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Miloš VYSTRČIL
President of the Senát
Valdštejnské naměstí 17/4
CZ – 118 01 PRAGUE 1

Dear President,

The Commission would like to thank the Senát for its Opinion on the Communication to the European Parliament, the European Council and the Council "A united front to beat COVID-19" {COM(2021) 35 final}.

The Commission welcomes the Senát's broad support for the aims of the proposal and is pleased to have this opportunity to provide a number of clarifications.

In advance of the upcoming European Health Emergency Preparedness and Response Authority (HERA), the Commission adopted on 17 February 2021 a Communication on the "HERA incubator: Anticipating together the threat of COVID-19 variants"[1]. This EU bio-defence preparedness plan outlines the support provided by the Commission to the Member States to increase sequencing capacity. Indeed, sequencing capacity varies greatly across the EU/EEA. For the period 10 May to 23 May 2021, based on data submitted by countries to GISAID[2] and TESSy[3], only 13 EU/EEA countries met the recommended level of 10% or 500 samples sequenced of positive cases. As part of the HERA Incubator and to support countries with low or limited sequencing capacities, the European Centre for Disease Prevention and Control (ECDC) has put in place a sequencing support service for Member States, allowing countries to send their vials to a commercial laboratory that sequences the samples for them. As of 10 May, 11 countries are making use of this sequencing support service.

The Czech Republic is making use of this supplementary sequencing service, and is sending in on average around 150 positive SARS-CoV-2 samples per week. It is pivotal for EU Member States to ensure that sequencing capacities reach at least 5% of positive test results, as the genomic information allows for careful monitoring of the emergence and spread of COVID-19 variants of concern, and is fundamental in guiding the continued public health response to the ongoing pandemic.

The Commission is pleased that the Senát shares the view that testing strategies should be updated in the light of new variants, including the use of rapid antigen tests with guidance on

[1] COM(2021) 78 final
[2] https://www.gisaid.org/
[3] https://www.ecdc.europa.eu/en/publications-data/european-surveillance-system-tessy

the use of these tests. Effective testing plays a key role in mitigating the spread of the virus, providing the key information for contact tracing as well as wider trends. It also facilitates the free movement of people and the smooth functioning of the internal market. While the development and implementation of COVID-19 testing strategies is a national competence, the Commission has played an active role in providing guidance and recommendations to EU Member States. On 28 October 2020, it adopted a Recommendation on COVID-19 testing strategies, including the use of rapid antigen tests. On 18 November 2020, a Commission Recommendation further specified the use of rapid antigen tests for the diagnosis of SARS-CoV-2 infections. The importance of addressing the emergence of SARS-CoV-2 variants by updating testing strategies was specifically addressed in the Communication of 19 January 2021, in which Member States were called upon to update their testing strategies to reflect the new variants during February 2021. Another key milestone was the agreement reached by the Health Security Committee on 17 February, in response to Council Recommendation 5451/21, on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU. Finally, in the light of the emergence of rapid antigen self-tests in different EU Member States, the ECDC published guidance for Member States on 17 March, outlining the public health considerations for the use of self-tests to detect SARS-CoV-2 by public health authorities in the EU.

With respect to vaccines, the Commission, through its EU Vaccine Strategy[4], has brought access for EU Member States to a broad portfolio of vaccines using different technologies. The Commission would like to confirm to the Senát that a medicinal product can be placed on the European Union market only after a marketing authorisation has been granted in accordance with the pharmaceutical legislation[5] either by the Commission for the entire EU (EU authorisation) or by the competent authority of a Member State for its own territory (national authorisation). In both cases, a marketing authorisation is granted to a medicinal product only after its quality, safety and efficacy have been evaluated and a positive benefit-risk balance related to its use has been concluded. This assessment is carried out by the European Medicines Agency for EU authorisations or by the Member States in the case of a national authorisation. Most of the COVID-19 vaccines are based on new recombinant technologies, which results in a mandatory marketing authorisation through the EU centralised procedure. Finally, the Communication on "HERA incubator: Anticipating together the threat of COVID-19 variants" proposes actions setting the response of the EU to COVID-19 variants. In particular, it includes the strengthening of research activities on variants and the setting up of an EU clinical trial network covering trials of modified and/or novel COVID-19 vaccine candidates, with a focus on candidates adjusting to new variants.

The Commission believes that to prepare for the future, and while drawing on the lessons from the first phase of its response to the pandemic, the EU might need booster vaccines to reinforce and prolong immunity and to defeat the virus decisively. In order to develop vaccines that are adapted to new variants and to receive them early and in sufficient

[4] COM(2020) 245 final

[5] Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, OJ L 136, 30.4.2004, as amended, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, as amended.

quantities, on 14 April, President von der Leyen announced that Europe needs to focus on technologies that have proven their worth, notably mRNA vaccines. On 20 May, the Commission signed a third contract with BioNTech and Pfizer. It reserves an additional 1.8 billion doses on behalf of all EU Member States, between end 2021 to 2023. It will allow for the purchase of 900 million doses of the current vaccine and of a vaccine adapted to variants, with the option to purchase an additional 900 million dose. This contract also stipulates that not only the production of the vaccines, but also all essential components, be based in the EU. This contract constitutes a further important step in Europe's response to the pandemic. Other contracts, with other companies, may follow.

With regard to the vaccine Sputnik V (Gam-COVID-Vac)[6], the European Medicines Agency (EMA) has started a rolling review, based on results from laboratory studies and clinical studies in adults. The rolling review will continue until enough evidence is available for a formal marketing authorisation application. The EMA will assess Sputnik V's compliance with the usual EU standards for effectiveness, safety and quality. While the overall timeline cannot be predicted in the case of a possible application, it should take into consideration the work done during the rolling review. The EMA will communicate further when the marketing authorisation application for the vaccine has been submitted.

The Commission is fully committed to ensuring global access to COVID-19 vaccines and will continue to lead international solidarity efforts through the COVAX Facility under the Access to Covid-19 Tools Accelerator (ACT-A). COVAX aims to purchase 2 billion doses by the end of 2021, including over 1.3 billion for low and middle-income countries. It is building a diversified portfolio of vaccines, similar to the EU approach. Team Europe (formed by the Commission and the EU Member States) is one of the lead contributors to COVAX with over €2.2 billion in financial support. The European Union is also supporting the establishment of a COVAX humanitarian buffer with some 100 million doses.

The Commission hopes that these clarifications address the issues raised by the Senát, and looks forward to continuing our political dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

Stella Kyriakides
Member of the Commission

[6] EMA starts rolling review of the Sputnik V COVID-19 vaccine | European Medicines Agency (europa.eu)