EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 01 June 2022

Health Security Committee

Audio meeting on Hepatitis in children and Monkeypox

Draft Summary Report

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, RO, SE, SI, SK, NO, IS, UK, DG SANTE, DG EMPL, DG JUST, DG RTD, HERA, ECDC, DG ECHO, WHO, HADEA

Agenda points:
EU/EEA + UK
MONKEYPOX

1. Overview on the current Monkeypox situation – presentation by ECDC + countries
2. Update by HERA on Imvanex and Tecovirimat – presentation by HERA

EU/EEA only
COVID-19

3. Overview on the current COVID-19 pandemic situation – presentation by ECDC
4. HSC survey results: EU DCC and countries' responses to BA.4 and BA.5 – presentation by DG SANTE
5. Recognition of COVID-19 as an occupational disease – presentation by DG EMPL

Anti-microbial resistance (AMR)

6. Update on the study of the AMR National Reference Laboratories – presentation by Prof. Rene Hendriksen (European Union Reference Laboratory for Antimicrobial Resistance (EURL-AMR) and Head of unit, Research Group of Global Capacity Building, Division of Global Surveillance, Technical University of Denmark National Food Institute, DTU-Food.

AOB

7. Study on assessing Joint Procurement Agreement for medical counter measures – update by DG SANTE

Key messages:

1. Monkeypox

ECDC gave an overview on the epidemiological situation and their most recent activities. The outbreak started on 16 May and most of the cases are among young men, who identify as men who have sex with men (MSM). There have been no deaths related to the outbreak, but there have been a couple of cases that have required hospitalization. Worldwide, there are 557 confirmed cases (this excludes cases where the disease is endemic), of which 321 cases have been confirmed in the EU/EEA. Most cases in the EU/EEA are reported in Spain and Portugal.

The ECDC has hosted two webinars (24 and 31 May) with public health institutes, clinicians, community organizations, social networking applications and European agencies (WHO Regional Office for Europe, the European Commission and the European Medicines Agency). The objective of the webinars was to share information between European stakeholders on the monkeypox outbreak, with a focus on communication and to identify needs for Europe-wide guidance.

During the 31 May webinar, 3 countries gave an update on the outbreak in their respective countries, and indicated there were no changes in the case characteristics. The discussion during the webinar was mostly on how to communicate and engage with MSM communities, how to encourage testing and isolation measures without stigmatization and how to protect healthcare workers.

ECDC will continue to work with STI (sexually transmitted infections) and EVD (Laboratories for emerging viral diseases) networks on how to identify needs and priority areas. On communication, ECDC will continue to support Member States by: providing messaging for the general public and for MSM communities; providing guidance for MSM events; guidance on surveillance and reporting in the EU/EEA; guidance for vaccination, antiviral treatment, contact management and contract tracing; and laboratory support.

EE wanted to know if the ECDC was drafting an updated risk assessment. The ECDC clarified it would provide an updated risk assessment if the risk changed but next week it would produce a risk assessment brief to update the number of cases.

FI asked whether asymptomatic contacts could transmit the disease. ECDC mentioned there are no indications for this.

DG RTD presented its work on research projects on monkeypox. An observational cohort study for the treatment of monkeypox in humans is ongoing to help assess the clinical and virological outcomes of treatment with vaccines and antiviral drugs. The sponsor of the study is in the United Kingdom, and the principal investigator responsible for it in the EU is France and participation is intended by Italy, Spain, the Netherlands, Belgium, and Norway. The idea would be for other Member States to join the initiative to harmonize the collection of data and to make sure that the data on safety and effectiveness is not lost.

IE asked for the contact information to receive more information on the study. DG RTD shared the contact point during the meeting.

FI asked if there were any written instructions on how to carry out the studies. DG RTD invited interested Member States to get in touch with the lead in France for more information.

ES asked for the national contact point participating in the different Member States to know how to better coordinate with hospitals. On the safety of vaccines and antivirals, ES raised the issue that these issues might not reflect the effectiveness given that they are not randomized. DG RTD clarified these are not placebo controlled trials, they are observational studies to compare people who have been treated to those who received no treatment. DG RTD also shared the contact information of the contact points in the different Member States.

On preparedness and vaccines, SE asked whether the stockpiles of vaccines was taken into account. DG RTD explained that information should be shared in the current context, keeping in mind that information on stockpiles is sensitive.

ES gave an update on their national situation where the first cases were identified on 17 May. On the same day, ES prepared the first draft of a protocol for handling cases and on 19 May, ES discussed with non-governmental organizations (NGOs) working with LGBTI communities and scientific advisors on how to make sure the protocols are adapted to the risk communities and how to communicate this information. ES also produced a 'Question and Answer' document and shared the protocol with the autonomous regions. ES also started assessing the need for vaccines and antivirals and discussions with HERA to identify access to medical counter measures. ES has started to discuss with the Ministry of Agriculture to draft a guideline on how to manage pets. As of 01 June, 135 positive cases have been identified in ES, of which 36 cases have been sequenced, and another 165 cases have been suspected but have tested negatively. One case was hospitalized but all other cases have been mild. The onset of symptoms was the last week of April, and the peak in cases was around 12 and 15 May, and cases have been falling since then. Two events have been identified and other parties in Madrid and the Canary Islands as points of infection.

In BE, the disease is under increased surveillance, 10 cases have been confirmed, and a 21-day period for isolation has been applied.

FR has 21 confirmed cases, none of which have been hospitalized. FR also launched vaccination of high risk contacts with the Imvanex vaccine and 10 people have been vaccinated so far.

31 cases have been confirmed in NL, and the pattern is similar to the one in ES, with the onset of symptoms in the middle of May. All cases have been male, identifying as MSM.

The UK has 190 confirmed cases, with about 10 new cases per day, with the majority being in England, in the London area. Cases have been detected as early as April, and there is no indication of the cases going down. Most cases are in young adult males between the ages of 20 to 49 who identify as MSM. A proportion (about one in three) have travel history within the last 21 days prior to the onset of symptoms and another have a history of high risk sexual behaviours. The UK will

initiate studies on the risk around public sex venues, and festivals and also on the risk on animal health.

PT also reported having a similar situation to ES, with the onset of symptoms starting around 29 April and a peak around 12-15 May. There have been 119 confirmed cases, with all cases being male. 85% of the cases have been identified in the region of Lisbon. PT has implemented a management team to respond to the increase in cases and also to disseminate key messages to the civil society, and also to draft guidelines to healthcare professionals. PT has also discussed with the national medicine agency for the use of the smallpox vaccine for a monkeypox infection and is discussing with HERA on the joint agreement for vaccines. PT is assessing the evidence as well on antivirals before they begin purchasing them.

HERA gave an overview on their plans for the procurement of vaccines and antivirals. On Tecovirimat, the HERA Management Board has agreed to carry out a Joint Procurement and the information has now been sent to the Joint Procurement Steering Group for them to indicate their interest. HERA will then discuss with the company and negotiate the contract.

On vaccines, the HERA Management Board has also agreed to proceed with a Joint Procurement. To respond to the need of Member States, the company will supply the Imvanex vaccine, which is currently approved by the United States Food and Drug Administration (FDA). The Commission will work under the EU4Health to purchase the vaccines and will donate the vaccines to Member States who have indicated immediate need. Since the vaccine is approved by the FDA, each Member State will need to issue an authorization for emergency use. The HERA Management Board will finalize the donation agreement in the coming days. The donation agreement will not address all requests but this could be complemented with a Joint Procurement.

FI asked how the European Medicines Agency (EMA) is taking part in the purchase of vaccines. HERA clarified that they are discussing with the EMA and waiting for Member States to request a scientific opinion.

SE asked for clarification on the storage temperature of the vaccines to start preparing for the distribution. HERA clarified the shelf life is 3 years if the vaccine is kept under -20° C.

FI asked if there were any indications of when the vaccines would be available. HERA has launched a negotiated procedure for the immediate purchase of the vaccines, but reminded Member States that these vaccines are FDA compliant, and if Member States would like to have an EU approved vaccine, this version would be available as of September.

2. COVID-19

ECDC gave an update on the current COVID-19 epidemiological situation. The notification rate in parts of the EU continues to be high, and testing rates remain low in several Member States. Some regions have seen decreases in notification rates and overall, the notification rate continues to decline in all but two EU/EEA countries. Transmission among people aged 65+ has continued to decline with only two countries reporting increases. The death rates and hospitalization rates have

also been decreasing. On the sub-lineages of the Omicron variant, the BA.2 sub-lineage continues to be predominant in the EU/EEA but there have been increases in circulation of the BA.5 sub-lineage. There have been no major changes in the uptake of vaccines as compared to precious weeks.

A survey was shared with the Health Security Committee for their feedback on several issues, including: the validity of EU COVID certificates after a person has been infected; the mutual acceptance of EU vaccination certificates for participants in clinical trials; and the response to the BA.4 and BA.5 Omicron sub-lineages.

21 EU Member States and three EEA countries replied to the survey. Some Member States agree that the current EU Digital COVID Certificate (EUDCC) rules for vaccination and recovery certificates are suitable and sufficient. A few Member States would be in favour of modifying the recovery certificates.

In case a political agreement is reached that Member States may issue a EUDCC to persons participating in COVID-19 vaccines clinical trials, the majority of Member States indicated they do not have an opinion yet. Some Member States indicated they would accept all clinical trials, as long as they have been approved by Member States' ethical committees and competent authorities.

Since the ECDC reclassified the Omicron sub-lineages BA.4 and BA.5 as variants of concern, most Member States have not made any changes to their non-pharmaceutical interventions. Only 5 Member States indicated to have made changes to their testing and/or sequencing strategies.

EE asked to have more information on Member States' plans for a second booster dose and how Member States are preparing for the autumn. The Commission took note of the question and will bring this up for discussion in another HSC meeting.

DG EMPL presented on the recognition of COVID-19 as an occupational disease. The Commission adopted an EU Strategic Framework on Health and Safety at Work in 2021 which has three objectives: Anticipating and managing in the new world of work brought by the green, digital and demographic transitions and improving prevention of workplace accidents and illnesses and increasing preparedness for any potential future health crises. The tri-partite EU Advisory Committee on Safety and Health at work, consisting of representatives of Member States, workers and employers, agreed that COVID-19 should be recognized as an occupational disease in specific sectors and situations.

Based on this decision, a Commission Recommendation was updated, and Member States can now adapt their national laws accordingly. As a result, workers in relevant sectors who have contracted COVID-19 at the workplace, may acquire specific rights according to national rules, like the right to compensation.

NO asked for a clarification on how to differentiate how COVID-19 was transmitted. DG EMPL explained there is a clear definition where it refers to cases where COVID-19 was caused by work in disease prevention, in health and social care and in domiciliary assistance, or in a pandemic context, and in sectors where there is an outbreak in activities in which a risk of infection has been proven.

3. Anti-microbial resistance (AMR)

The Commission is supporting two Reference Laboratory projects linked to AMR. The purpose of this work is to strengthen coordination, support and capacity in national microbiology reference laboratory functions. The two projects particularly focus on resistances in priority healthcare-associated infections as well as in *Salmonella and Campylobacter*. Professor Rene Hendriksen, from the University of Denmark National Food Institute was invited to present on the project progress and areas where Member State input is needed.

The objective of the projects is to strengthen laboratories' capabilities and capacities to detect and effectively prevent and control spread of healthcare-associated infections and Salmonella species and Campylobacter at local and national level, across Europe and globally.

The goal of the project, is in the next 4 years, to provide to a range of training, external quality assessment (EQA) schemes and networking activities to improve public health reference laboratory functioning through improved laboratory functioning at local, regional and national levels in all countries participating in the EU health program.

Member States were reminded of the importance of their participation as these projects are intended to help build national capacity.

The Commission reminded Member States on the ongoing survey for their input for the preparation of the upcoming Joint Action on AMR. The survey will remain open until 07 June.

4. AOB - Study on assessing Joint Procurement Agreement for medical counter measures

The European Commission is carrying out a study on assessing the functioning of the Joint Procurement Agreement (JPA) for purchasing medical countermeasures for cross-border health threats as referred to in Article 5 of Decision 1082/2013/EU.

The study started on 11 of April, a validation workshop of study findings with the stakeholders is planned for the first week of October and the final report is expected by the end of November 2022. The study is conducted by a consortium of companies, including Open Evidence and PricewaterhouseCoopers, as well as Intellera Consulting as subcontractor.

The study will gather data and stakeholder views to inform the evaluation of the JPA against the underlying policy objectives.

Between June and early October 2022, the contractor will implement the study consultation strategy among key stakeholders (such as Member States representatives, Central Purchasing Bodies, industry, academia, think tanks, etc.) aiming to: Gather evidence on each evaluation questions through targeted surveys; Filling gaps and gather evidence through in-depth interviews; and validate preliminary findings through a validation workshop.

The Health Security Committee being one of the key stakeholders will be contacted and the Commission asked the Health Security Members to supply the contractor with the necessary information to conduct the activities related to the study.

Information on the practical arrangements will be shared with the Health Security Committee.

5. Close of the meeting

The next Health Security Committee will be held on 15 June and an ad hoc meeting to discuss issues related to Ukraine is planned for 03 June.