COVID-19 EU update

European Commission

- The European Commission introduced the principles of reciprocity and proportionality as new criteria to be considered for authorizing exports under the transparency and authorization mechanism for COVID-19 vaccines. With regards to reciprocity, the Commission will consider whether the country of destination restricts its own exports of vaccines or raw materials. With regards to proportionality, the Commission will consider whether the conditions prevailing in the destination country are better or worse than the conditions in the EU.
- On March 17th, The European Commission has proposed a new digital green certificate. The new Digital green certificate will be proof that a person has been vaccinated against COVID-19, received a negative test result or recovered from COVID-19. The Commission will build a gateway to ensure all certificates can be verified across the EU. Member states are responsible to decide which restrictions can be waived for travelers holding a Digital Green Certificate.

European Parliament

- On 16 March, the ENVI Committee held an exchange of views with the EMA, ECDC and WHO on COVID Variants and the vaccines efficacy against them. MEPS expressed their concerns regarding fast-spreading variants given the vaccination rate across the EU remains lower than expected. Commission Deputy Director-General for Health Pierre Delsaux presented the Commission's communication on the HERA incubator. The Commission has also proposed to amend the current regulatory procedure to allow for COVID-19 vaccines that are adapted to new variants to be approved more quickly.

Council of the EU

- Ministers held an exchange of views on the implementation of non-pharmaceutical interventions during the Informal video conference of health ministers on March 16 2021. Fergus Sweeny, head of the EMA's Clinical Studies and Manufacturing Taskforce informed ministers that the EMA is carrying out a full assessment and investigation on correlation between the AstraZeneca vaccine and thromboembolic events. Ministers emphasized the need for greater cooperation in information sharing and crucial prevention measures.

European Council

- Following its meeting on 25 March, the European Council published a statement addressing i.a. the need to continue the vaccine roll-out in a spirit of solidarity, confirming a pro-rata population key for the allocation of vaccines; the need to restrict non-essential travel and at the same time work on digital vaccination certificates; and to ensure the EU takes responsibility also at global level.

EMA

- EMA published a communication on risk of thrombocytopenia and coagulation disorders associated with COVID-19 Vaccine AstraZeneca: the European Medicines Agency published the Direct Healthcare Professionals Communication (DHPC) which contains important information for professionals

prescribing, dispensing or administering COVID-19 Vaccine AstraZeneca. The communication notes that, among others:

- Benefits of the COVID-19 Vaccine AstraZeneca outweigh the risks despite possible link to very rare blood clots with low blood platelets.
- A combination of thrombosis and thrombocytopenia, in some cases accompanied by bleeding, has been observed very rarely following vaccination with COVID-19 Vaccine AstraZeneca.
- Healthcare professionals should be alert to the signs and symptoms of thromboembolism and or thrombocytopenia.
- Those vaccinated should be instructed to seek immediate medical attention if they develop symptoms such as shortness of breath, chest pain, leg swelling, persistent abdominal pain following vaccination. Additionally, anyone with neurological symptoms including severe or persistent headaches and blurred vision after vaccination, or who experiences skin bruising (petechia) beyond the site of vaccination after a few days, should seek prompt medical attention.

You can find the full text of the DHPC here.

- EMA provides an update on ongoing evaluation of blood clot cases associated with AstraZeneca COVID-19 Vaccine: Last week, EMA's safety committee, PRAC, concluded its preliminary review of cases of blood clots, including very rare cases of blood clots with unusual features such as low numbers of platelets, in people vaccinated with the AstraZeneca vaccine. The committee confirmed that the vaccine is not associated with an increase in the overall risk of blood clots and that the benefits of the vaccine in combating the still widespread threat of COVID-19 continue to outweigh the risk of side effects. The committee recommended including more information and advice for healthcare professionals and the public in the vaccine's product information. PRAC is continuing its assessment of the reported cases. In this context, EMA is convening an *ad hoc* expert group on 29 March to provide additional input into the assessment. External experts in haematology (thrombosis and haemostasis), cardiovascular medicine, infectious diseases, virology, neurology, immunology and epidemiology will meet to provide their views to PRAC.The outcome of the expert meeting, together with further analysis of the reported cases, will feed into PRAC's ongoing evaluation. The updated recommendation on the issue is expected during its April plenary meeting (6–9 April).
- EMA advises against use of ivermectin for the prevention or treatment of COVID-19 outside randomised clinical trials: EMA has reviewed the latest evidence on the use of ivermectin for the prevention and treatment of COVID-19 and concluded that the available data do not support its use for COVID-19 outside well-designed clinical trials. Laboratory studies found that ivermectin could block replication of SARS-CoV-2 (the virus that causes COVID-19), but at much higher ivermectin concentrations than those achieved with the currently authorised doses. Results from clinical studies were varied, with some studies showing no benefit and others reporting a potential benefit. Most studies EMA reviewed were small and had additional limitations, including different dosing regimens and use of concomitant medications. EMA therefore concluded that the currently available evidence is not sufficient to support the use of ivermectin in COVID-19 outside clinical trials.
- EMA published updated product information for COVID-19 Vaccine AstraZeneca in all EU languages, following its review of a signal of blood clots

- EMA published the assessment report for its review of the antibody combination bamlanivimab / etesevimab in COVID-19 patients

ECDC

- ECDC published considerations on the use of self-tests for COVID-19 by public health authorities. The document only considers rapid antigen detection tests (RADTs) for self-testing for direct detection of SARS-CoV-2 virus particles in infectious individuals.
- ECDC published a report presenting a coherent, yet non-prescriptive framework for tuning COVID-19 response measures in the European Union and European Economic Area. Its aim is to ensure efficiency and encourage public trust and compliance, while continuing to protect the health of European citizens.

WHO-Europe

- WHO Global Advisory Committee on Vaccine Safety (GACVS) COVID-19 subcommittee reviews safety signals related to the AstraZeneca COVID-19 vaccine: the WHO committee has adopted a statement which supports the EMA's approval for the continued use of the AstraZeneca vaccine.
- WHO engages health workers in Romania to reach out on the benefits of COVID-19 vaccines in pilot project: Health professionals have been offered a training in patient communication to address specific questions and concerns arising the context of the COVID-19 vaccines, including on safety and non-pharmaceutical countermeasures. WHO also introduced a COVID-19 Vaccination Patient Communication Algorithm to assess tailored interventions based on patients' individual level of vaccine acceptance.

OECD

- Closing vaccine borders provides a false sense of security. Enabling global flows allows vaccine supply chains to deliver more vaccines to all: this blog article looks at the importance of global trade flows for the sustainable production and supply of vaccines and their ingredients. It advises against export controls and calls instead to increase production in all locations where it is technically feasible.

Webinars/Other reports:

- The Irish Department of Health has published the following documents on Ethical considerations in critical care: Ethical considerations relating to critical care in the context of COVID-19 and Ethical Considerations Critical Care: Supplementary Information. Other ethical documents relating to Covid can be found here.
- Switzerland has published triage guidelines for intensive care units concerning COVID-19 here. They are available in French and English.