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NOTE

From:	Presidency
To:	Permanent Representatives Committee/Council
Subject:	COVID-19 – Current and future response to the pandemic – *Exchange of views*

Delegations will find in Annex a revised note from the Presidency intended as a basis for the exchange of views on 'COVID-19: Current and future response to the pandemic' due to take place at the EPSCO (Health) Council session scheduled for 7 December 2021.

ANNEX

Background paper on COVID-19 vaccination and therapeutics

Current COVID-19 situation

The epidemiological situation in the EU/EEA is of high or very high concern in most of the Member States and characterized by a high and rapidly increasing notification rate and a low but slowly increasing death rate. Together with the hospital and intensive care unit admissions, these rates are forecasted to increase over the next two weeks. Notification rates are currently highest for people that are under 50 years old, but are also rapidly increasing among older age groups. The situation varies considerably between countries but countries with lower vaccination uptake continue to be the most severely affected.

New Omicron variant

The Omicron variant is the most divergent variant that has been detected in significant numbers during the pandemic so far, which raises concerns that it may be associated with increased transmissibility, significant reduction in vaccine effectiveness and increased risk for reinfections.

At this stage, based on experience with previous variants, it is important to contain the spread of the variant to the extent possible, allowing additional knowledge to be gained, which could better inform epidemiological measures.

In view of containing the spread of the Omicron variant, Member States agreed to activate the emergency brake foreseen in recommendation 2020/912 and urgently impose temporary restrictions on all travel into the EU from southern African region, including suspending passenger flights and to discouraging travel to this region.

Avoiding travel to and from the known affected areas, as well as increased testing with sequencing of confirmed cases and contact tracing of COVID-19 cases with an epidemiological link to the affected areas is needed at this stage. Genomic surveillance remains of utmost importance for early detection of the presence of this variant, to enable the following of epidemiological trends and guide containment measures.

Member States are invited to consider special attention to the availability of sufficient capacities for sequencing (incl. capacity provided by ECDC), wastewater monitoring, PCR and rapid antigen tests and to signal possible bottlenecks as well as enhancing contact tracing and the use of Passenger Locator Forms (PLFs). Member States are encouraged to put additional efforts in increasing vaccination and use of 'booster' doses.

Validity of COVID vaccination certificates

Unlike for recovery certificates, the EU Digital COVID Certificate Regulation does not contain a maximum validity period for vaccination certificates yet. This is due to the limited knowledge about the duration of protection when the Regulation was adopted.

According to ECDC, the available evidence regarding vaccine effectiveness and the duration of protection shows that all EU-authorised vaccines are highly protective against COVID-19-related hospitalization, severe disease and death. The studies however show some decline of protection against infection and mild disease at around 6 months after the primary vaccination.

To promote harmonized measures within the EU, the Commission has proposed to establish, for the purpose of travel, in the Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic, a standard acceptance period of 9 month for vaccination certificates. This takes into account the guidance of ECDC regarding administration of booster doses as of six months after completion of the primary vaccination, and provides an additional period of three months to ensure that national vaccination campaigns can adjust and citizens have access to the administration of boosters.

A delegated act will be proposed on a coordinated approach regarding the validity period of vaccination certificates.

Boosters

In its risk assessment of 24 November, ECDC recommends the rollout of vaccine booster doses for adults, which should be prioritised for those aged 40 years and over, targeting those most vulnerable for severe disease such as the elderly (particularly those living in closed settings) and those with comorbidities and healthcare workers, at the earliest six months after completing a primary schedule. Booster doses could also be considered for all adults 18 years and older to increase protection against infection due to waning immunity which could potentially reduce transmission in the population and prevent additional hospitalisations and deaths.

All EU/EEA countries have begun administration of 'additional dose' vaccination and 'booster' vaccinations.

Available evidence emerging from Israel and the UK shows a significant increase in protection against infection and severe disease following a booster dose in all age groups in the short term.

COVID-19 adolescent and pediatric vaccination

Currently two COVID-19 vaccines are authorised in the EU for children and adolescents: Comirnaty (Pfizer BioNTech) for children between 5 and 11 years of age and Spikevax (Moderna) for children between 12 and 18 years of age.

The EMA has also started the evaluation of the Moderna vaccine for children from 6 to 11 years. In addition, other nine paediatric COVID-19 vaccines are in development.

The EMA is monitoring the rare occurrence of myocarditis and pericarditis after the administration of mRNA vaccines in young adults and adolescents.

All EU/EEA countries are now recommending vaccination for all 12-17 year-olds and the vaccination is ongoing. Countries are offering vaccination for adolescents at vaccination centers, and vaccination by general practitioners/family doctors is the second most popular option. Several countries also offer vaccinations at schools, hospitals, pediatrician clinics, mobile vaccination sites or pharmacies.

As of 18 November, the uptake of full vaccination among adolescents across the EU/EEA is 13.9%, with 16.7% having received at least one dose of the COVID-19 vaccine.

Discussions have been held in the Health Security Committee about the plans of the Member States to expand vaccination to children under the age of 12.

COVID-19 therapeutics

Vaccination is the most effective tool to prevent COVID-19 hospitalisations and deaths, and as such, it is the only way out of this pandemic. In the meantime, however, COVID-19 patients need safe and effective treatments to fight the infection, improve their prospect of a swift recovery, reduce hospitalisations and most importantly, to prevent loss of life.

On 6 May, the Commission adopted the EU COVID-19 Therapeutics Strategy to support the research, development, manufacturing, procurement and deployment of those medicines.

In October 2021 the Commission published a broader portfolio of ten most promising therapeutics candidates, following a science-based selection by experts[1].

Ensuring a rapid and flexible regulatory process is the priority. In November 2021, the Commission granted two marketing authorisations for monoclonal antibodies, namely Regkirona (regdanvimab) and Ronapreve (casirivimab/imdevimab) and could authorise additional four treatments by the end of the year.

There are currently six pending assessments[2] of COVID-19 therapeutics in EMA.

The Commission is helping to ensure that therapeutics are procured and delivered to Member States as soon as they are authorised. With this objective in mind, the Presidency proposed the launch of an EU joint procurement of therapeutics to secure timely and equal access to all Europeans.

1 https://ec.europa.eu/commission/presscorner/detail/en/IP_21_5366

2 https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/treatments-covid-19/covid-19-treatments-under-evaluation

The Commission has already concluded four joint procurement[3] contracts for the purchase of COVID-19 therapeutics and stands ready to launch more by the end of 2021. In addition, the possibility stockpiling promising therapeutics following a decision of the Steering Board could be considered.

Questions for discussion

1. How can we better coordinate our measures to detect and control the spread of the new Omicron variant of SARS-CoV-2? How should this be supported at EU level?
2. Are you planning to expand vaccination to children under the age of 12? What are the challenges you are or expect to be facing in the roll-out of the booster and paediatric vaccinations? How quickly do you estimate to be able to complete your vaccination campaigns?
3. Would you be ready to engage in the procurement of COVID-19 therapeutics at EU level through joint procurement, and for HERA to build a stockpile?

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[3] https://ec.europa.eu/commission/presscorner/detail/en/ip_21_4827