EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 22 June 2022

Health Security Committee

Audio meeting COVID-19 and Monkeypox

Draft Summary Report

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

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

Agenda points:

COVID-19

1. Overview on the current COVID-19 pandemic situation– presentation by ECDC
2. Surveillance, testing and sequencing needs strategy for autumn/winter – Presentation by ECDC + discussion with countries
3. Vaccination strategy for autumn/winter – presentation by ECDC

Monkeypox

4. Epidemiological update on the monkeypox outbreak – presentation by ECDC
5. Update on availability of vaccines and antivirals – presentation by HERA
6. Advice for the use of vaccination and antiviral treatment against monkeypox – presentation by ECDC and EMA + discussion with countries

Key messages

COVID-19

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

The ECDC gave an update on the current epidemiological situation in the EU/EEA. After several weeks of decline, COVID-19 notification rates for the EU/EEA increased since last week (24). Overall, hospital and intensive care unit occupancy have declined over recent months. Sub-lineages BA.4 and BA.5 are expected to become the dominant variant in the EU/EEA. BA.5 is already the dominant variant in Portugal since week 19, 2022. There has been no indication on the change in severity of symptoms, but growth in the number of cases can lead to more hospitalisations. Currently, there is no data available on vaccine effectiveness.

2. Surveillance, testing and sequencing needs strategy for autumn/winter – Presentation by ECDC

The ECDC presented their operational considerations for respiratory virus surveillance in Europe during winter 2022-2023. ECDC identified four common objectives for integrated surveillance of respiratory viruses in Europe: 1) monitoring the intensity, geographical spread and seasonal activity of influenza, COVID-19 and other respiratory viruses; 2) monitoring the severity of risk factors for severe diseases and assess the impact on health systems of influenza, COVID-19 and other respiratory viruses to inform mitigation measures; 3) monitoring the characteristics of circulating and emerging viruses, to inform treatment, drug and vaccine development; 4) describing the burden of disease associated with influenza, COVID-19 and other respiratory viruses. Another important aspect stressed by the ECDC, is the importance of right sizing the surveillance systems. Data collection from non-sentinel sources remain important, specifically from non-sentinel primary or secondary care laboratories, to complement the data from sentinel systems.

The ECDC's respiratory virus surveillance proposal is based on a survey carried out among the Member States to get a better understanding on the current surveillance status and strategies. The survey results have been published on the ECDC website. Member States showed unanimous agreement on the fact that common objectives should be established for sentinel surveillance of respiratory viruses. Most countries are in the process of discussing, planning, or implementing integrated surveillance at national level. Changes in testing strategies have been implemented or are foreseen to be implemented for the majority of the countries for community testing. The majority of the countries implemented or plan to implement an integrated surveillance sentinel system in primary care (ILI/ARI) and hospital sentinel (SARI).

The ECDC will share the document on surveillance, testing and sequencing needs strategy for autumn/winter with the HSC for their comments. ECDC intends to publish the final report in early July 2022.

FI asked how ILI and SARI diagnosis are made, in particular related to diagnosis code and case definition. **ECDC** explained that the general principal is to apply the case definition. The case definition can be further discussed at an operational level, as it would be important to understand what it entails in practice, in order for Member States to assess the situation.

AT asked ECDC to elaborate on the need for surveillance of asymptomatic cases and any recommendations on this. **ECDC** agreed this is a good point to reflect upon. In an emergency phase, other objectives are in place and different types of approaches are considered. ECDC is already looking at a situation where there are waves (periods with a higher number of cases), but where it is no longer necessary to suppress the transmission; instead, the focus is on reducing the impact on the healthcare system. ECDC will take this point into account.

ES mentioned that sequencing in parts of the population will provide a good sample of the circulating variants within the general population. However, some variants might escape the sentinel surveillance system. ES suggests to consider extra sampling in hospitals, cases from people with different symptoms, or an outbreak with an increased number of cases to identify emerging variants of interest. This might

be important to address in the document. **ECDC** indeed considers this an important point and will ensure that it is better reflected in the document.

IT asked if there are monitoring and alert indicators in place. IT also highlighted the importance of right sizing the surveillance sentinel system. **ECDC** is currently developing such indicator. The indicators and thresholds can be discussed.

In **SK**, COVID-19 sequencing is an ongoing process. At the executional level, a group of experts meets regularly to assess the current situation and decide on the next steps.

3. Vaccination strategy for autumn/winter – presentation by ECDC

The ECDC published a document on public health considerations for second booster doses. **A second booster dose may be considered for all or some adults between aged 60 years and above.** Countries should plan for the deployment of booster doses in this population group if they detect signals of increased SARS-CoV-2 circulation or risk of severe COVID-19 among vaccinated individuals. Currently, 17 EU/EEA countries are recommending a second booster for immunocompetent individuals. Two countries (FR, SE) have published their vaccination campaign recommendations for autumn, and a number of other countries are discussing their future COVID-19 vaccination strategies and the need for additional booster dosses. At this stage, mRNA technology is the only platform that could deliver updated versions of vaccines in time for the vaccination campaigns for this autumn/winter. New vaccines have been developed but have not been approved yet. Main factors to guide vaccination strategies will be the epidemiological situation and the availability of new vaccines. ECDC is planning to publish preliminary public health considerations on autumn/winter COVID-19 strategies mid-July. This document will serve as a background for further discussion by the HSC.

Monkeypox

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

The ECDC gave an epidemiological update on the monkeypox outbreak. So far, 1 891 confirmed cases in the EU/EEA. As of 26 April, an increase of cases has been identified in the EU/EEA countries. ECDC launched a monkeypox surveillance bulletin jointly with the WHO regional office for Europe.

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

HERA gave an update of their current work regarding antivirals and vaccines against monkeypox. HERA signed the contract with Bavarian Nordic for the purchase of vaccines. Allocation of the vaccines is on a country pro rata basis, based on the number of cases identified as of 9 June. HERA identified nine priority countries, which will receive the first vaccines in June 2022. The other countries will receive the vaccines in July 2022. Countries have to send a letter proving their country is able to receive and administer the vaccines. Regarding antivirals, 28 countries expressed interest for a Joint Procurement for the antiviral Tecovirimat SIGA. Once the tender document has been finalised, the tender procedure can be launched.

6. Advice for the use of vaccination and antiviral treatment against monkeypox – presentation by ECDC and EMA + discussion with countries + UK

ECDC presented considerations for vaccine use based on the document shared with HSC in advance to the meeting. Currently, a few EU/EEA countries recommend vaccination with MVA-BN vaccine to

prevent monkeypox disease for certain risk groups either as pre- and/or post-exposure prophylaxis but there is no unified approach across Member States.

ECDC's considerations for monkepox vaccination:

- In the context of limited vaccine supply and mild symptoms so far, post-exposure prophylaxis of contacts of cases should be considered. The vaccination of contacts and of contacts' contacts, according to a ring vaccination scheme, could also be considered.
- Community engagement efforts for the identification of contacts around cases should be put in place in order to achieve a significant impact in terms of lowering disease burden and transmission.
- Data on effectiveness and safety of post-exposure prophylaxis should be collected to refine benefits and risks in the context of monkeypox prevention strategies.

Professionals in healthcare or laboratory settings and outbreak response team members may be targeted for vaccination based on risk assessment. HIV+ and on antiretroviral therapy patients can receive the vaccine. Data for severely immunocompromised individuals and use in pregnancy are not available yet or is limited.

ECDC updated the HSC on their work on monkeypox outbreak modelling.

On 14 June, WHO published an interim guidance on vaccines and immunisation for monkeypox.

The **UK** gave a brief overview on a new vaccination guidance on monkeypox (published on 21 June). The UK is currently offering vaccines to healthcare professionals caring for patients with monkeypox. Due to difficulties with contact-tracing procedures given the preference for anonymity, the UK focuses mainly on pre-exposure vaccination, rather than post-exposure vaccination. Individuals from high-risk groups are offered a single dose at this stage. Once more vaccines are available, a second dose might be offered. The UK is mostly using existing HIV/pre-exposure prophylaxis networks/clinical visits to reach individuals from high-risk groups.

NO asked if the UK's policy is being followed up by any research on the effectiveness of the vaccine. The **UK** responded to be keen to follow-up, but this is challenging. Existing IT systems are in place by the sexual health clinics and departments. The UK is currently exploring which case studies should be put in place and how to implement them.

FI asked if a second dose is needed for post-exposure vaccination. The **UK** is currently not offering a second dose (unless further transfer is expected). It may be offered in the future, but it is too early to say.

The **NL** asked if there are any post-exposure prophylaxis studies in international settings with standardised baseline and outcome measurements. **ECDC** responded that EMA is working on such protocols.

Also **RTD** (Research and Innovation department, European Commission) is doing some work related to this subject. RTD explained that FR developed a protocol for evaluating monkeypox vaccine (Imvanex) use in post-exposure prophylaxis. This protocol has been discussed at the Emergency Task Force (ETF). Ideally, all interested Member States combine forces and do a common single submission in the European Clinical Trials Information System (CTIS) so that involved Member States do a coordinated assessment (as opposed to each country submitting the same protocol to the national authorities, which involves the risk of fragmentation of trials). The VACCELERATE vaccine trial network could be used to

support this coordinated approach. Member States can send an email to the HSC, or directly to RTD, if they are interested in joining this monkeypox vaccine trial.

ECDC mentioned that it would be useful to know whether any countries are considering repeating EMIS (European Mens Internet Surveys) to inform on sexual behaviours and inform monkeypox modelling and vaccination planning. The last pan-European study was conducted in 2017 before pre-exposure prophylaxis and pre-pandemic.

Conclusions/follow-up:

- Today's meeting focused on the current COVID-19 epidemiological situation and the surveillance, testing, sequencing and vaccination strategy for the autumn/winter period.
- DG SANTE will to follow up on HSC replies to the questions sent in advance to the meeting.
- The HSC is going to continue discussing surveillance, testing, sequencing and vaccination strategies for the autumn/winter in July based on two guidance documents by ECDC.
- SANTE will follow up with the HSC on questions on considerations for monkeypox vaccination, circulated in advance to the meeting.