

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health Health Security

Luxembourg, 11 July 2023

Health Security Committee

Audio meeting

Summary Report

Chair: Head of Unit, European Commission, DG SANTE B2

Audio participants: AT, BE, CY, CZ, DE, DK, EE, FI, FR, HU, IE, IS, IT, LT, MT, NL, NO, PL, PT, SE SI, SK, UK, ECDC, EFSA, EMA, DG HERA, DG RTD, DG SANTE, CDC, WHO

Agenda points:

1. Avian flu H5N1

- 1.1. Epidemiological bulletin presentation by EFSA/ECDC
- 1.2. PL authorities to update on the situation of H5N1 infection in cats presentation by Poland
- 1.3. UK active screening programme of workers of farms with outbreaks share country protocols/experience presentation by UK

NOTE: Mention that UK is invited on an exceptional basis to the point on HPAI and will be asked to de-connect after point 1 on the agenda

- 1.4. Active surveillance plan presentation by France
- 1.5. Short update on the outbreak of the H5N1 presentation by Italy

2. Monkeypox

- 2.1. Epidemiological update and report about the vaccine deployment survey results presentation by ECDC
- 2.2. Updates on studies on antiviral treatment presentation by RTD
- 2.3. Update on vaccine and therapeutics procurement for the EU and for donation by HERA

3. Mosquito-borne diseases

- 3.1. Overview of current and planned initiatives on vector borne diseases, including mosquito borne diseases epidemiological update (if new events detected) presentation by ECDC
- 3.2. Medical countermeasures for dengue, chikungunya, zika, yellow fever & west nile fever Report on approved medical countermeasures (vaccines and therapeutics) and those under current research presentation by HERA
- 3.3. Presentation from USA (including report on malaria cases & measures on vector control) presentation by CDC

4. <u>AOB</u>

4.1. Update on the AMR working group meeting with discussion over Art 13 and Art 14 – by DG SANTE 4.2. Brief announcement about EpiPulse event about echovirus subtype E-11 – by ECDC

Main messages:

1. Avian flu H5N1

1.1. Epidemiological bulletin – presentation by EFSA/ECDC

EFSA produces every 2 months jointly with ECDC and the EU reference laboratory an epidemiological report on the avian influenza situation in poultry, captive and wild birds, mammals and humans in and outside of Europe (next publication is planned for 13 July). By observing the overall epidemiological curve since 2016 in domestic and wild birds, two peaks can be noticed in the last years with the latest one being a sharp increase of cases in April towards May 2023. Overall, the current reporting period shows that the most outbreaks in poultry are reported by France. Other important concerns on the side of the wild birds, is the surge of the cases in seabirds with a net increase since beginning of 2023. In general, the situation in wild birds is similar in 2022 and 2023 except the distribution of wild birds was mainly along EU coastland in 2022 while now it is also spread inland in 2023.

When it comes to the situation outside of Europe, an increase of poultry and wild bird detections has been reported. The outcome of the molecular analysis confirmed that the H5N1 virus has avian species as the main target and mammal specific molecular markers were rarely detected in birds. The short-term forecast is that highly infectious avian influenza (HPAI) outbreaks in poultry would remain sporadic across the Europe, but caution is needed in case of extensive secondary spread. The virus will continue to circulate in wild birds during this summer with the risk of inter-continental spread due to bird migration. The presence of at least one of the adaptive markers in mammals is the reason for triggering potential public health implications. Wild and domestic carnivores are the most affected mammalian species by HPAI viruses with recent cases in Italy and Poland affecting domestic animals. Specific approaches to be applied for wild birds and mammals using targeted active surveillance, enhanced species identification in birds; close monitoring; preparedness and prevention strategies; data sharing including genomic data in a timely manner.

In terms of human cases due to avian influenza, there are seven H5N1 cases reported so far in 2023, none in EU/EEA countries. The other subtypes have been only reported in China. It is important to notice that most viruses are susceptible to all 3 classes if antivirals licensed for use in influenza infections and 2.3.4.4b viruses are considered antigenically similar to the proposed candidate vaccine. Based on current data the ECDC Public Health Risk Assessment for H5N1 is that the risk of human infection due to avian influenza viruses of the currently circulating clade 2.3.4.4b in Europe is **low** for the general population and **low to moderate** for people occupationally or otherwise exposed (including exposed to infected domesticated cats). Public health recommendations are to take protective measures, testing, isolation, antiviral post exposure prophylaxis and timely reporting to national authorities via EWRS. Lastly, a hospital surveillance system with virus subtyping for detecting avian influenza infections has been recommended to be put in place this summer (outside the classical influenza season) to timely detect if the diseases would occur among humans.

1.2. Update on public health measures taken after the reports of a H5N1 outbreak in cats – presentation by Poland

At this stage, there are 24 laboratory confirmed cases among cats, the first was detected on 15 June. Contaminated food could be a source, but there is currently no certainty regarding the source. No cases have been reported since the beginning of July. Poland started an epidemiological investigation and provided cat owners with a questionnaire for early detection of symptoms. Regardless of symptoms, all people that have been in contact with a contaminated animal will undergo serological testing. Current discussions are ongoing regarding the protocol to be followed for the serology.

1.3. Active screening programme of workers of farms with outbreaks – presentation by UK

A surveillance study to detect asymptomatic avian influenza has been launched in March 2023. The aim is to investigate the possibility for an asymptomatic infection in humans (e.g. workers on poultry farms) in contact with H5N1 virus infected birds/poultry. The swabbing and serological samples are being analyzed through Polymerase chain reaction (PCR) and serological testing for positivity to A(H5N1) clade 2.3.4.4b. The protocol is publicly available: <u>UK Health agency</u>. So far only 2 asymptomatic persons have been detected but recruitment is still ongoing. Based on those findings UK initiated a public health response with enhanced National Incident reporting and IHR notification to WHO. UK concluded that the level of risk to human health has not changed. UK will be publishing on 14 July a <u>current technical briefing</u>.

1.4. Active surveillance plan – presentation by France

France has put in place the "zoonotic influenza active surveillance" (SAGA or Surveillance Active de la Grippe Aviaire) for an early detection of human infections. In case of an outbreak and human exposure a protocol is initiated with a step-by-step process in which several national partners are involved at different levels of the process. The cases are handled according to a case classification algorithm. The SAGA protocol has several limitations but comes as additional source to complement a passive surveillance protocol. The launch is foreseen for September 2023.

In terms of the current HPAI outbreak situation in France, there have been four waves since August 2022 with 2 big peaks in December 2022 and April/May 2023. It is important to notice that 6.5 million poultry have been killed in the outbreaks (excluding preventive culling). It shows the limit of the control measures and the need for vaccination, focusing on ducks. France developed its HPAI vaccination action plan based on the following five main areas of work:

- Using available and effective vaccines and ensuring future authorizations of vaccines for ducks
- Defining scenarios and strategies by identifying species to vaccinate
- Implement a vaccination campaign
- Influencing actions at international level to avoid barriers to access EU market if France starts vaccinating
- Communication: target the audience, commercial partners, EC, and governmental organizations

1.5. Short update on the Epidemiological investigations in a farm with poultry affected by H5N1 – brief report by Italy

In case of any risk of exposure, protective measures should be put in place for exposed workers (use of PPE, physical distancing etc) including the monitoring of the health status of the workers. Diagnostic tests are carried out by the sub-national regions and health authorities for asymptomatic cases 5-7 days after exposure or immediately in case of symptoms. Since the last outbreak in April, a recent detection o H5N1 virus in dogs and cats on a poultry farm with a HPAI outbreak, suggests a possible adaptation of the virus to mammals. The risk assessment remains the same. Guidance and recommendations have been shared with the population. Surveillance is ongoing. Exposed individuals from different regions have been tested and aggregate data is to be collected.

2. <u>Mpox</u>

2.1. Epidemiological update and report about the vaccine deployment survey results – presentation by ECDC

Globally there are 88 144 confirmed monkeypox cases reported until 4 July 2023. There was a peak in July 2022 with the highest rates in Spain. Based on the Joint ECDC-WHO Regional Office for Europe Mpox Surveillance Bulletin, 25 935 cases have been identified from 45 countries in the European Region, through IHR mechanisms, official public sources and TESSy. Most of the cases are among 31 – 40 years old male individuals. The symptoms remain mild in most cases. So far a very small proportion of cases required hospitalization, 40 % of them were HIV positive.

A total of 378 332 vaccine doses have been administered, with 96% of them being used as primary preexposure vaccination. The vaccination rate has gradually declined over the last months. Most of the vaccinated individuals that contracted MPOX, had only one dose administered. Regarding the vaccination roll-out and vaccine supply, most of the countries use vaccines donated via HERA and/or other sources for supply. It is recommended to use primary preventive and post exposure vaccination knowing that the vaccination effectiveness ranges from 66 – 88.5% after the administration of two doses.

2.2. Updates on studies on antiviral treatment – presentation by RTD

Currently there are three EU-funded MPOX-RESPONSE studies (UNITY, EPOXI, MOSA) that are based on the WHO CORE protocol with one shared Data Safety Monitoring Board and one data repository. Only the UNITY study however is currently enrolling. The two others are still in the submission or soon to be launched phase, depending on the number of cases occurring giving the sharp decline of cases that might require a replanning.

2.3. Update on Mpox vaccine and therapeutics procurement for the EU and for donation – presentation by HERA

Vaccines

- HERA purchased 334,540 doses of Mpox vaccine (Jynneos by Bavarian Nordic) (€46m from the EU4Health 2022 budget) and has donated and delivered approximately 300,000 doses across Europe.
- HERA also signed a framework contract with Bavarian Nordic under the joint procurement agreement, which allows the participating 14 MS to purchase up to 2M additional doses of Mpox vaccine.
- A second amendment to the framework contract to index the price was signed on 5 July 2023. HERA is collecting the needs for additional quantities. The contract is valid until end 2024.

Therapeutics

- HERA is finalising a framework contract under the joint procurement agreement for tecovirimat, which will allow 13 participating countries to purchase up to 100,000 treatments.
- HERA purchased 10,008 treatments under the rescEU stockpile, which can be requested by countries through the Union Civil Protection Mechanism, as a last resort. HERA is purchasing additional tecovirimat under rescEU (through grants awarded to Member States) starting later in 2023.

3. Mosquito-borne diseases

3.1. Overview of current and planned initiatives on vector borne diseases, including mosquito borne diseases – epidemiological update (if new events detected) – presentation by ECDC

There are no Dengue nor West Nile Virus cases reported so far this year. At this stage ECDC is in the process to work towards a EU Reference Laboratory network which would cover part of the activities currently carried out by the emerging vector borne-disease laboratory network.

3.2. Medical countermeasures for dengue, chikungunya, zika, yellow fever & west nile fever Report on approved medical countermeasures (vaccines and therapeutics) and those under current research – presentation by HERA

Although there are several studies ongoing and with different vaccines under development. We are facing a lack of medical countermeasures with only two vaccines for dengue and 1 for yellow fever for human use. Against other diseases (e.g. Chikungunya) there are no authorized vaccines available at the moment.

3.3. Presentation from USA (including report on malaria cases & measures for vector control) – presentation by the US CDC

The main source of malaria in the US is US residents travelling abroad and bringing back the infection to the country that then spreads locally. However, the most recent outbreak has been reported in 2023 with six identified cases acquired and transmitted locally. All those cases are very localized in a small perimeter of 6 km. As response the state health departments and CDC are working together. The task of CDC is to provide laboratory support and communication with guidance and education materials. The arbovirus surveillance and control is mostly focused on West Nile virus with a data collection for human surveillance in place. Data reported is collected and transferred via a national system called "Arbonet" to CDC. On their website, CDC shares the data publicly. Vector control measures focus mainly on integrated pest management, but there is marked variation in capacity among the 2000+ vector control organizations. Capacities are generally high in Florida. Insecticide resistance is problematic in many areas and CDC has worked with vector control organizations to improve their ability to test for insecticide resistance.

4. <u>AOB</u>

4.1. Update on the AMR working group meeting with discussion over Art 13 and Art 14 – by DG SANTE The second meeting of the 'Technical Working Group on antimicrobial resistance and healthcareassociated infections' (TWG-AMR) of the Health Security Committee took place **6 July**.

The next AMR One Health Network meeting will take place on 21 September. Invites will be sent via the mailing list for that group which is managed by another SANTE unit that will send the details shortly.

At the last meeting, two articles were presented and discussed in detail:

- DG SANTE shared an overview of provisions in article 15, focusing on items of particular relevance for AMR and HAI experts on the EU reference laboratories (EURLs).
- DG SANTE presented an overview of provisions in article 13, particularly those relating to the list of notifiable diseases, focusing on items of relevance for AMR and HAI experts. An implementing act is foreseen for updating the list of diseases and case definitions.

The Terms of Reference (ToR) (which had been discussed at the 1st meeting 14 June), were sent to the senior HSC for approval via written procedure with deadline 14 July. Several countries have already given their green-light on the ToR.

The dates for the next meeting of the TWG-AMR have not yet been set. It will take place after the summer and dates will be communicated in advance via email.

4.2. Brief announcement about EpiPulse event about echovirus subtype E-11 – by ECDC

There have been 19 severe echovirus infections reported among neonates, with possible long-term sequelae. Studies from IT and FR suggest a virulent lineage. Robust risk assessment is needed. Hence, all countries are invited to report in EpiPulse – including clinical and epidemiological characteristics, information about circulation among communities, and information on sequencing. ECDC also will inform the national focal points to accurately monitor the situation. Cases with epidemiological link needs are to be checked to make sure, if the background has any impact on the seriousness of the infection. There is a network of virologists doing research on non-polio enterovirus, they will start a retrospective data collection possibly testing stored samples.