COVID-19 EU update

European Commission:

- On 8 January 2021, the Commission proposed to purchase up to 300 million additional doses of BioNTech-Pfizer vaccine. The additional doses will be delivered starting in the second quarter of 2021. Please find more here.
- On 6 January 2021, the Commission granted a conditional marketing authorisation for the second vaccine against COVID-19 developed by Moderna. This authorisation follows a positive scientific recommendation based on a thorough assessment on safety and effectiveness by the European Medicines Agency (please find more in the EMA section of this document).

EMA:

- The University of Oxford/AstraZeneca will submit their jointly-produced coronavirus vaccine to the EMA next week — with a decision on approval for use across the bloc expected by the end of January, the Agency informed during a public meeting today. The EMA already has the drug-makers' phase 3 data as part of a rolling review, but the vaccine producers are yet to hand a formal submission for conditional marketing authorization from the EU regulator. The U.K. regulator approved the vaccine on December 30 and has begun rolling it out.
- EMA has recommended that six doses should be extracted from a single BioNTech/Pfizer coronavirus vaccine vial, rather than the original five. After the vaccine — which is sold as Comirnaty in the EU — was approved by several regulators, health professionals discovered that they could draw enough for a sixth dose despite the formal product information indicating that the vials contained five doses. The EMA is recommending that special syringes — called low dead-volume syringes — are used to ensure that the full six doses can be extracted. However, if there isn't enough vaccine remaining to make up a full sixth dose, the EMA says that the contents must be discarded. Leftover vaccine from several vials should also not be combined to make up an additional dose, it said in a statement.
- EMA recommends conditional marketing autorisation of Moderna coronavirus vaccine: On Wednesday, the EMA recommended and the Commission granted a conditional marketing authorization (CMA) for Moderna vaccine to be used for people over the age of 18. In a clinical trial of around 28,000 people, the two-dose mRNA vaccine was 94.1 percent effective in preventing COVID-19 cases, and almost 91 percent effective in preventing severe cases. CMA means that Moderna must provide more information throughout the next two years, including how long immunity lasts and whether the vaccine prevents the transmission of the virus. But the EMA decision means that the vaccine is safe, effective and ready to use. The Commission has already secured 160 million doses of the vaccine, and deliveries will start next week. It is the most expensive vaccine at $18 a dose, according to a leaked price list from December. In addition to the price, Moderna has limited production capacity in Europe. The company will be able to supply 10 million doses by the end of the first quarter of 2021, 35 million by the second quarter and another 35 million by the third quarter. The additional 80 million doses that the EU secured in December will also be distributed in 2021, but the company did not clarify when that would take place.
- EMA provides an update on rolling review of AstraZeneca's COVID-19 vaccine: So far, some evidence has been assessed on safety and efficacy coming from a pooled analysis of interim clinical data from four ongoing clinical trials in the UK, Brazil and South Africa. The latest clinical package was received on 21 December and is currently being assessed. The Agency has already assessed data from laboratory studies (non-clinical data) and is currently assessing data on the vaccine's quality (on its ingredients and the way it is manufactured). Further information from the ongoing clinical trials is also expected from January. Interim data from a large trial ongoing in the USA are expected in Q1 2021.

- EMA publishes a paediatric investigation plan for the COVID-19 vaccine developed by AstraZeneca, in collaboration with the University of Oxford.

ECDC:

- ECDC releases an update on COVID-19 vaccination and prioritisation strategies in the EU. The report notes that the choice of optimal vaccination strategy depends on the objective, e.g. reducing mortality, saving life years or reducing pressure on the healthcare system as well as on the characteristics of the vaccine, in particular its efficacy against infection and therefore onward transmission. If a vaccine does not protect against transmission, the most effective and efficient approach is to prioritise the vaccination of those groups at highest risk of severe disease and death.
- ECDC releases an update on COVID-19 in children and the role of school settings in transmission. The document points out that there is a general consensus that the decision to close schools to control the COVID-19 pandemic should be used as a last resort. The negative physical, mental health and educational impact of proactive school closures on children, as well as the economic impact on society more broadly, would likely outweigh the benefits.
- ECDC publishes a new risk assessment relate to spread of new SARS-CoV-2 variants of concern in the EU. The Agency points out that viruses constantly change through mutation, and so the emergence of new variants is an expected occurrence and not in itself a cause for concern; SARS-CoV-2 is no exception. A diversification of SARS-CoV-2 due to evolution and adaptation processes has been observed globally. While most emerging mutations will not have a significant impact on the spread of the virus, some mutations or combinations of mutations may provide the virus with a selective advantage, such as increased transmissibility or the ability to evade the host immune response. In such cases, these variants could increase the risk to human health.

WHO/WHO Europe:

- COVID-19 and the disruption of noncommunicable disease services: WHO-Europe has published survey results which offer a snapshot of the backlog of health services including rehabilitation, cancer treatment and cardiovascular emergencies in different countries. Main causes of disruption are cancelled elective surgery, closed screening programmes and closed NCD clinics, however patients' reluctance to seek out healthcare services also played an important role. The report notes that the WHO-European region was unique in that it used digital health solutions and task-shifting to mitigate some of the consequences.
- Health inequity and the effects of COVID-19: WHO-Europe has assessed the pandemic's impact on exacerbating health inequalities and found three main root causes: unequal socioeconomic impacts arising from both (i) the health effects of COVID-19 and their inequities and (ii) COVID-19 containment measures; and (iii) the bidirectional effects between the unequal socioeconomic impacts of COVID-19 and non-COVID-19-related health inequities. In addition to mapping out indicators of inequalities, it looks at solutions both in terms of prevention and mitigation. Its conclusions highlight the importance of long-term political commitment to tackling the underlying factors.
- Rational use of personal protective equipment for coronavirus disease (COVID-19) and considerations during severe shortages: The WHO technical guidance considers transmission scenario, setting, and activity of healthcare professionals to assess need for PPE and provides updated recommendations for the decontamination or reprocessing of PPE.

Webinars/Other Reports:

- On 13 January, 14:45-16:45 in conjunction with three European Commissioners, several MEPs and representatives of CureVac, Pfizer, Biontech and Moderna discuss the European Health Union, live on:

Facebook:https://www.facebook.com/EPPGroup/live/, YouTube:https://youtu.be/wmZuciFz5DA, Twitter:@eppgroup

- Webinar: Ethics in the Covid-19 Pandemic, Wednesday, 13.01.2021, 13.00 - 14.00 pm (Brussels Time), Panel discussion with Bishop Dr. Franz-Josef Overbeck, Vice-President of the Commission of the Bishops' Conferences of the EU (COMECE) and Prof. Dr. Christiane Woopen, Cologne/Brussels, Professor of Medical Ethics and Chair of the European Group on Ethics in Science and Technologies. Registration here.
- International survey results on COVID-19 management strategies by J. Braithwaite, P. Lachman et al. in preparation of the Florence ISQua congress.
- Vaccinate medical staff to ensure an effective campaign against COVID-19: The Federation of the European Academies of Medicine (FEAM) is calling for “high priority vaccination of health personnel and support staff providing direct and daily care for COVID-19 patients during the earliest phases of vaccination. As health personnel and support staff can transmit the disease to patients and fragile individuals while being asymptomatic, we also support the vaccination of all health personnel and support staff as soon as possible."
- A survey of over 7000 doctors conducted by the BMA in December found that, while many thought that their colleagues were coping with work during the covid-19 pandemic, most had concerns about the standard of patient care being delivered.