EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public Health, Cancer and Health security
Health Security

Luxembourg, 28 October 2022

Health Security Committee

Audio meeting

Summary Report

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

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

1. COVID-19 measures for autumn/winter 2022-2023

a. Epidemiological update, modelling on expected increases, scenarios if the variant are changing – presentation by ECDC

After weeks of increases in case rate and partly deaths, a small decreasing trend in the EU/EEA is evident. A decreasing trend is also seen for hospital admissions, whereas ICU indicators have remained stable when compared with the previous week. The pooled EU/EEA COVID-19 death rate remained low, with a 13% decrease when compared with the previous week. In many EU/EEA countries, the vaccination uptake for the second booster dose remains suboptimal, especially in target groups, but the situation is very heterogeneous among countries. Continued protection from doses 1-3 is unclear, and 2nd booster uptake is still low so far and the effect of hybrid immunity is also unclear, but with waning vaccine effectiveness more severe outcomes are likely again. Variant BA.4/BA.5 is still dominant (BQ.1 and BQ.1.1 not reported separately, yet). By end-November to early December 2022, more than 50% of infections are expected to be due to sub variant BQ.1/BQ.1.1 (again with a large variation among countries). The growth rate advantage of BQ.1/BQ.1.1 is due to partial immune evasion and as more social mixing is likely in the coming festive season, it may result in increased transmission and corresponding burden and pressure to our healthcare systems (despite no signals of increased severity). Two scenarios were presented: the first with a 75% increase in transmission and a 20% increase in severity and the second with a 20% increase transmission and a 0% increase in severity. Despite uncertainties, in both scenarios a large pressure on healthcare systems, workforce and school attendance is likely. COVID-19 burden (cases and deaths) from January to October 2022 alone is higher than the yearly burden of other infectious diseases (influenza included). Scenario modelling predicts a high incidence in winter 2022-2023, with pressures likely on healthcare systems, workforce and school attendance. Indeed, 10-50% of the total population is expected to become (re-)infected. ECDC shared links to the country overview reports, including information on SARS-CoV-2 variants and to the COVID-19 Vaccine Tracker tool. After a question by DG SANTE on the so called tripledemic (Flu, R.S.V and Covid-19), expected for the coming winter, ECDC explained that the general population is now much more

susceptible to influenza virus due to the last two years of Covid-19 infection prevention and 2 control (IPC) measures.

DE asked how to interpret the currently observed declining incidence and hospitalization rates in countries with relatively high proportions of BQ.1 and BQ.1.1. **ECDC** replied saying that the effects and impact on the epidemiological situation will be evident when BQ.1 will be responsible for at least 50% of all Covid-19 infections.

b. Update on new vaccines for infants – presentation by EMA

EMA recommended approval of Comirnaty and Spikevax COVID-19 vaccines for children from 6 months of age on 19 October 2022 and provided today the scientific background information. Spikevax (Phase 2/3 trial carried-out with 5 500 recruited children) is recommended on a 2-dose regimen with half dose (25 µg). Good correlation has been shown between neutralizing antibodies and vaccine efficacy for COVID-19, but no antibody threshold has been found. Efficacy was evaluated as exploratory in seronegative subjects at baseline, and preliminary data showed low efficacy due to the fact that Omicron variant was circulating at the time of the study. Comirnaty (Phase 2/3 trial carried out with 1 300 recruited children) is recommended on a 3-dose regimen (3µg). The efficacy against symptomatic COVID-19 was demonstrated in the age group 6 months to <5 years. EMA is evaluating Comirnaty bivalent BA.4-5 in 5-11 year old children and the final opinion is expected in November. Spikevax bivalent Original/BA.1 extension of indication in 6-12 year old children is still under evaluation. As for safety, most common side effects are comparable to the ones in older age groups, with some specificities like irritability, crying, sleepiness and loss of appetite. The risk of heart complications is higher with COVID-19 infection than after vaccination. In addition, emerging data indicate that COVID-19 vaccines are well tolerated in children and no cases of myocarditis have been reported in 1.4 million children aged 6 months to 4 years until October 2022 (including USA). Data on the effectiveness of vaccines against the Omicron variant in children are still limited. However, preliminary data from adults indicate COVID-19 vaccines remain effective against severe disease and hospitalization caused by Omicron variant. Adapted vaccines are not yet approved as primary series or as boosters below 12 years of age. After a remark from **HR**, EMA highlighted that the risk estimate for myocarditis is based on clinical signs, symptoms and preclinical biomarkers, in line with the definition for both clinical trials and pharmacovigilance.

c. HSC survey results - presentation by DG SANTE

Building on actions put forward in the Commission Communications of 27 April and 2 September as well as earlier HSC surveys, a follow-up survey was launched aiming to identify the COVID-19 measures taken and to assess progress made by Member States in preparation of the autumn/winter period. Outcomes of this survey showed that bivalent mRNA vaccines have largely replaced monovalent vaccines for booster vaccination, and that an increasing number of countries is offering the adapted vaccines to the whole population or individuals interested in receiving their next booster. 18 countries stated not to distinguish between specific target groups receiving the BA.1 and the BA.4/5 adapted vaccine, but that administration mainly depends on availability. 15 countries have stated that no specific targets nor objectives for the roll out of the autumn/winter booster vaccination campaign have been defined, and that the objective is therefore to reach vaccination coverage as high as possible. However, booster uptake has been challenging until now in most countries, with many having therefore running targeted communication campaigns. Most countries believe that this lower booster uptake is mainly related to

pandemic fatigue and the perceived lower risk of severe disease and death. Overall, surveillance, testing, sequencing and NPI strategies have not been adapted in preparation of the next wave, as countries consider the current strategies in place to meet the current needs. Compared to September, more countries now have integrated, all-year round surveillance systems for acute respiratory illnesses in place.

d. Current COVID-19 measures – update by invited countries

AT shortly presented their COVID-19 testing strategy as of fall 2022, offered not only to citizens but also to foreign residents. The current legal basis is in force until the end of 2022 but it will be possibly extended for six months. AT authorities initiate a PCR test for symptomatic individuals, contact tracing purposes, and suspected cases (i.e. positive RAT). Broad test screening programs are also introduced (low-threshold, population-wide, voluntary, free of costs): up to five PCR tests per person/per month and five RAT kits per person and month (provided via pharmacies). In addition, targeted screening programs are used for vulnerable institutions and groups (e.g. hospitals, retirement homes, refugee centers, patients, healthcare workers, etc.), with unlimited RAT and PCR testing. As for surveillance, AT makes use of representative and targeted genomic surveillance and wastewater monitoring (covering about 52% of the population), in line with ECDC and Commission recommendations.

CH presented its latest vaccination and testing recommendations as well as the state of play regarding non-pharmaceutical measures. Currently, vaccination is recommended strongly only to vulnerable people (75 and older, or 65 and older with comorbidities, or pregnant women). Booster vaccination (also with adapted formulations), is recommended after 4 months infection or last vaccination, and not recommended under 16 years of age. Pandemic fatigue is apparent also in CH. As for testing strategies, since from April 2022 isolation and quarantine are not in place anymore, testing is recommended only for individuals at high risk or their contacts. Individual PCR tests are payed for symptomatic patients and contacts, too. RAT are free but not recommended in the general population. Wastewater monitoring is ongoing (also for variants), and genomic surveillance is now limited to hospitalized patients. All national measures have been lifted, also no isolation is required in case of infection. All border measures for Schengen have been lifted on February 2022 and all remaining entry restrictions for non EU/EEA countries have been also lifted in April 2022. No mandatory NPI in place, and no plan to reintroduce NPI as for now.

2. Monkeypox

a. Short epidemiological update, de-escalation of Public Health Emergency level – presentation by ECDC

Since the start of the Monkeypox outbreak, 20 675 cases have been reported from 29 EU/EEA countries and 4 deaths have been reported. There is a marked and clear decrease in the number of cases starting late July (week 30). ECDC plans to de-escalate its PHE level to “zero” – recovery phase. A number of activities will be continued within the normal ECDC structure with a smaller team.

b. WHO/EURO and WHO/HQ on monkeypox – oral up-date on monkey pox

WHO EURO described how after a large and remarkable community mobilisation, now the EU region is experiencing the tail of this epidemic. However, since Monkeypox was a previously unknown disease in

the region, we do currently not know how long this epidemic tail will last. Hence, the importance of not turning the attention away from the response, especially if the aim is to limit and eliminate human-to-human transmission in the region. In fact, the EU area is still susceptible to the virus, so there is a concrete risk of recurrence. Outside EU/EEA region, many cases are still reported (e.g. in the USA), and some other countries do not have access to the vaccine yet. In South America Monkeypox response is very heterogeneous among countries, and in some African countries an epidemic is currently going on (e.g. in Ghana), also in refugees camps. So, at a global level, Monkeypox is still an emergency and it remains critical to work on surveillance and reporting. The risk of importation into the EU region is still high and maybe higher than before, due to the current outbreaks in other regions of the world. Important to be vigilant and not to drop measures like surveillance, community engagement, risk communication and medical countermeasures.

3. Ebola

a. Short epidemiological update – presentation by ECDC

There is an ongoing outbreak of Ebola disease (EVD) caused by Sudan Ebolavirus strain with cases detected in several districts in Uganda. ECDC provided an update on the epidemiological situation. Currently, 115 cases have been confirmed (among which 15 healthcare workers). Furthermore, 32 confirmed deaths have been recorded, so far. 7 districts are involved (Kampala and Wakiso being newly reporting districts). In the capital Kampala, 17 cases have been recorded (of which 13 are contact cases of a previously deceased man from Kassanda, 2 are other contacts of other two cases and the last 2 with no information and data as for now). Case Fatality Rate (CFR), being 28% for confirmed cases and 40% including probable deaths. As for vaccine trials, the Ugandan Ministry of Health announced that three vaccine candidates are currently being evaluated: vaccines from Oxford (UK), the Sabin Vaccine Institute and Merck (US). The aim is to evaluate the vaccine efficacy in primary contacts of EVD cases within 29 days of contact. Contacts of 150 cases (approx. 3 000 people) will be vaccinated initially. Overall, the current risk for citizens within the EU/EEA is considered very low, while the risk for citizens living or traveling in affected areas in Uganda is considered low.

BE remarks its intention to discourage officially all non-essential travel to Uganda, especially as cases have been detected in Kampala now. As for the time being and the current epidemiological situation, ECDC does not make any recommendation on travel.

4. AOB:

a. Upcoming AMR Joint Action

The Commission updated the HSC on the preparatory work for the upcoming Joint Action on antimicrobial resistance (AMR), which will be 4 years long. All EU countries, plus Norway, Iceland and Ukraine participate in this joint action; the EU co-funding is 50 million €. The French National Institute of Health and Medical Research hosted a workshop on the 20 October in Paris with the support of Commission for developing the upcoming Joint Action proposal (deadline to submit the technical description and the budget in January 2023). Countries are in the early stages of developing the proposal. The aim of the meeting was to fine-tune proposed work-packages (content, scope, deliverables, and partners), discuss potential overlap / duplication, strategic matters, timelines and how the JA partner will work and interact. Altogether, the joint action will have 10 work-packages (WP).

Besides the mandatory WP such as coordination (work package 5), evaluation and dissemination, the work packages cover: infection prevention and control (work package 7); surveillance (work package 8); antimicrobial stewardship (work package 6); awareness-raising (work package 10); access to antimicrobials (work package 9) and Member States engagement regarding National Action Plans. The activities envisaged cover the One Health spectrum, with new activities notably in the area of the environment.

b. AMR detected in patients evacuated from Ukraine

Anecdotal evidence and information received from WHO/Europe on cases of Ukrainian medically evacuated patients received by EU hospitals seems to show high levels of antimicrobial resistant infections. This is why the Commission announced a short survey among the Health Security Committee to understand the situation better. SANTE and ECDC developed the survey together. It seeks to identify the scale of the problem and the main pathogens that show resistance. The aim is twofold: to raise preparedness in EU/EEA hospitals, to channel this information back to Ukraine and to provide possible support at EU level.

c. AT point on COVID-10 international contact tracing

AT pointed out that international contact tracing for Covid-19 is still an obligation but it is not really happening right now anymore, because most countries are not tracing any more across borders. AT asked whether the obligation for international contact tracing should be reviewed and reconsidered, especially as EU/EEA is entering a de-escalation phase for COVID-19. It is important to agree to a common approach concerning international contact tracing procedures. SANTE suggested to circulate the Austrian question to the HSC in writing and to come back to it in another HSC meeting.