COVID-19 EU update

European Commission:

- The contract between the EU and AstraZeneca is published. This follows the critique by Commissioner Kyriakides of AstraZeneca's announcement to supply considerably fewer doses than agreed upon. The Commissioner stated that "(t)he view that the company is not obliged to deliver because we signed a 'best effort' agreement is neither correct nor is it acceptable."
- The European Commission proposes an update to the Council Recommendation of October 2020 coordinating approach on free movement restrictions in the European Union. This update is part of the commission's ongoing efforts to ensure better coordination of travel measures across the EU. Non-essential travel is strictly discouraged. Concerning color coding, the Commission is proposing to add dark red (additionally to green, orange, red and grey) to indicate areas where the virus is circulating at very high levels. This would apply to an area where the 14-day notification rate is more than 500 per 100 000 people.
- On 29 January, the Commission put in place transparency and authorization mechanisms for exports of COVID-19 vaccines. Such exports outside the EU of COVID-19 vaccines will require authorization by Member states until the end of March 2021. This scheme only applies to exports from companies with whom the EU has concluded Advance Purchased Agreements, see Press Release

Council:

- On 28.01.2021, the Council published the results of their reviewed list of third countries for which member state should gradually lift restrictions on non-essential travel (Australia, New Zealand, Rwanda, Singapore, South Korea, Thailand and China (which is still subject to reciprocity confirmation). In this context, residents of Andorra, Monaco, San Marino and the Vatican should be considered as EU residents. Schengen associated countries, such as Iceland, Lichtenstein, Norway and Switzerland, are also part of this recommendation.

EMA:

- EMA recommends Oxford/AstraZeneca coronavirus vaccine for authorisation in the EU. The decision by the European Commission is pending. EMA has recommended granting a conditional marketing authorisation in people from 18 years of age. This is the third COVID-19 vaccine that EMA has recommended for authorisation.
- On 29 January, EMA updated the Comirnaty vaccine safety. The update concludes that safety data collected on Comirnaty use in vaccination campaigns is consistent with the known safety profile of the vaccine, and no new side effects were identified. This safety update includes the assessment by EMA's safety committee (PRAC) of deaths reported after vaccination with Comirnaty, including deaths in frail, elderly people. PRAC carried out an analysis of the cases and took into account the presence of other medical conditions and the death rate for corresponding age groups in the general population. PRAC concluded that the data did not show a link to vaccination with Comirnaty and the cases do not raise a safety concern. Further reports will continue to be carefully monitored. EMA will publish monthly safety updates for all authorised COVID-19 vaccines, in line with exceptional transparency measures for COVID-19.
- On 28 January, EMA has updated the product information for the Comirnaty COVID-19 vaccine, clarifying its position regarding the interval between the first and second dose. The new

recommendations state a 3-week interval between the two doses as opposed to previously having stated “at least 21 days”.

WHO/WHO Europe:

- On 19 January, the GACVS COVID-19 Vaccine Safety subcommittee met to review reports of deaths of frail elderly individuals, vaccinated with the BioNTech/Pfizer COVID-19 mRNA vaccine. The Press Release following this meeting states that current reports do not suggest an unexpected increase in mortality following the vaccina administrations with the information available not confiring a contributory role for the vaccine in reports events. The committee thus considered the benefit-risk balance remaining in favor for elderly, not suggesting revision to the recommendations at present. The Press Release further states that countries should continue to monitor the safety of vaccines and promote after care on a routine basis following immunization. The committee also recommends the collection of data for continuous review nationally, regionally and globally and they will continue to monitor the safety data from these vaccines.
- On 22 January, COVAX announced the signing of an advance purchase agreement of up to 40 million doses of the Pizer / BioNTech vaccine with rollout to commence with successful agreements being. Made. Additionally, it was announced that nearly 150 million doses of the AstraZeneca vaccine candidate, pending WHO emergency use listings, are anticipated in the first Quarter of 2021

Webinars/Other Reports:

- UN expert says global coordination and more equitable sharing of COVID-19 vaccines key to recovery. “A globally coordinated vaccine distribution programme is highly preferable to the individualised approaches adopted by all-too-many of the richer states. International vaccine solidarity should be much preferred over international vaccine competition, such as the COVID-19 Vaccine Global Access Facility (COVAX) led by the World Health Organization that aims at global equitable access to COVID-19 vaccines by fairly distributing two billion doses by the end of 2021.”
- The Council of Europe Committee on Bioethics had made recommendations, particularly concerning vulnerable groups with difficult access to health services and have issued a press release entitled: COVID-19 and vaccines: Equitable access to vaccination must be ensured
- Health and care workers are owed a better future: The Lancet editorial highlights the need for policies to support healthcare professionals, in particular in relation to vaccination programmes.