COVID-19 EU update

European Commission:

- On 10 February 11:00-13:00, the Commission will host a webinar for healthcare professionals on COVID-19 vaccination. Please join here and find the agenda here. The webinar aims to reply to questions and concerns that healthcare professionals have about COVID-19 vaccines.
- On 2 February the European Commission admitted redaction errors when publishing the AstraZeneca vaccine contract. Parts of the redacted passages could be deciphered using the bookmark tool in Adobe Acrobat reader. EU commission spokesperson Eric Mamer told reporters "It was certainly not our intention for this to happen". Redacted parts of the contract were made readable and revealed that the contract was worth 870 million Euros and provided a breakdown of what is covered under the "costs of goods". However, the estimated delivery schedule remained redacted.
- On 31 January President Von der Leyen met CEOs of pharmaceutical companies that have signed advance purchase agreements with the European Commission. The discussion explored requirements of an EU Health Emergency Preparedness and Response Authority (HERA), to deliver a more structured approach to pandemic preparedness. HERA should anticipate threats and identify responses.

Council:

- On 2 February the Council updated its recommendations on travel restrictions from third countries into the EU.
- On 1 February the Council adopted updated recommendations on a coordinated approach to COVID-19 travel measures in the EU. A new color, dark red, has been added to the existing categories. This color applies to areas where the virus is circulating at very high levels. Member states should strongly discourage all non-essential travel to red and dark red areas and require persons travelling from such an area to undergo a test for COVID-19 prior to arrival and undergo quarantine / self-isolation.

The European Parliament

- On 5 February MEPs urge EU countries to be transparent about their COVID-19 vaccine supplies. Data on the number of vaccine doses supplied and on the vaccination schedules for each country must be transparent and provided on a monthly basis until the summer.
- On 1 February Budget MEPs quizzed DG Sante Director General Sandra Gallina on vaccine availability and the use of the EU budget. The Chair of the Budget Committee, Johan Van Overtveldt, emphasized that MEPs did "their duty by adopting the Emergency Support Instrument in April and by managing to triple the EU4Health and boost Horizon Europe research programs". MEPS asked about the disclosure of the contract with AstraZeneca arguing that "deals with pharmaceutical companies are of overriding public interest and should be disclosed". Some MEPs demanded 1.5 Billion Euros of unused funds from research programs and the EU budget margins to be used for the vaccine rollout in the EU. Gallina maintained that this money should be spent on tackling COVID-19 variants. With regard to the vaccine rollout, Gallina said she is relying on a breakthrough in the second quarter of 2021, on

companies whose vaccines are not yet registered, and on the second contract with BioNTech to reach the Commission vaccination objectives.

EMA:

- EMA starts rolling review of Novavax's COVID-19 vaccine. The Agency's decision to start the rolling review is based on preliminary results from laboratory studies (non-clinical data) and early clinical studies in adults. These studies suggest that the vaccine triggers the production of antibodies and immune cells that target SARS-CoV-2. The company is currently conducting trials in people to assess its safety, immunogenicity (how well it triggers a response against the virus) and its effectiveness against COVID-19. EMA will evaluate data from these and other clinical trials as they become available.
- EMA begins assessing coronavirus antibody treatments. The Agency will look at the clinical data associated with a combination antibody treatment against coronavirus developed by U.S. drugmaker Eli Lilly. The treatment involves two monoclonal antibodies, bamlanivimab and etesevimab. Both antibody drugs are being assessed as treatments for patients who aren't using supplementary oxygen, and who are at high risk of developing severe COVID-19. The two treatments have clinical evidence suggesting that they can reduce the viral load associated with a coronavirus infection, and by extension, lower the number of hospitalizations linked to COVID-19. It will provide more details when the data had been looked at.
- EMA starts rolling review of REGN-COV2 antibody combination (casirivimab / imdevimab), which is being co-developed by Regeneron Pharmaceuticals, Inc. and F. Hoffman-La Roche, Ltd (Roche) for the treatment and prevention of COVID-19. The decision to start the rolling review is based on preliminary results from a study that indicate a beneficial effect of the medicine in reducing the amount of virus in the nose and throat of non-hospitalised patients with COVID-19.
- EMA is piloting a new 'OPEN' initiative, the goal of which is to increase international collaboration on the evaluation of COVID-19 vaccines and therapeutics. The pilot started in December 2020. The collaboration allows sharing of scientific expertise during the evaluation of COVID-19 vaccines and therapeutics at a time when regulatory authorities and pharmaceutical industry are all facing common challenges. It will promote overall transparency and contribute to public trust in the vaccines and therapeutics. Regulators from Australia, Canada, Japan, Switzerland and the World Health Organization (WHO) are participating in the pilot.

ECDC

- ECDC starts monitoring COVID-19 vaccination progress across Europe. To monitor the progress of vaccination efforts across the EU, ECDC has set up a monitoring system for collection of key vaccine rollout indicators. The first set of data is now available on the ECDC website through the COVID-19 Vaccine Tracker, an interactive 'live' dashboard that provides the latest data reported by EU/EEA countries. To add context to the rollout numbers available in the Vaccine Tracker, ECDC releases an overview report on national COVID-19 vaccination strategies, vaccine deployment plans and their implementation, including new insights into some of the critically important challenges that countries are facing.
- A new report was published by the ECDC to provide an initial illustration of how the COVID-19 response could unfold in the vaccination era, given the emergence and replacement of the predominant strain with a novel, more transmissible variant. The report finds that due to the emergence of more transmissible variants of SARS-CoV-2, it will be necessary to strengthen and maintain response

measures in the coming months to avoid further rises in mortality, even in the context of a rapid, prioritised vaccination programme. Moreover, delays in vaccine procurement, distribution and administration would mean that non-pharmaceutical measures must be held in place for longer.

- ECDC released an overview of the implementation of COVID-19 vaccination strategies and vaccine deployment plans in the EU. It also provides new insights into some of the critical aspects and challenges of the implementation.
- A final report on stress test on logistical aspects of COVID-19 vaccination deployment plans. ECDC, together with the European Commission's DG SANTE, organised a stress test of the logistical aspects of COVID-19 vaccination deployment plans. Twelve EU/EEA Member States participated in this test, a focused simulation exercise conducted in two rounds, one in mid-December 2020 and the second in early January 2021. One of the most important aspects of the stress test was to provide an opportunity for those involved in developing their vaccine deployment plan to test it against a realistic scenario, to work through all the elements of deployment and provide reassurance that the plan was robust and that any issues identified could be addressed.

WHO/WHO Europe:

- COVID-19: Occupational health and safety for health workers: WHO has published an updated interim guidance on duties, rights and responsibilities for health and safety at work in the context of COVID-19. It sets out i.a. the role of employers in providing safe working conditions, including training. It also addresses support on mental health, stigma and harassment.
- WHO launches free OpenWHO.org training on rehabilitation for COVID-19: As part of its open access online courses providing training to health professionals on COVID-19 patient care, WHO has launched an eLearning event which addresses rehabilitation as well as living with impairments.
- Statement – Catastrophic impact of COVID-19 on cancer care: On the occasion of the launch of the Pan-European Cancer Initiative 'United Action Against Cancer', WHO-Europe Regional Director Hans Kluge highlighted the impact of the pandemic on cancer care, reporting i.a. that "[a]t the Kyrgyzstan National Center of Oncology, the number of cancers diagnosed in April last year dropped by 90%, while in the Netherlands and Belgium in the first lockdown of 2020, it dropped by 30–40%."
- Redoubling public health measures needed due to COVID-19 virus variants: WHO-Europe has published a factsheet on the SARS-CoV-2 Variant of Concern (VOC) first detected in the UK, summarising the status quo on transmissibility and effectiveness of vaccines.

OECD:

- Webinar on 'Vaccine equity and resilience building: two tests for global solidarity': On 8 February 2021, 12:00-14:00 (Brussels time), OECD Secretary-General Angel Gurria will host a discussion with political leaders, heads of international development agencies and civil society organisations on how to ensure a fair roll-out of COVID-19 vaccinations at global level. Registrations can be submitted here.

Webinars/Other Reports:

- Webinar on 'Covid-19 and the sustainability of health financing: anticipated effects and policy options': The European Observatory on Health Systems and Policies is hosting the next of its series of webinars on 9 February 2021, 12:00-13:00 (Brussels time).
- UK regulators say extra AstraZeneca vaccine data highlights efficacy in elderly, see Reuters article here.