EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health, country knowledge, crisis management
Health Security and Vaccination

Luxembourg, 27 October 2020

Health Security Committee

Audio meeting on the outbreak of COVID-19

Summary Report

Chair: Wolfgang Philipp, European Commission, DG SANTE C3

Audio participants: AT, BE, BG, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PT, RO, SE, SK, IS, NO, CH, UK, BA, ME, RS, UA, MD, DG SANTE, DG ECHO, DG JRC, DG HR, ECDC, EMA, Council Secretariat, WHO

Key Conclusions

1. ECDC rapid risk assessment

The Chair referred to the rising numbers of COVID19 cases in Member States, which have led to the reintroduction of restrictive measures – including state of emergency- to contain the pandemic. The ECDC latest Rapid Risk Assessment (RRA) published on 23 October showed a deterioration of the epidemiological situation in a large number of Member States of the EU/EEA and the UK. Urgent action is needed to prevent health care systems from being overwhelmed.
ECDC highlighted the following points:

- 14 day rate has been increasing over the past three months with test positivity steadily increasing in the EU/EEA and the UK with marked escalation in recent weeks
- Testing rates showing increased infections in both younger and older age groups
- Hospital/ICU occupancy indicator is high
- There are 25 countries with epidemiological situation of "serious concern". Only 6 countries show "stable trends"

In terms of options for response, ECDC emphasised upscaling and targeting of non-pharmaceutical interventions, testing and contract tracing protecting of individual at higher risk and health care providers. Risk communication should focus on overcoming pandemic fatigue and communicating the dynamic of the epidemiological situation.

The Chair opened the floor for comments. CZ welcomed the rapid risk assessment and appreciated the fact that rapid antigen tests are included, nevertheless there is urgent need for case definition to be modified to include rapid antigen tests not just PCR tests.
C3 noted that given the need for targeted, swift regional and national responses, it would be very important to have more specific recommendations/response options based on different

epidemiological scenarios. C3 asked ECDC to provide more specific, context-tailored and scenario related recommendations for response.

With respect to case definition, ECDC responded that work is ongoing. Concerning the need to have more specific recommendations for non-pharmaceutical interventions, ECDC stressed the need to reinforce testing, tracing and distance measures, every country should identify the best strategy according to their capacities.

Follow-up:

- *ECDC to update case definitions considering rapid antigen testing*
- *ECDC to provide more specific response options that work best in a given situation / scenario*

2. Vaccines – post marketing authorisation for COVID-19 vaccines: monitoring, safety and effectiveness studies

The Chair mentioned the paper on "monitoring the use and performance of authorized Covid-19 vaccines in the EU/EEA" circulated to EU/EEA HSC members, reminding the deadline of 30 October to provide answers to the 3 questions related to countries' plans for possible post-marketing authorisation studies.

ECDC presented the ongoing post-marketing authorisation studies.
ECDC and EMA joint work is to set-up monitoring framework to estimate vaccination impact, effectiveness and detect analyse safety signals. ECDC will continue to collaborate closely with EU- NITAGs and with WHO to support Member States to develop vaccine deployment plans and vaccinations strategies. ECDC and EMA joint work will continue to promote the development of electronic immunisation registries and support MS in decision-making for vaccine deployment, by developing scenarios for prioritisation strategies based on modelling. A technical report on prioritisation was published yesterday on ECDC website.

ECDC noted that the data generated by the pre-authorisation vaccines clinical trials in phase III - which is ongoing for the EU market- will likely provide information on how effectively the vaccines will protect against laboratory-confirmed symptomatic COVID-19 of any severity estimating efficacy of at least 50%. Adults and elderly including subjects with co-morbidities are to be included. Phase 3 studies will likely not provide information on effectiveness of vaccines against severe disease and death due to COVID-19 and its complications including in the longer term. To this end, only post-marketing studies can provide an answer. Phase 3 studies will not provide information on how effectively the vaccines will protect against COVID-19 subgroups of populations not included in phase 3 trials such as children, pregnant women, immunosuppressed individuals and other special populations.

ECDC pointed that post-authorisation monitoring studies are needed to assess safety and effectiveness, to identify risks factors, collect data on hospitalisation, ICU. However, given the wide variety of technologies being used, only large European studies will be able to assess product specific effectiveness and safety. More funding is needed to this end.

ECDC aims at starting a pilot project on monitoring vaccine effectiveness hoping that are more public funds will be available to develop a monitoring framework with EMA on both effectiveness and safety. The project will look at post marketing phase in specific population at risk. In preparation for the deployment of COVID-19 vaccines ECDC will undertake mapping of vaccination policies, vaccines deployment plans and support countries with no

specific monitor mechanisms in place. EMA project "ACCESS" aims at harmonizing event definitions and create common protocols tools, using also electronic health care data. EMA is also working on framework contracts with limited budget focusing on early monitoring in the three member states only.

The Chair opened the floor for discussion. ES asked whether countries have been already selected for the pilot study projects. ECDC answered countries selection is not pre-determined. DE welcomed EU level studies

Follow-up:

- *Countries to reply to the three questions regarding their plans for possible post – marketing authorisation studies by Friday 30 October.*

3. National vaccination strategies

The Commission published a communication on preparedness for COVID-19 vaccination strategies and vaccine deployment on the 15 October, based on the blueprint of the HSC. The Communication outlines key factors, including the capacity of vaccination services, easy access, infrastructure, logistics and having a good communication strategy to build public trust. As there will be a gradual roll-out from the production, countries need to give careful consideration to risk groups. The Communication follows the Commission's EU Vaccines Strategy and its advance purchase contracts with leading vaccine manufacturers. Three contracts have been signed for advance purchase agreement and further discussions are ongoing The HSC and Steering Board meet last week, liaising on deployment and vaccine uptake.

ECDC presented an overview of vaccination preparedness plans, in response to the previous Commission request. ECDC conducted a survey and are collaborating with EU NITAG, particularly on identifying literature and evidence on COVID-19 for bi-weekly distribution. Amongst 31 countries, 21 replied to the survey which identified that amongst respondents, all countries were developing national vaccination strategies or plans. Some have interim recommendations. The survey also identified that the most frequently stated priority groups included healthcare professionals, social workers, elderly (aged 60+) and individual risk groups due to comorbidities. Most evidence was based on epidemiological modelling and projections. Regarding vaccine delivery, the most countries emphasised equality and fairness. Ensuring delivery with a continuous cold-chain was also highlighted as a challenge, with some vaccines possibly requiring -70 degree Celsius temperatures. For product specific monitoring a few countries have product specific monitoring frameworks via immunisation registries. Several countries were also looking into expanding national immunisation registries.
The Chair asked if the HSC wanted a coordinated approach on vaccination strategies. Concerns over duplication between the work of the WHO and NITAG were expressed.
ES welcomed similar vaccination approaches in the EU and highlighted the need to address vaccine hesitancy. FI shared their experience on liability challenges. SE plans to register non-vaccinated individuals for follow-up. FR informed that their vaccination strategy still under review, but healthcare professionals are definitely part of their priority groups. NL hope to share details of their strategy early November. The Chair welcomed technical discussions in the NITAG and WHO group and that recommendations coming out of these discussions should be brought to the HSC for alignment of vaccination strategies.

Follow-up:

- *HSC to be informed of 'end-point' of work by WHO and ECDC on vaccine strategies*

- *EE and WHO to share information with the HSC on the electronic vaccination certificate.*
- *The Commission will get back on elements for the alignment of vaccination strategies at the next HSC.*

4. Joint Procurement

Participating countries can order vast amounts of gloves, coveralls, goggles, face shields, FFP2 masks, FFP3 masks, surgical masks, ventilators, 30 types of laboratory equipment and treatment courses of therapeutic remdesivir. Contracts are also being signed for ICU medicines. The Chair highlighted that 10 countries have drawn on these contracts, however 90% of quantities remain available.
A joint procurement on medical equipment for vaccination is also currently under evaluation.
The HSC were updated on the Joint Procurement for rapid antigen tests. Out of 37 signatories of the Joint Procurement Agreement, 22 countries replied, with 17 expressing an interest in such an undertaking. The Chair thanked countries for good cooperation and urged for needs to be specified in a timely manner. The Commission also informed that 100m EUR have been mobilised to buy rapid antigen-tests for EU countries. Further details will follow.
If countries want to pursue further product purchases, 4 countries are required to launch a Joint Procurement, as specified in the Joint Procurement Agreement.

Follow-up:

- *Further details of the rapid antigen test Joint Procurement are to be discussed in the specific steering Committee.*

5. Testing, contact tracing and isolation/quarantine, hospital capacities

Testing
As stressed again in the latest RRA, a robust system of testing with short (<24 hour) turnaround times for results is central to the public health response. Testing strategies should be flexible and rapidly adaptable to change, depending on the local epidemiology, population dynamics and resources.

The Chair informed the HSC that the Commission will soon publish a Recommendation on COVID-19 testing, including the use of rapid antigen tests. The content of this document is strongly based on the HSC agreed document for a common EU testing approach for COVID-19, which was published in September. It also further builds on new developments, particularly in the field of rapid antigen tests and the increasing use of these tests by EU countries. The Recommendation on COVID-19 testing is part of a larger package that will address wider COVID-19 measures across the EU, with a focus on travellers.

Further building on the topic of rapid antigen tests, the Chair thanked those HSC members that provided additional details on the use of these tests in their countries. The updated overview table was circulated among the HSC, showing which rapid antigen tests are being used/considered/validated by countries in the EU. The table shows that the tests by Abbott and SD Biosensor/Roche are, at the moment, the most commonly used or considered rapid antigen tests across the EU.

Moreover, the table showed, and this will also be stressed in the Commission Recommendation on testing strategies, that it would be of great value to agree on a HSC common position on the use of rapid antigen tests. In particular, clarity is required regarding the scenarios and situations

where such tests should or should not be used. The practical experiences by countries and results from national validations are thus of great importance.

The Chair also informed the HSC that the Commission is advancing in the preparations of a Joint Procurement on rapid antigen tests.

The HSC members made no further comments, and it was decided that the topic of COVID-19 testing would be further discussed at the next HSC meeting, which will take place after publication of the Commission Recommendation on COVID-19 testing.

Follow-up:

- *The 6 MS that have not yet provided information on the use/consideration/validation of rapid antigen tests in their countries are encouraged to submit this information to the Commission.*
- *ECDC to provide further details on whether the COVID-19 case definition will be updated, taking into consideration not only RT-PCR results but also rapid antigen test results.*
- *Topic on testing will be further discussed at next HSC meeting.*

Isolation / quarantine measures

An updated overview of current isolation and quarantine measures was circulated amongst the HSC. A wide variety of measures continue to prevail, in terms of isolation, quarantine requirements and duration.

Follow-up:

- *Topic to be discussed at next HSC, in particular the possibility for the HSC to agree on a common position, taking into consideration the ongoing reassessment of ECDC on quarantine and isolation measures.*

Hospital / ICU capacities

The JRC presented on hospital and intensive care units (ICU), in particular their capacities in the current epidemiological situation and projected forecasts. JRC has developed a model in close collaboration with ECDC, and the data is derived from countries reporting ICUs, which are limited. The model shows that, assuming that the epidemiological developments will continue, and not taking into consideration the NPI interventions that have been put in place recently by various countries across the EU, the maximum pressure will be reached in November and December. This is based on data on ICU capacity from 2019, which has been doubled as an estimate of what current capacities may look like (as actual data on this does not exist). Further work will involve daily forecasting, monitoring of the impact of NPIs, and further modelling of scenarios for intervention (together with ECDC).

In the context of the limiting hospital and ICU capacities, the Chair urged for all HSC countries to use EWRS for requests on cross-border patient or medical personal transfer, as highlighted during previous HSC meetings. Moreover, in light of the limited data on ICU occupancy at EU level, the Chair encouraged MS to share information with JRC and the ECDC, via usual channels for better data in this critical sector.

ES asked for further details on how the JRC came to the conclusion that ICUs is obtained as a fraction of infected people, between 5% and 15% (average of 9%) of new positive cases. ES also added that the State of Alarm was reactivated in the country, which allows the government

to reintroduce a general lockdown if necessary. At the moment, the priority is to limit night life and to reduce social interactions, particularly among youth.

DE added that, at the moment, the country has sufficient hospital capacities but that this may change considering the epidemiological situation. The point was raised that acceptance of measures among the population is key, especially among youth. The Chair responded that this topic will be addressed in further detail at the next HSC meeting.

Follow-up:

- *Countries are encouraged to share data on ICU and hospital capacities and occupancy.*
- *The SOP on the transport of cross-border patients and medical personal will be re-circulated by the Commission amongst the HSC.*

6. Social-distancing / confinement measures

Until safe and effective vaccines become available, non-pharmaceutical interventions continue to serve as the main public health tool for control and management. The Commission is ready to support Member States where needed, including coordination via the HSC. The Commission would particularly welcome sharing of evidence on specific measures recently introduced (e.g.; circuit breakers and social bubbles). The Chair reminded that all measures need to be notified via EWRS. MS discussed challenges around the acceptance of measures. IE shared an overview of their recently measures, which have been similar to those during the first wave, however with an emphasis on keeping schools, essential work and non-COVID patient care in hospitals operational. IE will report on impact in the next HSC meetings.

Follow-up:

- *ECDC to give an overview of effective measures at the next HSC.*