COVID-19 EU update

European Commission:

- On 20 August, the European Commission concluded exploratory talks with CureVac to purchase a potential vaccine against COVID-19. The envisaged contract would provide for the possibility for all EU Member States to purchase the vaccine, as well as to donate to lower and middle income countries or re-direct to European countries. It is anticipated that the Commission will have a contractual framework in place for the initial purchase of 225 million doses on behalf of all EU Member States. The Commission pursues intensive discussions with other vaccine manufacturers.
- On 14 August, the European Commission has reached a first agreement with AstraZeneca to purchase a potential vaccine against COVID-19 as well as to donate to lower and middle income countries or re-direct to other European countries. Once the vaccine has proven to be safe and effective against COVID-19, the Commission now has agreed the basis for a contractual framework for the purchase of 300 million doses of the AstraZeneca vaccine, with an option to purchase 100 million more, on behalf of EU Member States. The Commission continues discussing similar agreements with other vaccine manufacturers. The agreement will be financed with the Emergency Support Instrument, which has funds dedicated to the creation of a portfolio of potential vaccines with different profiles and produced by different companies.
- On 13 August, the European Commission concluded exploratory talks with Johnson & Johnson to purchase a potential vaccine against COVID-19. The envisaged contract would provide for the possibility for all EU Member States to purchase the vaccine, as well as to donate to lower and middle income countries or re-direct to EEA countries. It is anticipated that the Commission would have a contractual framework in place for the initial purchase of 200 million doses on behalf of all EU Member States and could further purchase up to an additional 200 million vaccine doses. The Commission pursues intensive discussions with other vaccine manufacturers.
- On 31 July, the European Commission has concluded exploratory talks with Sanofi-GSK to purchase a potential vaccine against COVID-19. The envisaged contract would provide for an option for all EU Member States to purchase the vaccine. It is envisaged that the Commission would have a contractual framework in place for the purchase of 300 million doses, on behalf of all EU Member States. The Commission continues intensive discussions with other vaccine manufacturers.
- On 18 August, the European Commission approved funding for training of healthcare professionals in intensive care skills. The €2.5 million funding comes from the Emergency Support Instrument available for training of healthcare professionals supporting and assisting Intensive Care Units (ICU) during the COVID-19 pandemic. The training will provide skills to healthcare professionals not regularly working in ICUs. This will help increase the capacity of staff that could be deployed at a time when there is need for rapid, temporary and significant scale-up of ICU capacity. This programme, implemented evenly across the EU, will cover a minimum of 1,000 hospitals and 10,000 doctors and nurses, and will be deployed between August and December 2020.

Council:

- Following a review under the recommendation on the gradual lifting of the temporary restrictions on non-essential travel into the EU on 7 August, the Council updated the list of countries for which travel restrictions should be lifted. As stipulated in the Council recommendation, this list will continue to be reviewed regularly and, as the case may be, updated.
- The Council made available a simplified infographic on the EU budget 2021-2027 and recovery plan. Please, find it here.

ECDC:

- The ECDC shares a summary of Member States' experiences and perspectives relating to the different population-wide testing approaches. The report finds that different population-wide testing approaches have already been used in various countries, including household testing, individual testing and the testing of incoming travelers, irrespective of whether or not they are displaying symptoms. It discusses these options in the context of the EU/EEA and the UK.
- The ECDC describes COVID-19 clusters and outbreaks linked to occupational settings (including healthcare and non-healthcare settings) and identifies possible factors contributing to transmission in these settings. The report observes that besides health sector, large numbers of occupational COVID-19 clusters reported were from the food packaging and processing sectors, in factories and manufacturing, and in office settings. It also emphasizes the importance of testing for COVID-19 in workplace settings, combined with robust polices on physical distancing, hygiene and cleaning and appropriate use of personal protective equipment (PPE) where recommended.
- The ECDC provides an overview of major aspects of testing, contact tracing, contact identification and contact follow-up in school settings. It identifies several objectives for testing in schools, i.e. to ensure early identification of cases among students and staff, and to identify infection in students and staff at high risk of developing severe disease due to underlying conditions. Moreover, appropriate testing can also support investigations and studies concerning the role of children in the transmission of COVID-19.
- The ECDC provides an overview of the epidemiology and disease characteristics of COVID-19 in children (0-18 years) and an assessment of the role of childcare (preschools; ages 0-<5 years) and educational (primary and secondary schools; ages 5-18 years) settings in COVID-19 transmission. It notes that less than 5% of overall COVID-19 reported cases are among children and that when diagnosed with COVID-19, children are much less likely to be hospitalized or have fatal outcomes than adults. Moreover, the report points to difficulties in the detection of outbreaks of COVID-19 in schools due to the relative lack of symptoms in children. The overview was followed by a dedicated infographic.
- The ECDC provides a guidance to facilitate the re-start of operations of cruise ships in the EU, by recommending minimum measures expected to be implemented. It is addressed to EU/EEA flagged ships engaged in international voyages and for ships calling at an EU/EEA port irrespective of flag. The guidance was supplemented by an infographic.

EMA:

- EMA starts review of dexamethasone: EMA is reviewing results from the RECOVERY study arm that involved the use of dexamethasone in the treatment of patients with COVID-19 admitted to hospital. This part of the study looked into the effects of adding dexamethasone to usual care in adults receiving invasive ventilation, those given oxygen (e.g. through a mask) or those receiving no oxygen. Dexamethasone is a corticosteroid medicine that has been authorised in the EU by national medicines authorities and has been available for several decades. It can be used by mouth and by injection for treating a range of inflammatory conditions and for reducing the body's immune response in the treatment of allergies and autoimmune diseases.
- Regulators have agreed on acceptable clinical-trial endpoints to facilitate rapid and consistent clinical trials for COVID-19 treatments. International regulators have published a report on the acceptability of various primary endpoints in the clinical trials conducted for the development of treatments for COVID-19. Many developers of medicines for the treatment of COVID-19 have already or are in the process of conducting clinical trials and have approached their regulatory authorities with proposals for phase 3 clinical trials.

- Global regulators participated in the 3rd workshop on COVID-19 real-world evidence and observational studies. The main topics of the meeting were vaccines surveillance and vigilance, collaboration on pregnancy studies and building international patient cohorts. The main findings of the workshop are summarised in a report.

WHO/WHO-Europe:

- WHO Bulletin: The August issue includes the following articles:
  Pandemic risks for refugee populations
  Finding the SARS-CoV-2 source
  Expediting regulation for COVID-19-relevant medical products
  Testing messages used in the pandemic response
  The impact of airline travel restrictions on SARS-CoV-2 transmission
- WHO helps reshape hospitals as COVID-19 eases its grip: WHO-Europe is liaising with hospitals to improve the use of physical space in the facilities, to facilitate the management of future pandemics. This includes the proposal to shift from categorising wards as 'COVID-19 wards' and 'non-COVID-19 wards' to low-risk and medium-risk spaces.
- Home care for patients with suspected or confirmed COVID-19 and management of their contacts: this updated WHO guidance sets out considerations on the basis of which to assess if COVID-19 patients can safely stay at home, what implications this has for family members or other contacts, and what hygiene measures should be followed in the patient's home to avoid further transmission.

OEDC

- Greater harmonisation of clinical trial regulations would help the fight against COVID-19: the OECD policy response calls for international coordination of clinical trials, to streamline not only regulatory requirements but also processes such as patient recruitment. It looks i.a. at a review of national Health authorities' guidance to establish which barriers are still slowing down the search for a vaccine. As one solution, it is proposed to follow the OECD Recommendation on the Governance of Clinical Trials to assess risk and adapt protocols accordingly.

COVID-19 and Data Protection:

- On 28 July, the EDPB published its response to MEP Mrs Ďuriš Nicholsonová's letter on follow up questions in the fight against the COVID-19 pandemics. The EDPB confirms the need of carrying out a data protection impact assessment (DPIA) for the contact tracing apps and that time pressure is not a justification for not conducting it. A DPIA is part of the privacy by design approach promoted by the GDPR.
- On 29 July, the JRC published a report on 'Artificial Intelligence and Digital Transformation: early lessons from the COVID-19 crisis'. The COVID-19 pandemic has acted as a booster for artificial intelligence, but concerns about security, potential misuse of data and growing inequalities remain. The researchers noted an **increased adoption and use of AI in scientific and medical research**, in particular in applications such as telemedicine, medical diagnosis, epidemiological studies, and clinical management of patients. There was also a shift in attitudes towards AI and data sharing. According to the study, the crisis resulted into a greater acceptance of robots in the workplace and of data sharing for the monitoring of the spread of the virus. Similarly, the crisis made it possible to overcome barriers in the sharing of data between commercial entities, and between business and governments (ex. using data provided by private mobile network operators). **Teleworking gained wider acceptance** as part of the normal working arrangements,

with potential social and environmental benefits. The COVID-19 crisis underlined the **absolutely critical role of the governance of digital data** in modern societies. How data is collected, by whom, for what purpose, how it is accessed, shared and re-used have become central questions during the crisis (ex. concerns about possible misuse of people's private data for purposes other than contact tracing or the monitoring of the spread of the virus. The **lockdown also highlighted the European dependency on non-European collaborative platforms** and accelerated the process of market polarisation on big digital platforms. This dependency adds to the **cybersecurity concerns**. The report calls for a strong coordination to strengthen European technological and data sovereignty and address the increasing inequalities.

COVID-19 and Human Rights:

- On 30 July, the Fundamental Rights Agency published the 4th Bulletin on the Coronavirus pandemic in the EU - Fundamental Rights Implications - Bulletin 4. The report outlines some of the measures EU Member States adopted to safely reopen their societies and economies while continuing to mitigate the spread of COVID-19. It highlights the impact these measures may have on civil, political and socioeconomic rights. For previous Bulletins see here.

Reports from other sources/Webinars:

- The hospital of the future in times of COVID-19: From 20-30 July, the European Observatory on Health Systems and Policies organised an online summer school in cooperation with the Veneto Region of Italy, the European Commission and WHO. The topics for discussion ranged from trends in balancing care in the community and hospital care, task-shifting, and new approaches to financing, to the role of hospitals in managing the pandemic. Recordings of all sessions and presentations are available online.
- The article "Low Incidence and Mortality from SARS-CoV-2 in Southern Europe. Proposal of a hypothesis for Arthropod borne Herd immunity" by Dr Martin Balzan has been published in the Journal of Medical Hypotheses.
- Launched on 22 July 2020, the COVID-19 Law Lab initiative gathers and shares legal documents from over 190 countries across the world to help states establish and implement strong legal frameworks to manage the pandemic. The goal is to ensure that laws protect the health and wellbeing of individuals and communities and that they adhere to international human rights standards. The new Lab is a joint project of United Nations Development Programme (UNDP), the World Health Organization (WHO), the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the O'Neill Institute for National and Global Health Law at Georgetown University.