EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

Luxembourg, 11 May 2022

Health Security Committee

Audio meeting on the outbreak of COVID-19, other communicable diseases and the Ukraine Conflict

Draft Summary Report

EU/EEA only

Chair: Head of Unit, European Commission, DG SANTE C3
Audio participants: AT, BE, CZ, DE, DK, EL, ES, FI, FR, HU, IE, IT, LT, LV, NL, PL, PT, RO, SE, SK, NO, IS, LI, DG SANTE, DG ECHO, DG JUST, HERA, ECDC, EMA, WHO

Agenda points:

Covid-19 and other communicable diseases

1. Overview on the current COVID-19 pandemic situation – presentation by ECDC
2. Mutual recognition of EU DCC vaccination certificates for participants of COVID-19 clinical trials – discussion point
3. Update on the restructuring of the EU common list on COVID-19 rapid antigen tests – presentation by DG SANTE

Support to Ukraine

4. Treatments and medicine for displaced people from UA
   A. Ensuring high-quality of HIV Care for displaced people from Ukraine – presentation by ECDC/WHO
   B. HSC Survey on UA - treatments and medicine – presentation by DG SANTE
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5. AOB: short update on the Hepatitis cases by ECDC
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Covid-19 and other communicable diseases

1. Overview on the current COVID-19 pandemic situation – presentation by ECDC

The European Centre for Disease Prevention and Control (ECDC) gave an update on the COVID-19 pandemic situation. The overall notification rates of COVID-19 remains high, with case rates continuing

to **decrease** in all but three EU/EEA countries (18% decrease compared to previous week). Three countries reported increasing transmission in the 65 years and older age group. It therefore remains **important to continue monitoring** the disease burden in older age groups and the overall transmission.

ECDC summarised the non-pharmaceutical interventions (NPIs) in EU/EEA countries according to the latest data available. Seven countries have no or very few NPIs in place, 10 countries lifted most NPIs measures but left them in place as recommendations to shield vulnerable groups, 12 countries still have mandatory NPIs in place for the general population. Concerning COVID-19 variants, the sub-linage BA.4 shows still limited circulation in EU/EEA countries and sub-linage BA.5 shows more sporadic cases (South Africa is showing increasing trends, but this is not reflected in hospitalisation rates). ECDC also gave a brief summary of the epidemiological situation in **China** where there is an increase of cases since March 2022. COVID-19 sub-lineage BA.2 is the dominant variant according to data reported in GISAID from China.

ES mentioned that while in China the COVID-19 situation does not seem to be fully under control, most EU Member States seem to have higher cases and mortality rates. Therefore, ES wanted to know if China's current strategy is related to the zero COVID-19 strategy. **ECDC** responded that it might indeed be related to the zero COVID-19 strategy.

PT referred to a media announcement from the European Aviation Safety Agency (EASA) and ECDC published on 11 May, that as of 16 May, masks wearing will no longer be mandatory, only recommended on airports and airplanes. **ECDC** confirmed that these guidelines have been developed and published. EASA and ECDC issued an update to the health safety measures for air travel, paving the way for a relaxation on the need to wear medical masks on board a flight, but noting that a facemask is still one of the best protections against the transmission of COVID-19.

2. Mutual recognition of EU DCC vaccination certificates for participants of COVID-19 clinical trials

The Commission's proposal to amend the Regulation for the EU Digital COVID Certificate (EU DCC) is currently being discussed in the Council and European Parliament. In the proposal, the **HSC** is asked to issue guidance on the acceptance of certificates for vaccines undergoing a clinical trial, to ensure coherence. Where certificates are being issued, it is important that they are recognised and accepted also in other Member States. The Commission proposes establishing an HSC agreement regarding mutual acceptance of EU DCC certificates issued for COVID-19 vaccines undergoing a clinical trial, on the basis of the clear benefit to all Member States and the scientific community outweighing the minor risk (stressing the negligible number of participants). The integrity of clinical trials, including in terms of data blinding and confidentiality, must be preserved to ensure the validity of these studies. A few Member States already expressed they would agree with general mutual recognition of certificates.

FR presented their suggestions on mutual recognition of the EU DCC. Recognition of clinical trials is currently based on bilateral agreements: only Spain recognises the French clinical trials and France recognises the Spanish one. To promote these clinical trials, the objective is to make this recognition mutual within Europe by bilateral exchanges. This means that individuals participating in clinical trials might have difficulties with travelling, when a certificate has to be showed at the entry of a country.

The **Commission** highlighted that this topic has been discussed in the HSC several times. Clinical trials participants should not be affected e.g. by travel restriction because of their participation in clinical trials.

ES reported only having clinical trials ongoing for booster doses, not for primary vaccination. In other words, every participant in the clinical trials already has a certificate for the primary COVID-19 vaccination. ES is ready to accept and recognise clinical trial participants from other countries.

The **NL** presented their guidance. Participants should not experience any disadvantages for participating in the vaccination trials. Participants that are **proven to be protected** can receive a certificate for local use, issued by the main researcher, as the EU regulation currently does not allow issuing an EU DCC. Therefore, the NL decided not to provide a local DCC during the trial when the effectiveness was still unclear, given the epidemiological situation at that time. To receive an EU DCC, at least one extra doses of an approved vaccine should be administered. NL mentioned several challenges with the provision of an EU DCC to clinical trial participants, including: 1) who decides if the vaccine is effective enough; 2) acceptance of trial vaccines with the EU; 3) EU DCC validity (for placebo group and participants in a failed trial).

FI supports the issuance of the EU DCC for participants in clinical vaccine trials. Clinical vaccine trials are vital in order to develop efficient vaccines and to protect the population health from vaccine preventable diseases. If the EU DCC would not be issued for trial participants, their participation in trails could be discouraged. FI would like to hear the views from other Member States on issuing certificates for persons participating in clinical trials and in practice, how information on trial vaccines should be entered to the certificates. FI would like to know whether the Commission is preparing guidance (under the eHealth Network) on the technical issuance of the EU DCC for participants in clinical trials. The technical definitions must be compatible with current certificates. The **Commission** confirmed that the eHealth Network is indeed preparing guidelines.

IE supports the recognition of a DCC issued following participation in a vaccine trial. However, IE does currently not require the use of a DCC either at borders or internally at present.

NO agrees with IE.

The **Commission** mentioned that it is important that the HSC gives further guidance on this topic. For example, whether there is a need to distinguish between EU and non-EU clinical trial participants. The Commission will get back in writing to the HSC representatives for their feedback.

3. Update on the restructuring of the EU common list on COVID-19 rapid antigen tests

DG SANTE presented the proposed restructuring of the EU common list document on COVID-19 rapid antigen tests (RATs), as discussed and agreed with the Technical Working Group on 3 May 2022. There is a need to restructure the document because:

1) as agreed by the HSC mid-March, as of 1 June the EU common list of COVID-19 rapid antigen tests will undergo several changes, including the split up in an 'A category' (prospective clinical field studies) and a "B category" (retrospective in vitro studies) list;

2) since February 2021, when the EU common list was first published, a lot of information has been added and some of the information is outdated or can be simplified;

3) a plethora of COVID-19 rapid antigen tests is available on the market and there is a need to better distinguish between devices included in the EU common list. The proposal for the updating and restructuring of the document was circulated among the HSC on 6 May for review.

The HSC representatives can send their comments and suggestions by**16 May**. In case no comments are received, the Commission will assume that the HSC agrees and the document will be used as the basis

for the next update of the EU common list, expected to be agreed early June. In parallel, the JRC is also updating its COVID-19 In Vitro Diagnostic Devices and Test Methods Database.

IE expressed appreciation to the Technical Working Group and to the Commission for the huge amount of work undertaken on RATs.

Support to Ukraine

4. Treatments and medicine for displaced people from UA

A. Ensuring high-quality of HIV Care for displaced people from Ukraine– presentation by ECDC/WHO

It is estimated that in 2020 there were around 257 000 people (between 0.6 and 1% of total population) living with HIV in Ukraine, of whom around 146 000 were receiving antiretroviral therapy. ECDC is working on estimating the number of people living in Ukraine with HIV who have entered the EU since 24 February, which is critical to inform prevention, treatment and care programmes in the EU. As the displacement of people from Ukraine escalates, it is imperative that countries across Europe receiving these displaced people are prepared to ensure high standards of HIV prevention, treatment and care. To this end, on 19 April, ECDC, WHO, European AIDS Clinical Society (EACS), the Euroguidelines in Central and Eastern Europe (ECEE) network group and European AIDS Treatment Group (EATG) issued a statement on 'Ensuring high-quality of HIV Care for displaced people from Ukraine'. ECDC will hold a webinar on 19 May on "Key considerations for the provision of the HIV continuum of care for refugees from Ukraine".

In April, WHO published a Standardized protocol for clinical management and medical data-sharing for people living with HIV among refugees from Ukraine, which outlines recommended principles of clinical management . Considering 1% HIV prevalence in general population in Ukraine, it is estimated that that 1 in 100 refugees are HIV positive and may need antiretroviral treatment. The Ukrainian Public Health Centre has developed a '**Statement of the provision of information on health and treatment**' form to be used by patients with support from the clinic outside Ukraine to receive any medical information needed. The patients can send the document to stop.hiv@phc.org.ua.

B. HSC Survey on UA - treatments and medicine – presentation by DG SANTE

The Commission launched a survey among the Member States to obtain feedback on any issues experienced so far regarding medicines and treatment for refugees (16 replies received). The survey focused on any problems experienced by the countries with the identification of treatments started in Ukraine (before relocation), or in providing alternative treatment options or corresponding EU-authorised medicines when needed. All Member States except one reported being able to address any possible problems encountered with national resources. Several countries suggested that the European Medicines Agency could provide advice on EU-approved medicines that could be used instead of any UA-authorized medicines that cannot be sourced.

ECDC provided feedback from their mission to PL to assess stock of HIV medicine in PL and the potential use if the Civil Protection Mechanism to counter any possible shortages.

BE is still gathering information from the regions, once available, BE will share their feedback in writing to the Commission.

In **PT**, displaced people from UA are protected under the "temporary protection" regulation, and not as refugees, meaning that several approaches for displaced people from UA differ from those for other refugees. Suspected cases are reported.

C. Ensuring availability of medicines: state of play, regulatory flexibilities, good practices and other mechanisms – presentation by EMA

EMA is monitoring the availability of medicines in the EU/EEA. EMA has compared lists of **Ukrainian essential medicines** for oncology, HIV and TB (from WHO Europe) with the **products authorised in the EU**, almost all products have corresponding EU authorised products with same active substance(s). There are some limitations with availability of certain fixed dose combinations, specific formulations or due to a low number of Member States that have some of the products authorised. Member States are asked to inform EMA if they identify a concrete required medicine for which an EU alternative cannot be identified and which cannot be provided under national exemptions.

Any other business

5. AOB: short update on the Hepatitis cases by ECDC

ECDC has reacted to the Hepatitis cases in setting up a Public Health Emergency Team and is working on an action plan. ECDC summarised what is known about the cases. So far, 106 cases have been reported in the EU/EEA countries. Significant amount of cases were reported in Italy and Spain. ECDC encourages Member States to investigate and understand the background and transmission of the cases. Reporting cases by Member States to the European Surveillance System (TESSy) is still incomplete (only 55 out of 106 cases have been reported). ECDC will continue monitoring, collecting data, communicating with EU/EEA countries, and producing regular outputs.

6. AOB: Information for the Joint action 2022 Work Plan on Antimicrobial Resistance

The Commission informed the HSC that preparations have started regarding the next Joint Action on AMR, foreseen under the EU4Health Work Programme 2022, which has a sizeable budget of EUR 50 million. The Commission is planning to organise two special HSC meetings on AMR in the coming weeks, to have an informal discussion on the new Joint Action and what activities it should cover. The new Joint Action should have a primary focus on public health, as it is funded by EU4Health, but it should nonetheless allow for One Health activities and thus may include other national authorities as affiliated entities. The dates foreseen for the special HSC meetings are **18 May** and **8 June**. The Commission will also engage with the One Health Network and will use already planned meetings of this group on **31 May** and **13 June** to stimulate further discussions.

The **next HSC meeting** will most likely take place on 1 June. A physical meeting will be planned for September/October.