

COVID-19 EU update

European Commission:

- On February 10, President Ursula von der Leyen gave a [speech](#) in the European Parliament about the state of play of the EU's COVID-19 Vaccination strategy. So far 26 million vaccine doses have been delivered in Europe since December with over 17 million people being vaccinated. President Von Der Leyen conceded that the EU was late in granting authorization for Vaccines and took for granted that the vaccine doses would arrive on time. Furthermore, President Von Der Leyen expressed her regrets about the export restriction decision. The new Health Emergency Preparedness and Response Authority (HERA) was brought up, with President Von Der Leyen stating that the core task of HERA will be to prepare better, enable sharing of data across networks and improve the coordination of supply of key ingredients so that European citizens are safer from future health crisis.
- Commissioner Stella Kyriakides made several [remarks](#) on February 10 about the EU Vaccine Strategy. Three key messages were expressed in Commissioner Kyriakides speech: First that it was right that Europeans procured the vaccine together in solidarity. Second, the EU has a moral duty to show the same solidarity to partners in "our neighborhood" and across the world. Third, that lessons were learned and improvement needs to be directed at the regulatory environment, the industrial ecosystem, and the operational environment. In a response to a question on transparency, Commissioner Kyriakides proposed the creation of a contact group on vaccines to allow the Commission and Parliament to regularly exchange views on pressing issues and work together. Commissioner Kyriakides also announced the launch of a new Bio Defense Preparedness program under HERA and the launch of a public and private collaboration to develop and manufacture vaccines at scale to respond to the threat of new variants.

The European Parliament:

- [MEPs called for EU and global solidarity](#) for COVID-19 Vaccination on February 11. MEPs emphasised that the EU had made the right key decisions such as the collective European approach to vaccination and standing up for citizens' rights by putting safety first. However, it was also acknowledged that the EU has a responsibility for the rest of the world, and must ensure vaccines are fairly distributed across the globe.

EMA:

- On 12 February 2021, [EMA's human medicines committee \(CHMP\) started the rolling review of CureVac's COVID-19 vaccine \(CVnCoV\)](#). CureVac is currently conducting clinical trials to assess the vaccine's safety in humans as well as the effectiveness against COVID-19 and how well an immuneresponse to COVID is triggered. CVnCoV is an mRNA-based vaccine.
- On 10 February 2021, the EMA gave a [presentation](#) for healthcare professionals on the safety aspects of COVID-19 vaccines. The webinar was organised by the European Commission.
- [EMA is developing guidance on how to tackle the COVID-19 variants](#) from the manufacturers side, with planning changes to existing COVID-19 vaccines. EMA has requested developers to investigate if their vaccine is also effective against new variants such as the ones identified in South Africa, the UK and Brazil, to be able to consider options for additional testing and development of vaccines that are

effective. EMA will publish a reflection paper that will “include data and studies needed to support adaptations of the existing vaccines to current or future mutations of SARS-CoV-2 in the European Union”.

- On 10 February 2021, EMA [issues clarifications on the Sputnik V vaccine in the EU approval process](#), stating that EMA has to date not received an application for a marketing authorization or rolling review for the Sputnik V vaccine, even though reports may say something differently. EMA goes on to clarify, that the developers of the vaccine have received scientific guidance from EMA for the vaccine development and that the vaccine is included in the [list](#) of COVID-19 medicines and vaccines that EMA gave scientific advice for. EMA and the Gamaleya National Centre of Epidemiology and Microbiology in Russia, developers of the Sputnik V vaccine, are in dialogue to define how to proceed, with developers having expressed interest in the vaccine being considered for a rolling review.
- A [report](#) was issued, summarizing the results of an international workshop held by ICMRA on 25 January 2021, co-chaired by Health Canada and EMA, concerning COVID-19 Real-World Evidence and Observational studies. In this workshop, global medicine regulators underlined the importance of international collaboration and the sharing of best practices and expertise to aid in decision-making processes regarding the treatment of COVID-19 and vaccines.

WHO/WHO Europe:

- On 11 February, WHO Regional Director for Europe, Dr. Hans Kluge, issued a [statement](#) on the current COVID-19 situation. He mentions that an overall decline in case incidence of COVID-19 over 4 consecutive weeks as well as a decrease in number of deaths two weeks in a row can be observed. However, he stated that, whilst this is positive, the decline “conceals increasing numbers of outbreaks and community spread involving variants of concern” and that the overall trends in transmissions have to be observed. He also states, that the current number of cases is still too high and that on 9 February, 40 countries in the region have reported 3610 deaths due to COVID-19 in 24 hours. “At this point, the overwhelming majority of European countries remain vulnerable. Right now, it’s a thin line between the hope of a vaccine and a false sense of security.” From 29 out of 37 countries currently conducting vaccinations, 7.8 million people have completed their immunization, equivalent to 1.5% of the population in these countries. “Time and again have we seen countries reopen too fast and lose hard-earned gains. I must reiterate that decisions to lift public health and social measures need to be underpinned with data, based on epidemiological assessment and health system capacity. Criteria need to be evidence-based – and not based on observations of relative progress.”
- On 11 February the [EU and WHO Regional Office for Europe joined forces to support the deployment of COVID-19 vaccines and the vaccination in six EU eastern partnership countries](#), constituting their largest collaboration in the European Region to date. These countries include: Armenia, Azerbaijan, Belarus, Georgia, the Republic of Moldova and Ukraine. The collaboration, funded by the EU and implemented by the WHO Regional Office, will cover all phases of COVID-19 vaccine deployment and vaccination as well as also strengthening the routine immunization systems in the six countries.
- February 10, WHO Director General Dr. Tedros Adhanom Ghebreyesus and UNICEF Executive Director Henrietta Fore [made a joint statement on the COVID-19 vaccine race](#). They called for leaders to look beyond their borders and employ a vaccine strategy that can actually end the pandemic and limit variants, citing the need to protect health workers on the frontline in lower- and

middle-income settings. They closed with stating that “COVID-19 has shown that our fates are inextricably linked. Whether we win or lose, we will do it together”.

- On 8 February, COVAX issued a [Statement on the new variants of SARS-CoV-2](#), stating that everything possible has to be done to reduce circulation of the virus and prevent infections as well as to reduce opportunities for further mutations to arise which may reduce efficacy of existing vaccines. To that end, COVAX states additional recommendations.

OECD:

- [Strengthening the frontline: How primary health care helps health systems adapt during the COVID 19 pandemic](#): The OECD policy response examines the potential of reforming primary care to be “organised in multi-disciplinary teams and with innovative roles for health professionals, integrated with community health services, equipped with digital technology, and working with well-designed incentives”.

Webinars/Other reports:

- [Webinar: Covid-19 vaccination rollout: Reflecting on the Israeli experience](#): The European Observatory on Health Systems and Policies is continuing its webinar series on 16 February 2021, 12.00h (Brussels time). Registration is available at the link provided.