European Parliament

- The ENVI Committee adopted the draft negotiating position for a new regulation on tackling serious cross border health threats, with 65 votes in favour, 10 against and one abstention. The regulation will be voted upon by all MEPs during the September plenary session. MEPs call for clear procedures and increased transparency for EU joint procurement activities. They furthermore call for a One Health approach as well as ensuring that communicable diseases as well as the impact of pathogens on non-communicable diseases are monitored as part of an EU public health policy. The draft Report also calls for the involvement of relevant EU agencies in discussing political and technical topics. The full press release from the parliament is accessible here. With its support for stronger role for the Health Security Committee, the collection of health systems data and recommendation on minimum capacities, as well as strict rules for the collection of patient data, the EP position reflects the CPME’s recommendations very closely. For the CPME response to the vote, please see our press release here.

European Commission

- On 10 July, President von der Leyen made a statement on the EU reaching its summer milestone of vaccines delivered, stating that enough vaccines were delivered to member states to have at least 70% of EU adults vaccinated until the end of the month. She furthermore stated that by 11 July some 500 million vaccine doses will have been distributed across regions of the EU, stating that “now Member States must do everything, to increase vaccinations.”
- The Republic of Senegal and Team Europe agree to build a manufacturing plant to produce vaccines against COVID-19 and other endemic diseases. Team Europe formally agreed to support large scale investment in vaccine production by the Institute Pasteur in Dakar. The new manufacturing plant aims to reduce Africa’s dependency on vaccine imports and strengthen future pandemic resilience on the continent. Team Europe with other international partners has committed to support the medium and long-term sustainability of the projects, including funds from Germany, France and Belgium. The European Commission and European investment Bank will be providing further funds. Construction of the plant is expected to start later this year, creating a capacity of approximately 25 million vaccine doses being produced each month by the end of 2022.

EMA

- EMA advises against the use of the COVID-19 vaccine Janssen in people with a history of capillary leak syndrome. Three cases of capillary leak syndrome in people who had received the vaccine were reviewed, in which case the syndrome occurred within 2 days of the vaccination being administered. One of the patients had a history of capillary leak syndrome. Two patients subsequently died. EMA advises people vaccinated with the Janssen vaccine to seek immediate medical assistance if rapid swelling of arms and legs or sudden weight gain occur in the days following the vaccination.
- EMA declared a possible link between the Comirnaty and Spikevax (formerly Moderna) vaccines to very rare cases of myocarditis and pericarditis. It was concluded that these can occur rarely following the vaccinations. EMA recommends listing the two diseases as possible side effects. The case document occurred within 14 days after vaccination, more often after the second dose. The majority of cases was observed in young adult men. 145 cases of myocarditis and 138 cases of pericarditis were observed following vaccinations with Comirnaty in the EEA, out of 177 million doses Comirnaty administered as of May 31st. 19 cases of myocarditis and 19 cases of pericarditis
were observed following Spikevax vaccinations, out of 20 million doses administered in the EEA, as of May 31st. Out of these registered cases, 5 patients died. The course of the diseases was reported to progress similarly to normal progression of the diseases themselves. Healthcare professionals are asked to inform patients to seek immediate medical attention should symptoms of acute or persisting chest pain, palpitations or shortness of breath occur. A DHPC (direct healthcare professional communication) will be sent to professionals prescribing, dispensing or administering the medicine.

- Meeting highlights from the PRAC meetings, 5-8 July, furthermore included a warning for Guillain Barre syndrome in patients who have received Vaxzevria vaccinations (formerly AstraZeneca). PRAC recommends changing the product information and to raise awareness amongst healthcare professionals.
- In a summary report of the second workshop on COVID-19 vaccine development and virus variants, organized by the International Coalition of Medicines Regulatory Authorities (ICMRA), published today, the importance of regulatory alignment was described. With COVID-19 mutations and new variants continuously emerging globally, medicines regulators worldwide have stressed the urgent public health priority regarding regulatory processes and requirements for the development of new and adaptations of existing vaccines to protect against strains. The workshop brought together delegates from 20 countries representing 30 medicines regulatory authorities and the WHO to exchange information about efforts to develop vaccines against variants. It was co-chaired by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) and the UK’s Medicines and Healthcare products Regulatory Agency (MHRA). The full summary is available here.

ECDC
- ECDC has updated its webpage with the latest COVID-19 country overviews, noting an increased trend in 20 countries with a 64.3% increase COVID-19 cases compared to last week, as of 15 July. The most affected countries note the highest number of cases among 15- to 24-year-olds while the increase in case numbers in persons over the age of 65 is limited. ECDC states that reported hospitalisation rate for EU /EEA countries remains stable overall with the ICU occupancy rate decreasing for nine weeks overall, while increasing in some countries. For more information, please see the dedicated webpage.
- ECDC and EMA have published their update on COVID-19, stating that complete vaccination courses remain vital for maximum protection. EMA and ECDC urge EU citizens to get vaccinated, adhering to the recommended number of doses, stating that this is especially vital considering the spread of the delta variant. For the full update, please see here.

WHO
- WHO launched a new SARS-CoV-2 antigen rapid diagnostics test online course on 12 July. The course is accessible here.

Other reports/webinars
- On 12 July, France and Greece made statements declaring the COVID-19 vaccine mandatory for healthcare workers. President Macron announced that healthcare professionals, care home employees and those who work with vulnerable and frail patients will have to be vaccinated by 15 September. Healthcare professionals without the vaccination will not be paid after 15 September 2021. He furthermore stated that “Depending on the situation, no doubt we will have to ask ourselves the question of mandatory vaccination for all the French”. Similarly, the Greek government made a statement, making the COVID-19 vaccines mandatory for nursing staff in Greece, effective immediately. Individuals refusing to get vaccinated will be stopped from working
beginning 16 August. Healthcare professionals in wider sectors are expected to have been vaccinated by September. Both announcements followed the mandatory vaccine law for healthcare professionals in Italy, created on 1 April 2021. The United Kingdom had previously said that mandates for vaccinations of care home staff will be following, starting in October. For more information, please see here or here.