaccines (e.g. through hospitals, outpatient clinics, etc.). DE is currently not collecting data and is following the UK guidance.

IE mentioned having seen a large number of low risk contacts, but is focusing on the high risk contacts. Leverage takes place through existing network groups (HIV/PrEP). To date, vaccination in IE has been limited to healthcare workers in the National Isolation Centre (where cases requiring hospitalisation are managed). IE has an open appointments system for vaccination through clinical networks which works well for other infectious diseases (e.g. Hep A).

FI asked on the reasoning behind the 21 day quarantine recommendation. **ECDC** mentioned that the incubation period (interval from infection to onset of symptoms) of monkeypox is usually from 6 to 13 days but can range from 5 to 21 days.

IT is following ECDC's and WHO risk classification. No quarantine is in place but 21 days self-monitoring for close contacts is required.

The **Commission** informed the HSC that the SANTE Health Policy Platform is organising a stakeholder webinar on monkeypox for the exchange of activities. The meeting takes place on 17 June, with contributions from the ECDC, the WHO and others. The Commission will share the agenda with HSC members.

Ukraine

6. Suspicion of Cholera in UA – presentation by ECDC

There have been reports in the press on possible cases of cholera in the city of Mariupol, and other outbreaks. The ECDC summarised what is known about the cholera cases, as well as other news reports about anthrax and malaria. As of 9 June 2022, no confirmed cases of **cholera** were reported by the Ukrainian public health agency and the United Nations. The Ukrainian public health authorities are performing regular monitoring of human and environmental samples for cholera in non-occupied areas. Regarding media reports about the risk of **anthrax** from "cattle cemeteries" which are in poor condition. Statements from regional officials and Deputy Minister of Health emphasised that cemeteries are located away from residential areas. An audit of the cemeteries is ongoing in non-occupied areas and action is being taken in case of breach of integrity. Seven **malaria** cases were reported between January and April 2022 according to monthly report from Ukrainian public health agency, these cases were likely imported.

7. Temporary Protective Directive report drafted by the European Observatory – update by DG SANTE

The Commission circulated a document on the study of the implementation of the Temporary Protection Directive (TDP) that European Observatory has drafted. The report focuses on the legal framework with regards to Ukrainian refugees and their access to healthcare in EU Member States. The Commission welcomes any comments from the Member States until 22 June.

DE shared information on the visit of the German Minister of Health in Lviv and the German support to Ukraine. DE is currently working on a sustainable strategy to support UA in providing medicines and healthcare. DE established a special treatment centre for patients who suffer from trauma and severe burn injuries. DE currently lists about 200 physicians who can be deployed in UA and also contributes by providing materials, equipment and treatment advice.

The **Commission** would appreciate if other Member States could indicate in writing what they are doing to support Ukraine in the field of healthcare.

AOB

8. Debrief from special HSC on AMR (Joint Action preparation) and completed questionnaire

In preparation for the upcoming Joint Action on antimicrobial resistance (AMR), the Commission ran an **EUsurvey** and held **two special HSC meetings** to get ideas on concrete activities that should be funded under the joint action, which has a sizeable **budget of EUR 50M**. According to the survey results, countries are overall in favour of a one-health approach, they appreciate the exchanges of information and best-practices, as well as networking opportunities in the framework of the Joint Action. Countries indicated they wanted activities supporting implementation, and they supported actions on communication for use of antimicrobials at national level. Further discussion is needed on peer-to-peer country visits / mentorships. In certain areas, caution was expressed on potential areas of duplication, notably with ECDC. The Commission will circulate a summary report soon. In terms of the next steps, the

official deadline for nomination of competent authorities is **1 September** and the official period for drafting the proposal starts on **15 September**. The Commission will analyse the responses received and liaise back with France, who has expressed interest in leading the new joint action to organise a possible workshop in October or November to support the formulation of the proposal. Dates will be announced as soon as possible.

The following HSC meeting will take place on 22 June, with a focus on COVID-19 and monkeypox.