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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 27 July 2022

Health Security Committee
Audio meeting on Monkeypox
Summary Report

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

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

Agenda points:

Monkeypox

1. Epidemiological update on the monkeypox outbreak – presentation by ECDC
2. Update on the PHEIC declaration for monkeypox – presentation by WHO
3. Ongoing activities for clinical or observational studies with the vaccine and tecovirimat – presentation by EMA
4. Communication on monkeypox – presentation by ECDC and DG SANTE + discussing with Member States
5. Discussion on vaccine use tracking – presentation by ECDC + discussion Member States
6. Knowledge gaps related to monkeypox – presentation by RTD
7. Reporting on monkeypox (TESSy, EpiPulse, EWRS) – presentation by ECDC and DG SANTE

Key messages

At the beginning of the meeting the Commission set the scene highlighting already started activities to contain the monkeypox outbreak. The HSC already discussed monkeypox several times in previous meetings. ECDC published a multi-country outbreak [Rapid Risk Assessment](#) and [guidance](#) on contact tracing. HERA is already working on vaccine supply. Regarding communication activities, DG SANTE is having close contact with Member States in the HSC, HSC Communicators Network and Public Health Platform. ECDC already organised several webinars with stakeholders and published a communication tool.

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

As monkeypox cases continue to rise in Europe and globally, the ECDC gave an epidemiological update on the outbreak. As of 26 July, there are 10 346 confirmed cases in 27 EU/EEA countries. In the Western Balkans & Turkey, there are 7 confirmed cases in 3 countries. Demographic data in the World Health

Organization (WHO) European Region shows that most cases are detected in men aged 18-50 (with the majority of cases detected in the age range of 31-40).

2. Update on the Public Health Emergency of International Concern (PHEIC) declaration for monkeypox – presentation by WHO

In the WHO region, 18 081 cases have been confirmed so far. The second International Health Regulations Emergency Committee meeting on the multi-country outbreak of monkeypox was held on 21 July. The Committee Members did not reach a consensus regarding their advice on determination of a Public Health Emergency of International Concern. Nonetheless, having considered the views of Committee Members and Advisors as well as other factors in line with the International Health Regulations, the WHO Director General [declared](#) the global monkeypox epidemic a Public Health Emergency of International Concern on 23 July 2022. On 25 July 2022, the WHO Regional Director for Europe sent a letter to all Ministers of Health in the WHO European Region, enforcing the implementation of the [Temporary Recommendations](#) issued in conjunction with the declaration of the monkeypox outbreak as a Public Health Emergency of International Concern. All Temporary Recommendations are expected to be implemented in full respect of established principles of human rights, inclusion and the dignity of all individuals and communities.

PT asked how the WHO is planning on monitoring the implementation of the recommendations. WHO is already collecting data through their already in place systems. ECDC replied that the WHO recommendations are in line with the recommendations from ECDC. For almost two months, ECDC has been involved in monkeypox monitoring activities, the [first rapid risk assessment](#) was published on 8 July. ECDC provided toolkits, communication strategies, launched several webinars, increased awareness, and is currently launching a survey on monkeypox vaccination needs and acceptance. Some knowledge gaps have already been identified (e.g. effectiveness/safety of vaccines and antiviral, transmission and incubation period). ECDC has set up some surveillance activities in collaboration with WHO. ECDC urges Member States to provide timely reports.

3. Ongoing activities for clinical or observational studies with the vaccine and Tecovirimat – presentation by EMA

EMA gave an update on ongoing activities with respect to vaccines and therapeutics against monkeypox. Regarding **vaccines**, France Investigators set up an observational study that would be labelled as low intervention clinical trial looking into harmonised collection of data on effectiveness (breakthrough cases) and safety for post-exposure prophylaxis. This study started in France and there is interest in expanding it to other EU countries, including BE, IE, SE, and the NL. Discussions on coordination activities are ongoing.

Regarding **therapeutics**, studies on the antiviral drug Tecovirimat are ongoing in the UK and CH and will start soon in EU Member States after a discussion with EMA's Emergency Task Force. It is a cohort study that collects harmonised data on the use of Tecovirimat in treated and untreated patients. WHO has drafted a CORE protocol for studying this antiviral and others that may come in the future. This protocol is being finalised and could serve as basis for a global study.

4. Communication on monkeypox – presentation by ECDC and DG SANTE + discussing with Member States

Risk communication is an important and sometimes challenging element of the management of the Monkeypox outbreak, especially in the context of the currently affected community. Thus, the point was raised with the HSC to further support Member States communication activities. The ECDC gave a presentation on their work on Risk Communication and Community Engagement (RCCE). Complexities of the monkeypox outbreak in Europe call for a clear integration of RCCE in the response in order to

ensure: 1) timely and consistent health information provided to healthcare professionals and further to broader populations, 2) outreach to high-risk groups through direct channels ensuring dialogue and two-way communication, 3) work with relevant civil society organisations and community-based organisations to ensure that at-risk groups are empowered in prevention behaviour. ECDC has published a wealth of information, including two guidance documents for the summer season in the context of monkeypox: one on [risk communication and community engagement](#) and another [guidance](#) for public health authorities to guide prevention, awareness-raising and behaviour change interventions before, during and after summer events. A [Resource toolkit](#), jointly created with the WHO, provides health authorities and event organisers with ready-to-use and customisable tools and advice on monkeypox for mass gathering. Besides in the HSC, further exchanges on communication around Monkeypox will continue in the HSC Communicators Network (ComNet).

EE asked if ECDC could provide data on which civil society organisations have already been contacted or which associations have already participated in the ECDC webinars. **ECDC will** create a list and share this with the HSC.

HR asked what ECDC's position is on the UKHSA recommendation on protection during sex for 12 weeks after recovery as well as for semen testing following recovery after monkeypox in certain conditions. **ECDC** responded that as a precaution measure, as studies on the transmission in semen is still ongoing, condom use for 12 weeks after recovery of monkeypox is recommended.

5. Discussion on vaccine use tracking – presentation by ECDC + discussion Member States

A first wave of vaccine deliveries has already been made and some countries have started administering them. However, the indications for vaccination vary across countries. **ECDC** proposed a regular HSC survey to ask EU/EEA countries about their vaccination policies in response to the monkeypox outbreak and to collect data on vaccine distribution/use. The survey results will be prepared by ECDC and DG SANTE into a monkeypox vaccine deployment and vaccine use report.

PT asked which indicators are suggested by ECDC for vaccination. **ECDC** responded that several discussions are ongoing on the use and administration of the vaccine.

WHO proposed to no longer use the abbreviation of PreP for vaccines, so as not to confuse with HIV PREP, and so that the message can be given that protection is not immediate (as it is for HIV PreP) and that it takes several weeks for vaccines to generate an immune response (e.g. antibodies).

6. Knowledge gaps related to monkeypox – presentation by RTD

The scientific data on this Monkeypox epidemic is gradually coming in. However, there are still important gaps in scientific knowledge that need to be filled by structured and coordinated scientific work. **RTD** highlighted the need to use this opportunity to generate evidence. This requires collaboration between research and health communities, as well as with countries for the use of similar data collection tools in order to analyse vaccine and treatment effectiveness. RTD is currently exploring the mobilisation of research funds, both for observation and intervention studies. Discussions on the need to start clinical trials for the paediatric population group in ongoing.

7. Reporting on monkeypox (TESSy, EpiPulse, EWRS) – presentation by ECDC and DG SANTE

Surveillance data on monkeypox cases are fundamental for the development of national, European and global responses. For this to happen, the data must be robust, complete and up-to-date.

The reporting to ECDC and WHO/Europe of **case-based surveillance** data for monkeypox cases to the European Surveillance System (TESSy) has been ongoing since 2 June 2022. The data collection is coordinated jointly with WHO/Europe and variables reflect data requested by WHO at global level. Solid

and timely surveillance data are necessary to inform monkeypox control strategies including contact tracing, vaccination, and infection prevention and communication campaigns in EU/EEA countries. The **quality of the data** reported via TESSy is variable in quality. Age, gender, data of national reporting and clinical symptoms show a high data completeness. However, disease severity, sexual orientation, vaccination status, use of antiviral treatments, HIV status, immunocompromised status, pregnancy, information whether cases are health care workers, etc. show low data completeness. Countries are **encouraged** to submit **timely and complete** national case data to TESSy and to **retrospectively update** case information as more complete data become available.

DG SANTE emphasised the importance to report the public health measures undertaken and planned in response to the monkeypox outbreak, besides reporting cases in the EU Early Warning and Response System (EWRS). The Situation awareness report was activated, bringing the EWRS users access to the Monkeypox situation awareness in EpiPulse (the European surveillance portal for infectious diseases), which is updated twice a week. In EpiPulse, all ongoing outbreaks can be found, countries can consult each other, can find assessments, current risks, as well as recommended public health measures. DG SANTE encouraged Member States to provide more detailed/complete information in EWRS when posting: the actions performed to contain monkeypox should be described: public health measures under taken and planned, risk assessment, risk communication and other information.

IT informed the HSC about the reporting system used their country, IT is using of a single reporting system, used by the regions, to collect timely and high quality information.

Conclusions and next steps:

- ECDC and SANTE will follow up on the implementation of reporting tools including vaccine use tracking.
- Continued discussion and exchange of information regarding communication will continue via HSC and ComNet.
- Follow up discussions will continue on the identification of knowledge gaps and possible financial support for studies