EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 13 December 2023

General Working Group of the Health Security Committee
Audio meeting
Report

Chair: Head of Unit, DG SANTE B2, European Commission
Participants: AT, CZ, DE, DK, EE, EL, FI, HR, HU, IE, IS, IT, LI, LT, LV, MT, NL, NO, PL, PT, SE, SI, SK, DG HERA, DG SANTE, ECDC, WHO, Intellera Consulting

Agenda points:

1. Overview of respiratory virus epidemiology in the EU/EEA (COVID-19, FLU, RSV) – ECDC
2. Update on the current strategy for flu vaccines – EMA
3. Update on the Regulation (EU) 2022/2371 implementation (Art 21, Art 7, Art 8, Art 11) – DG SANTE B2
4. Update on the HSC opinion on avian influenza – DG SANTE B2
5. Report from the stakeholder webinar on Health Security – DG SANTE B2
6. Findings from a Study on the functioning of the Joint Procurement Agreement (JPA) for medical countermeasures – DG SANTE B2 and the contractor - Intellera consulting
7. AOB

Main messages:

1. Overview of respiratory virus epidemiology in the EU/EEA (COVID-19, FLU, RSV) – ECDC

ECDC changed the approach to surveillance by integrating surveillance of influenza, Respiratory Syncytial Virus (RSV) and SARS-CoV-2 viruses (Operational considerations for respiratory virus surveillance in Europe (europa.eu)) to adapt to the reporting of the EU/EEA countries. In terms of the sampling strategy primary (acute respiratory infections (ARI), influenza like illness (ILI)) and secondary care sites are used (severe, acute respiratory infection (SARI)). The main objective of the integrated surveillance is to monitor the burden of the respiratory illness and to understand the relative contribution of different viruses over time. The weekly updates of the surveillance data are available on European Respiratory Virus Surveillance Summary. The respiratory illness rates are increasing since September as expected every year. RSV activity began in early September and has been increasing since, resulting in increasing hospital admissions, particularly among the 0–4 years age group. The influenza rates and non-sentinel hospital admissions, ICU admissions and deaths remain low. All three subtypes are circulating but the influenza A subtypes and the A(H1)pdm09 subtype are predominant. There should be awareness also about other respiratory pathogens co-circulating during the cold period that contribute to the overall health situation. **IE** reported an intense RSV and influenza season and asked **FR** and **ES** for preliminary findings in terms of vaccines and passive immunization. **HR** reported a large outbreak 1f pertussis (3000 cases).

2. Update on the current strategy for flu vaccines and respiratory diseases – EMA

Following the WHO recommendation in September and after consultation with the stakeholders EMA's Emergency Task Force recommended on 8 December to exclude the B/Yamagata lineage from the live attenuated vaccine in 2024-2025, and to target 2025-2026 for the remaining inactivated vaccines. There is a need to consider all influenza seasonal vaccines authorized in Europe that are impacted by this recommendation. **EMA** asked for the **HSC for feedback** on this proposal while in parallel working with industry and EU public health authorities (aligned with this approach) and EC. **NL** welcomed the proposal and requested to clarify the rationale for not switching directly to trivalent vaccines. **EMA** is looking for a harmonization, but national approach could be feasible. On the zoonotic flu vaccines side, EMA informed that **Aflunov** will be updated to include a more recent clade (more information in Q1 2024). The monoclonal antibody vaccine **Nirsevimab** has been authorized against RSV in neonatal infants (variation till 24 month is planned). **Arexvy** was approved by EC in June 2023, and used for respiratory tract diseases for 60 years and older with an efficacy above 80% and an acceptable safety profile. **Abrysvo** is the second authorized vaccine using the same type of recombinant proteins but without the adjuvant and can be used in pregnant women. The efficacy and safety profile are comparable between both vaccines and co-administration is possible. For COVID-19 vaccines, **Valneva's** vaccine is withdrawn for commercial reasons. The protein SARS-CoV-2 vaccine (Nuvaxovid) has been updated in September to include the more recent strain **XBB.1.5** and posology was simplified. **IE** asked for MS views on the vaccination strategy to have yearly vaccine or twice a year. EMA supported the yearly vaccination approach to be evaluated against the disease burden and the evolution of the virus.

3. Update on the Regulation (EU) 2022/2371 implementation (Art 21 Art 8, Art 11) – DG SANTE B2

- Art 8: DG SANTE is at the final stage of consulting MS on the delegated act. The discussion takes place with the MS nominated public health expert group. The delegated act has been sent to MS for written comments with a deadline on 14 December. with the act spells out high level procedures and standardized criteria for the assessment by ECDC planned to start in 2024 based on MS reporting. SANTE recalled that the deadline for that reporting is 27 December in accordance with Regulation 2022/2371.
- Art 11: the EC works with a contractor to develop an EU health preparedness training programme. In 2024, national workshops will be arranged with the MS and regional pilot activities. Based on the needs assessment workshops organized by the contractor in Athens and Lisbon the main topics for training activities elicited are cross-border crisis management, the collaboration between the border regions, CBRN and communication. The contractor will be working closely with the task force on training, a sub-group of the HSC technical working group on preparedness. DG SANTE thanked the Ministry of Civil Protection and Climate Change in Greece for their initiative to host the first national workshop on preparedness and response at national and regional level to discuss the training needs to be held in the week of 18 December.
- Art 21 (implementing act): comments received on coordination and response and are being incorporated (ex. timely coordination within HSC; differences in public health measures; transparency in public measures). The updates will be available at one of the next HSCs in January 2024. Any additional comments should be sent by 22 December 2023.

4. Update on the HSC opinion on zoonotic avian influenza – DG SANTE B2

The first draft was initiated jointly with DG SANTE B and G, DG EMPL, DG HERA, ECDC and EFSA and discussed during the HSC plenary meeting on 18 and 19 October 2023. The draft was updated based on comments and sent for adoption in written procedure in November. The additional comments were addressed (background, One Health approach, human health and animal health sector actions) and a final version circulated for comments/approval by 14 Dec 2023. Changes conflicting with EU legislation and/or

with ECDC or EFSA After adoption, the opinion will be published on the HSC web site. ECDC informed that the new situation report on avian influenza would be published on 14 December. In 2024 ECDC, EFSA and DG SANTE will organize a simulation exercise on zoonotic avian influenza with EU/EEA countries.

5. **Report from the stakeholder webinar on Health Security – DG SANTE B2**

A public webinar on "*Stakeholder dialogue on Health Security*" was organized on 11 December by the EU Health Policy Platform in alignment with Article 10 Regulation (EU) 2022/2371 spelling out coordination of prevention, preparedness and response planning in the HSC. DG SANTE presented the new Regulation, ECDC its new mandate and Finland provided a Member State perspective. The webinar reached an attendance rate of 114 participants from ministries, expert governmental agencies, civil society etc. The HSC general working group will discuss further next year about coordination and interaction aspects.

6. **Findings from a Study on the functioning of the JPA for medical countermeasures – DG SANTE B2 and the contractor, Intellera consulting**

The Joint Procurement Agreement (JPA) on medical counter measures for cross-border health threats (set-up in April 2014) is a voluntary mechanism enabling participating countries and the EU institutions to purchase jointly medical countermeasures, referred in Article 12 of Regulation (EU) 2022/2371. Little used before, it was a crucial tool during the COVID-19 outbreak in 2020-2021. Up to 36 countries participated in 11 joint procurement procedures followed by over 200 contracts for a total value of EUR 12 billion. Based on some challenges with its use, few MS requested an evaluation of the JPA. The study assessed the **effectiveness, efficiency, relevance, coherence and EU added value of both the legal framework and the implementation of the JPA against the underlying policy objectives** as defined in the legal framework in two different periods and contexts (i.e. until and during the COVID-19 pandemic). Overall, the JPA **achieved its objectives** in terms of strengthening the security of supply, ensuring a more equitable access to medical countermeasures, being a flexible instrument for participating countries, **but not necessarily offering lower prices** of medical countermeasures. It was considered as a **flexible mean with low obligation, good platform for information exchange and practical arrangements**. Operational, administrative, and legal can be improved. In terms of efficiency, the **benefits offered by the JPA significantly outweighed the costs**. It was a right tool to use before and during the COVID-19 pandemic even if the costs and the preparedness aspect were less relevant during the crisis times. As a result of the study a set of tools for future were proposed: a market analysis, a cost-benefit decision-making tool and recommendations for monitoring the.

7. **AOB**

The next General Working Group HSC will take place on 20 December 2023 with the EU Task Force and the 2024 work plan of the EU4 Health programme as main points on the agenda.
SANTE informed the HSC that the European Health and Digital Executive Agency (HaDEA) published a call for tenders HADEA/2023/OP/0039 with an estimated total budget of EUR 25 million - Single Framework Contracts to support training programmes and tabletop exercises on preparedness and response to cross-border health threats including medical countermeasures. The subjects are in Lot 1: the design, delivery of training courses, the development of e-Learning/online content, and in Lot 2: the design and delivery of simulation exercises in health preparedness and response to cross-border health threats.