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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

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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, FI, FR, HR, HU, IE, IT, LT, LU, LV, MT, NL, PT, RO, SE, SK, NO, CH, UK, AL, BiH, ME, MK, RS, UA, MD, DG SANTE, DG ECHO, DG HR, CHAFEA, EMA, ECDC, WHO

Key Conclusions

1. COVID-19 testing: rapid antigen tests and testing strategies

I. RAPID ANTIGEN TESTS

The first topic of discussion was the rapidly evolving field of rapid antigen tests. The Chair explained that the purpose of today was to discuss the information received from countries in response to the various questions and surveys circulated among the HSC, and to reach agreement on the next steps and way forward. Firstly, after re-circulation of the short survey on the (consideration of) use of rapid antigen tests by Member States, additional feedback was submitted and the Commission has now collected details from 19 MS as well as CH, IS, LI, ME and the UK. It clearly shows a strong and increasing interest across the EU in the use of these tests. At the moment, there are 6 countries using rapid antigen tests in practice (BE, DE, ES, FI, FR, IT).

Based on the details provided on the types of rapid antigen tests being used or considered, countries focus so far on five tests: Abbott, ArcDia, ArcDia, Coris Bioconcept, Quidel, and SD Biosensor/ROCHE. The rapid antigen tests produced by Abbott and SD Biosensor/Roche are the most considered options: 7 countries are using or considering Abbott and 9 countries are using or considering SD Biosensor/Roche. For some countries, it was unclear which test exactly they are using or considering to use, so they are encouraged to provide the Commission with this additional information.

While there is a great interest in these tests, the Chair noted that there is also a large diversity in the application of the tests and the use of their results. In this context, the HSC was asked if there is a need for an aligned EU approach to the use of rapid antigen tests (e.g. a common position by the HSC), and if so, what elements should be considered? Secondly, would it be helpful to have a Joint Procurement on rapid antigen tests, and if so, which antigen test should

be considered and what should be the minimum thresholds of performance? Fifteen countries responded to these questions. The majority (13/15) were in favour of a common EU approach to the use of rapid antigen tests. Only BE and CZ had reservations. FI and SE noted that the field or rapid antigen tests is rather technical, and that discussions on the details of such a common approach would require input from national experts and ECDC. Moreover, NO added that guidance by ECDC/FIND on the use of antigen tests based on available publications and experiences by MS on the performance of rapid antigen tests in different settings would be helpful.

Concerning the elements to be included and addressed by a common HSC position on the topic, various suggestions were put forward, including: Criteria/threshold values for sensitivity and specificity (in line with WHO guidance or more strict); Performance (positive and negative predictive values: PPV, NPV); Settings and situations where rapid antigen tests could be used (priority targets, clinical picture of patients, epidemiological situation); Settings and situations where rapid antigen tests cannot be used; Cases where rapid antigen tests could replace RT-PCR; Confirmation of rapid antigen test result by RT-PCR (when negative, when positive, both, never); Validation of tests (if tests have CE and IVD marking, is additional validation at national level required?); Use of the results for national statistics (and reporting to ECDC); and Mutual recognition of rapid antigen test results for cross-border travellers.

The Chair opened the floor, specifically asking HSC members if they agree with a common position, along the lines put forward, and for further comments and views on a possible HSC common position on rapid antigen tests.

FR mentioned that soon, a large-scale testing campaign for rapid antigen tests will be deployed, focusing on airports in particular, as well as schools. It is foreseen that the rapid antigen tests will be used for symptomatic people, and not (yet) to test asymptomatic people or for contact tracing purposes. These groups are covered by France's current common testing strategy.

North Macedonia explained considering the use of rapid antigen tests (from Abbott) in universities and for health workers. The question was raised whether positive results have to be confirmed by RT-PCR and if so, if this would not result in overwhelming the PCR testing systems in place. This concern was highlighted by SE too.

The Chair referred to preliminary statistics recently received from Italy on the use or rapid antigen tests at Marco Polo airport in Venice from mid-August to mid-October, which showed that around a third of the positive rapid antigen test results were confirmed by PCR tests. Particularly during the influenza season, rather than being a burden, the use of rapid antigen tests could really help in providing a quick differential diagnosis. Moreover, the RT-PCR samples to be tested may be piling up, resulting in a long turn-around-time and therefore negatively impacting contact tracing efforts. Despite the reduce clinical performance of rapid antigen tests, the Chair concluded that there are several arguments why rapid tests provide advantages, and these will be taken into consideration and outlined in the common position paper.

SE stressed that it is important to conduct further evaluations of rapid antigen test performance, and the need of their use in specific contexts and for specific target groups.

The Chair stressed that it is up to the Member States to decide how to use rapid antigen tests and in which context, but a common position by the HSC should address the basic parameters and scenarios in which the tests make sense to be used.

DE presented its testing strategy to the HSC, which was updated last week and now includes the use of rapid antigen tests. DE does not recommend the use of these tests for suspected cases or symptomatic people, and is mainly planning to use them for screening purposes and for quick differential diagnoses, with a focus on healthcare facilities. In principle, RT-PCR is recommended for symptomatic suspected COVID-19 cases, contacts and outbreak-related testing, whereas asymptomatic individuals, e.g. health care personnel and visitors of health care facilities, will be tested by using rapid antigen tests. For now, it is mandatory to follow-up a positive rapid antigen test result with RT-PCR. Moreover, DE is currently carrying out validation studies of 8-10 different tests, including those from Abbott and Roche. Each test is being validated by at least two labs operating in different settings. Once the results are available, these can be shared with the HSC. The minimum sensitivity and specificity criteria defined are not very stringent in order not to ensure that the demand for rapid antigen tests can be met. Once the validation studies have been finalised, the criteria will be redefined accordingly.

BE clarified that, as the country is not facing particular problems with the use or rapid antigen tests, it does not consider it essential to have a EU common approach. However, BE is open to support a common position by the HSC. Moreover, it will share data it has from validation studies that are running at national level. FR added that it will also share this data.

FI explained that the country is in the process of validating data and cannot share anything definite yet. Moreover, it referred to the report of the Joint Action on Healthy Gateways, and stressed that a careful review of the conclusions are necessary, particularly in relation to the PPV and NPV.

PT put forward the question whether the COVID-19 case definition is going to be updated by ECDC, as it is currently based on the nucleic acid amplification test [NAAT] but the use of rapid antigen tests is thus increasing and should possibly be included. Secondly, PT explained that it is currently discussing its testing strategy, and that it is considering to introduce the use of rapid antigen tests with a sensitivity of 90% and specificity of 97%. The tests could possibly be used for testing symptomatic people during the first five days after disease onset. PT is considering to give people with mild symptoms (who don't require hospitalisation) the option to either be tested by RT-PCR or rapid antigen test. If the rapid antigen tests is negative but the person is showing symptoms, the result should be confirmed by RT-PCR. For systematic cases that require hospitalisation, RT-PCR would be the first choice, but in case of shortages, rapid antigen tests could possibly be used – this is under discussion. PT is also still discussing whether rapid antigen tests could be used for screening purposes in outbreak settings and for vulnerable contexts.

CH referred to a recent Dutch preprint article mentioned in Nature "COVID research updates" on the comparison of rapid antigen tests used in symptomatic people[1]. Moreover, he added that in the next 2 weeks, Switzerland will publish interim guidance on the use of rapid antigen tests for symptomatic people and in case RT-PCR capacity is overwhelmed (which could be the case at least locally/regionally) and in the case of outbreak management. Based on pilots, hospitals are very positive about using these tests and health professionals are pushing for further roll out of their use. It is still under discussion if CH will also use them for testing asymptomatic people

[1] In: https://www.nature.com/articles/d41586-020-00502-w on October 16th the following article is mentioned: From more testing to smart testing: data-guided SARS-CoV-2 testing choices. Janko van Beek, Zsofia Igloi, Timo Boelsums, Ewout Fanoy, Hannelore Gotz, Richard Molenkamp, Jeroen van Kampen, Corine GeurtsvanKessel, Annemiek van der Eijk, David van de Vijver, Marion Koopmans. medRxiv 2020.10.13.20211524; doi: https://doi.org/10.1101/2020.10.13.20211524

who did not have direct contact with confirmed cases. For the moment and as resources are limited, the guideline will restrict the use – most likely to symptomatic people and asymptomatic people either in outbreak management or in testing of close contacts identified by the SwissCovid App. The question was put forward if there are any validation studies available on the use of rapid antigen tests for asymptomatic people.

EL explained that the country has been using the Abbott test since last month, and the first time was in a refugee camp to test 8000-9000 people. Now, the tests are mostly used for outbreak clusters and so far, more than 40.000 positive rapid antigen tests have been conducted and the positive ones were confirmed by RT-PCR. More than 99% of these samples was also positive when tested by RT-PCR, which has made them wonder if it is necessary to continue the validation studies. EL will send the analytical data to the HSC and further added that on 20/10 there will be a massive testing campaign in the metro of Athens. They are using mobile units for testing and the experience so far with the rapid test has been very positive. EL considers the rapid antigen tests as a solution for general population screening, also at airports for example. The logistics of using RT-PCR are problematic, and rapid antigen tests offer many solutions.

PT added that they also have data on the use of rapid antigen tests in emergency services at hospitals and that this data can be shared with the HSC. PT is evaluating the Abbott and Roche tests and will also include other tests in their validation studies.

The Chair referred to a Joint Procurement for rapid antigen tests under preparation. It is important to receive more information on the types of tests used in which context as well as the validation data that countries are collecting through their national studies.

II. TESTING STRATEGIES

Next, the implementation of the Recommendations for a common EU testing approach for COVID-19 was discussed, which the HSC agreed on one month ago. The Chair asked the HSC whether this document has been further distributed within countries and also used, resulting in updated or adapted testing strategies based on the agreed common approach.

It was agreed that the Commission will circulate a short template that the HSC will be asked to complete and submit on if and how they have implemented the elements included in the agreed common testing approach.

Follow-up:

- *The HSC is encouraged to review the table setting out the (consideration of) use of rapid antigen tests by countries, and to provide the Commission with further details by* ***Wednesday 21 October COB****.*
- *The HSC is encouraged to share data and information on (national) validation studies of rapid antigen tests, independent from those produced by the companies, with the Commission. This will also be used for the launch of a Joint Procurement on rapid antigen tests.*
- *The Commission will draft a HSC common position paper on rapid antigen tests, based on the information collected so far and further discussed today. The paper will be structured along the points put forward by the HSC.*
- *ECDC to clarify if the case definition is going to be updated, based on the increasing use of rapid antigen tests in Europe.*
- *The Commission will circulate a short template to be completed by the HSC on the implementation of the "Recommendations for a common EU testing approach for COVID-19", that was agreed by the HSC one month ago.*

2. Quarantine/isolation provisions

The Chair recalled the previous HSC meeting (05/10) when Member States discussed the possibility of reaching an agreement on the implementation of isolation and quarantine measures. The Commission noted that there is no need to have the same measures in place but at least a similar justification for the implementation of these measures.

On **isolation of cases,** the Chair reminded that ECDC's recommendation states that, depending on the health status, cases should isolate for a minimum of 8 days, 14 days for more severe cases and could go up to 20 days for immunocompromised cases. Results of the matrix show that there are differences in the length of isolation and in the criteria to lift isolation (4 countries have 7 days isolation, 15 have 10 days isolation, 7 have 14 days isolation). In addition, most countries ask for a resolution of symptoms on top of the recommended length of isolation. Differences are on the duration since when symptoms have resolved: 24, 48 or 72 hours without symptoms.

The Chair asked the ECDC to comment on the isolation measures, its recommended length and lifting criteria. The ECDC noted that they recently published a guidance on Discharge and ending of isolation of people with COVID-19[2]. The document presents differential durations for different categories of cases, due to the outcome of the disease. For mild and moderate cases, isolation should last for 10 days after onset of symptoms.

CH noted that the national Science Task Force had been modelling the use of PCR test to shorten quarantine. Currently, isolation and quarantine for 10 days is in place and a PCR test at day 6 for people in quarantine has been considered by the national Science Task Force, in order to shorten quarantine upon a negative result. Currently, there are no plans to adopt these ideas. The isolation and quarantine rule for 10 days will stay in place.

IT Ministry of Health issued guidance on what is meant with isolation and quarantine. Isolation: impacted cases, while quarantine is for contacts with COVID-19 cases. IT reduced from 14 to 10 days the isolation period, and for asymptomatic cases a test is performed at the end of the 10 days. For symptomatic, isolation of cases is 10 days and at least 3 without symptoms. Isolation can generally be interrupted after 21 days.

On **quarantine of contacts,** in the latest risk assessment of the ECDC, the agency noted that 14-day quarantine is recommended for persons who have had contact with confirmed SARS-CoV-2 cases. This can be shortened to 10 days after exposure, if a PCR test at day 10 is negative. The matrix shows also various lengths for quarantine from 7 to 14 days (5 countries have 7 days, 11 have 10 and 14 have 14). The Chair asked the ECDC to comment on reduced quarantine periods and asked the HSC to discuss evidence for reduced length of quarantine.

ECDC noted that the latest documents are considering a reduced quarantine period to 10 days with a negative test to end the period. Indeed, reducing more could lead to missing asymptomatic cases. ECDC noted that cost-effectiveness elements have to be considered when implemented reduced quarantine measures (testing all contacts?).

[2] https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf

DE noted that a new legislation regarding quarantine is being discussed, that there are still lot of discussion on how to handle this point nationwide, but considerations are for a 10 day quarantine, that can be shortened by providing a negative test.

DK elaborated on their quarantine measures for close contacts, namely that close contacts are test 4 days after last exposure and then on day 6.

To conclude, the Chair asked the ECDC to develop an opinion on an assessment of a reduced quarantine for contacts while focusing on a minimised risk for public health perspective.

On **monitoring of compliance,** the Chair noted that compliance to isolation and quarantine ensures that transmission chains are interrupted and the diseases is not further spread to new contacts. Most countries have mandatory isolation and quarantine in place and legal measures to ensure that isolation and quarantine are respected. Nevertheless, some Member States are reducing length of isolation and quarantine to ensure compliance. Furthermore, it appears that some countries have no monitoring systems to follow up on cases and contacts.

The Chair asked Member States to comment, and share reasons for no implementation of monitoring.

AT commented that the discussion is about risk management and that it would be interesting to collect information on the results of the strategy implemented by DK. AT noted the economic pressure to reduce quarantine for the shortest possible length but it becomes harder to justify with basic medical evidence. AT asked therefore to elaborate on the different strategies and the risks taken.

DK will share input in writing.

Follow-up:

- *The ECDC will produce an opinion on reducing length of quarantine, after a negative COVID-19 test.*
- *HSC to share updates on isolation and quarantine measures.*

3. Masks and social distancing – control measures and effectiveness, emerging

The Chair asked countries to provide an update on response measures including on masks wearing and re-introducing confinement measures in view of the worsening epidemiological situation and strain on health care systems.

NL tightened measures as of 14 October until 27 October, the government will assess what measures are needed in the period after that. Measures include advice to work from home, restricting number of visitors and gatherings, opening of retail stores, night shopping, and selling and drinking alcohol. The use of facemasks is strongly advised in indoor public spaces, currently the need for compulsory measures is being discussed.

FR introduced local curfews in Paris, as well as Marseille, Lyon, Lille, Saint-Etienne, Rouen, Toulouse, Grenoble and Montpellier during the night from 21:00 to 06:00 as of 17 October for at least 4 weeks. Outing will only be authorized with a certificate. Across France, gatherings are limited, face coverings are compulsory in enclosed public spaces, while specific areas have introduced additional rules.

HR informed about the mandatory wearing masks in all closed places, including health care establishments, shopping malls, working places, working from home is recommended. Measures are tightened in some specific settings, such as long-term care facilities, and hospitals.

In BE, bars and restaurants, including coffee bars, have to close for 4 weeks except for takeaway meals and non-alcoholic drinks until 22:00, a ban on selling alcohol is introduced after 20:00. Teleworking where possible is mandatory. Restrictions are introduced regarding the number of guests and close contacts outside the household. There is a ban applicable to enter the public space between midnight and 5:00**,** except for essential movements. After two weeks, the measure will be evaluated.

Follow-up:

- *Countries to continue to notify on response measures via EWRS, including information on tipping points for confinement measures/lockdowns at regional/national levels.*

4. Preparedness at EU level, emerging areas for coordination and cooperation

The Chair asked countries for any updates on emerging needs or areas for coordination within the HSC.

Countries were reminded to communicate any emerging needs to the Commission. The Union Civil Protection Mechanism can also be activated, as well as notification sent through EWRS in relation to the exchange of health professionals and medical countermeasures.

CH noted the importance of coordination regarding travel and quarantine rules.

The Chair noted that ECDC will prepare and launch a survey to assess the national COVID-19 vaccination plans.

Follow-up:

- *Countries to inform the Commission in writing on emerging needs or areas for coordination within the HSC.*

5. AOB on shortages of medicines

EMA provided an update on their work regarding the shortages of medicines, monitoring and forecasting demand.

This includes launching a survey with Member States on preparedness, a project on forecasting demand data, and establishing an ad-hoc working group. EMA aims to provide information on demand data consolidated at EU level, as well as minimum requirements from Member States, to inform also planning of industry stakeholders. A reflection paper is being prepared concerning selected medicines/active substances. A survey was launched to gather information on second wave preparedness regarding the stockpiling of ICU medicines, as well as on expert restriction and bans issued by countries. The cooperation of Member States public health authorities is key in these areas.

Follow-up:

- *EMA to provide any further update to the HSC in writing.*