COVID-19 EU update

European Commission

- On 1 July 2021, the EU Digital COVID Certificate entered into application in the EU. It aims at facilitating safe and free movement in the EU during the pandemic. It is (digital) proof that a person has either been vaccinated against COVID-19, received a negative test result, or recovered from COVID-19. Please find more here.

- On 29 June 2021 the Commission issued a press release announcing that the first portfolio of five therapeutics that could be soon available to treat COVID-19 patients across the EU. These five products are in an advanced stage of development and have a high potential to be among the new COVID-19 products to receive authorization by October 2021, provided the final data demonstrate their safety, quality and efficacy. The products are Baricitinib immunosuppressant from Eli Lilly with a new COVID-19 indication for existing medicine, as well as four newly developed monoclonal antibodies under rolling review i.e. combination of Bamlanivimab and Etesevimab from Eli Lilly, combination of Casirivimab and Imdevimab from Regeneron Pharmaceuticals, Inc. And F.Hoffman-La Roche LTD, Regdanivimab from Celltrion, and Sotrovimab from GSK and Vir Biotechnology.

- In a press release issued on 29 June 2021, the European Commission announced that the EU is helping Norway to deliver over 180,000 doses of COVID-19 vaccines to Kosovo, following Kosovo’s request for assistance via the EU Civil Protection mechanism.

- On 29 June 2021, the Commission proposes coordinated measures for the safe reopening of the cultural and creative sectors, publishing EU guidelines to ensure the safe resumption of activities in the cultural and creative sectors across the EU. The guidelines, based on expertise of the ECDC and exchanges with the Health Security Committee, aim to provide a coordinated approach in line with the specific national, regional and local conditions, taking into account the different epidemiological situations in the Member States and their evolution. They are expected to guide the design and implementation of measures and protocols in EU countries to cover both the safe reopening as well as the sustainable recovery in the cultural and creative sectors. The guidelines provide indicators and criteria, such as viral circulation, vaccination coverage, use of protective measures and the use of tests and contact tracing to be taken into account when planning the resumption of certain activities.

- On 28 June, the Commission published the implementing decision laying down technical specifications and rules for the EU Digital COVID Certificate.

European Parliament

- The European Parliament’s ENVI Committee has adopted its negotiating position on the revision of the ECDC’s mandate with a large majority. MEPs are supportive of extending the mandate as proposed by the Commission and even suggest that ECDC should also monitor major non communicable diseases such as cardiovascular diseases, cancer, diabetes and mental illness. To better support the work of the ECDC, EU countries should develop national preparedness and response plans, and provide timely, comparable and high quality data on the surveillance of communicable diseases. ECDC and national authorities should agree on common timelines, case definitions, protocols, and procedures, as well as, indicators and standards to assess health systems’ capacities through inspections. MEPs support the creation of a permanent EU Health Task Force in close coordination with the Union Civil Protection Mechanism, a platform to monitor levels of national vaccinations coverage, improving consultation with civil society and industry through a new permanent framework for the prevention of communicable diseases, and ensuring
full respect of data protection principles. The Council has not yet adopted its position on this draft law, so trilogue negotiations between the co-legislators will not be launched yet.

- In a speech given at the EU Parliament on 24 June 2021, the newly re-elected UN Secretary General António Guterres reiterated the need for a global COVID-19 vaccination plan, stating that the virus remains “a threatening reality in many places around the world, and therefore to us all.” He furthermore reiterated the need for countries producing vaccines to come together in an emergency task force, supported by WHO, Gavi Vaccine Alliance and international financial institutions to mobilise pharma companies and industrial actors. The full speech is available here.

**EMA**
- EMA published a new guidance for manufacturers on submitting a variation application to address SARS-CoV-2 variants by updating the composition of an authorised COVID-19 vaccine. The guidance includes recommendations on how to name the variant vaccine.

**ECDC**
- On 29 June, ECDC published the report on countering online vaccine misinformation in the EU/EEA, with a focus on misinformation related to vaccination against measles (in combination with mumps and rubella), human papillomavirus (HPV), influenza, and COVID-19. The report explores the evidence base for how to counter online vaccine misinformation in the EU/EEA, current strategies used by public health authorities in a selection of EU countries, and training needs on this topic. This study provides insights for national public health authorities into the factors behind the spread of vaccine misinformation online and the options and capacities needed for responding to it. The study will also serve to inform the development of a training package to support those authorities (and other interested organisations) in their work in this area.
- ECDC, in cooperation with WHO-Europe has proposed an indicator framework to evaluate the public health effectiveness of digital proximity tracing solutions for COVID-19. This indicator framework is intended for use by relevant national health authorities, public health and related institutions and their partners involved in the planning, implementation, monitoring and evaluation of contact tracing activities. The framework proposes a list of indicators to assist public health authorities in measuring: i) the extent to which digital proximity tracing solutions have been used; ii) the extent to which they have been successful in detecting contacts at risk of infection; iii) the speed at which digital proximity tracing approaches can notify potential contacts, when compared to conventional contact tracing; and iv) enablers and barriers to their usage.

**WHO/Europe**
- On 24 June, the Directors General of WHO, WIPO and WTO agree to intensify their cooperation in support of access to medical technologies worldwide to tackle the pandemic. The three agencies will collaborate on the organisation of practical, capacity building workshops to enhance the flow of updated information on current developments in the pandemic. The first workshop in the series will address the technological transfer and licensing and is scheduled to take place in September. The three agencies furthermore aim to implement a joint platform for technical assistance to countries relating to needs for COVID-19 medical technologies. The platform will particularly support countries to assess and prioritise unmet needs for COVID-19 vaccines, medicines and related technologies and provide timely and tailored technical assistance in making full use of available options to access vaccines, medicines and technologies and coordinate between member states facing similar challenges.
Other reports/webinars

- **FRA Bulletin on Vaccine rollout and equality of access in the EU**: The Fundamental Rights Agency (FRA) has published a Bulletin that focuses on the equitable access to vaccines. It outlines the situation in the 27 EU Member States from 1 March to 30 April 2021. The bulletin looks at two main areas: planning and prioritisation in deploying Covid-19 vaccinations and their rollout in the countries. It covers information and communication campaigns, as well as (pre)registration channels for and the administration of vaccinations.

- **One year of CED work on COVID-19**: The Council of European Dentists (CED) has reflected on the impact on and role of dentists during the COVID-19 pandemic. The lessons learnt confirm dentists’ position in the health workforce and the need to provide adequate support both through PPE and where necessary compensation for income loss. It is underlined that dental services can be delivered safely and governments should ensure that there is no disruption to the provision of dental care. Lastly, dentists are called upon to take up the COVID-19 vaccination and promote it to patients.

- On 30 June, the eHealth network issued **Guidelines on Validation of EU Digital COVID Certificates**. Following the entry into force of the EU Digital COVID-19 Certificate Regulation, the eHealth Network Subgroup on Technical Interoperability, in cooperation with airline experts propose possible scenarios and technical solutions to swiftly implement the verification of Covid Certificates in the context of air travel. The Regulation allows passenger transport services operators to process data to verify and confirm the holder’s vaccination, test result or recovery. The data processed for this purpose shall not be retained. The verification should preferably take place before arrival at the airport and only once in the passenger journey.