COVID-19 EU update

European Commission:

- On 8 October, the Commission signed a joint procurement framework contract with the pharmaceutical company Gilead for the supply of up to 500,000 treatment courses of Veklury, the brand name for Remdesivir, and the opportunity to increase supply beyond the 500,000 treatment courses.
- On 7 October, the Commission approved a third contract with a pharmaceutical company, Janssen Pharmaceutica NV, one of the Janssen Pharmaceutical Companies of Johnson & Johnson. The contract allows the EU Member States to purchase vaccines for 200 million people. The Commission has already signed contracts with AstraZeneca and with Sanofi-GSK and concluded exploratory talks with CureVac, BioNTech-Pfizer and Moderna.
- On 7 October, the Commission published a <u>further set of reports</u> provided by the signatories of the Code of Practice on Disinformation (e.g. Google, Facebook, Twitter, Tik Tok, Microsoft, etc.) as part of the COVID-19 monitoring and reporting programme set out in the Joint Communication "Tackling COVID-19 disinformation Getting the facts right".
- The Expert Panel on effective ways on investing in health (EXPH) was mandated by the European Commission to look beyond the current crisis and consider how health systems can prepare better for future threats. Today, their draft opinion was <u>published</u>. An online hearing can be attended <u>here</u>. "Specifically, the mandate requested a new framework for the organisation of health and social care following the COVID-19 pandemic. The Opinion (1) identifies the building blocks of resilient health and social care organisation, (2) explores the elements and conditions for capacity building to strengthen health system resilience, (3) addresses healthcare provision for vulnerable patient groups and how to sustain such provision in a system under stress, and (4) defines an approach to develop and implement "resilience tests" of Member State health systems."

European Parliament:

■ The Parliament met in plenary 5 to 8 October. Next to the budget, a key aspect was the high number of COVID-19 related deaths in long-term care facilities. MEPs called for "lessons to be learned" and EU long-term care provisions to be renewed.

European Council:

On 1-2 October, the European Council adopted <u>conclusions</u> about the handling of the ongoing COVID-19 pandemic. The conclusions call on the Council and the Commission to take further steps in the overall coordination, development and distribution of a vaccine. The European Council will rediscus the Single Market, digitalization and industrial policies at its meeting in March 2021.

EMA:

■ EMA launches rolling review of BioNTech/Pfizer COVID-19 vaccine: on 6 October, EMA launched the <u>second rolling review</u> of the coronavirus vaccine candidate, this time, the one developed jointly by BioNTech and Pfizer. The two companies are developing an mRNA vaccine to protect against coronavirus. No mRNA vaccine has been approved by regulators before. The announcement means the agency's Committee for Medicinal Products for Human Use (CHMP) has begun reviewing the first batch of data for the vaccine candidate. BioNTech and Pfizer are conducting large-scale clinical trials around the world, including in Germany. The CHMP committee is currently looking at preclinical data and early clinical trial data. More data will be available "over the coming weeks and months," the agency wrote.

- EMA is monitoring Velkury (remdesivir) amid reports of kidney problems: EMA's <u>drug safety committee is monitoring</u> the coronavirus treatment remdesivir following reports of kidney injuries in patients. The Agency stresses that at this stage, it has not been determined whether there is a causal relationship between Veklury and the reports of acute kidney injury. However, there have been enough reports of kidney injuries in COVID-19 patients taking the drug to suggest the potential that the drug is responsible. The EMA backed a conditional marketing authorization for remdesivir in June for COVID-19 patients with pneumonia and who require supplemental oxygen. That means the benefits of the drug seemed to outweigh the risks for those patients based on available data; Gilead is obligated to provide more data going forward. For now, the EMA said, recommendations for the use of remdesivir have not changed. If further scrutiny does reveal that it's causing the kidney injuries, the regulator could take steps to further mitigate risk to patients.
- EMA Director pledges transparency in response to European ombudsman: the European Medicines Agency will implement exceptional transparency measures in response to questions raised by European Ombudsman Emily O'Reilly, according to EMA Director Guido Rasi. Among the measures, the agency will publish clinical data for all COVID-19 medicines that received market authorization. Remdesivir will be the first coronavirus drug that will have its data made public. It will publish it in the "coming weeks." Other new measures include publishing risk management plans for COVID-19 medicines and issuing new announcements on the first day of the start of a rolling review for COVID-19 medicines. Rasi was responding to a letter from O'Reilly, made public in July, which asked the EMA to "ensure transparency of its COVID-19 related activities."

ECDC:

- A new ECDC infographic presents measures for <u>infection prevention and control in primary care</u>. The Centre underlines that infection prevention and control practices are of critical importance in preventing the spread of COVID-19 in primary care settings. The advised measures relate to the care of vulnerable people in nursing homes, availability of personal protective equipment, wearing masks and other hygiene procedures.
- ECDC published two posters on influenza during the COVID-19 pandemic. The first one provides information on why it is important to get vaccinated against influenza during the COVID-19 pandemic. The second poster answers the question of how can someone protect herself/himself and others from COVID-19 during influenza vaccination?
- ECDC released a new leaflet on <u>mother-to-child transmission of COVID-19</u>. It provides basic information on COVID-19, how it spreads, symptoms, how to avoid catching or spreading the virus, and some specific advice for pregnant women on how to protect themselves and their babies.
- ECDC provides an update on infection prevention and control and preparedness for COVID-19 in healthcare settings. It provides guidance to healthcare facilities and healthcare providers on preparedness and infection prevention and control measures for the management of possible and confirmed cases of COVID-19 in healthcare settings, including long-term care facilities. Moreover, it addresses the management of clinical diagnostic specimens at laboratories. This is the fifth update of the guidance.

WHO/WHO-Europe:

WHO Regional Office for Europe recommendations on influenza vaccination for the 2020/2021 season during the ongoing COVID-19 pandemic (2020): this guidance identifies health professionals as the highest priority target group for the influenza vaccination, alongside older persons and other vulnerable groups. It also gives advice on the logistics of administering the vaccine, e.g. to make use of outdoor spaces, as well as considering pharmacy delivery, alongside

- other points of delivery such as mobile community vaccination clinics, home visits, or drive through vaccination.
- Pandemic fatigue Reinvigorating the public to prevent COVID-19: this report addresses the challenge of upholding adherence to pandemic prevention measures in the longer-term. It identifies key recommendations for effective communication, highlighting i.a. the need for coordinating consistent messages between government, health professionals, and other public statements.
- Estonia and WHO to work together on digital health and innovation: the objective is to develop an International Certificate of Vaccination, a "smart yellow card" to support the COVAX initiative. It contributes to the 'Empowerment through digital health' flagship initiative and the completion of the European Roadmap for the Digitalization of National Health System.

Human rights and COVID-19:

Access to social and medico-social services for ALL: a springboard out of poverty: On the occasion of the International Day for the Eradication of Poverty, the Conference of INGOs of the Council of Europe is hosting a webinar on 16 October, from 14:30 to 17:00 (CET time). The CPME President has been invited to speak on the topic of access to healthcare during the pandemic.

Data Protection and COVID-19

 Coronavirus accelerates drive to share health data across borders, see article in Horizon, the EU Research and Innovation Magazine

Other Reports/Webinars:

- The Health Policy Platform together with the Expert Panel on effective ways of investing in health will host a "Hearing of the expert panel on effective ways of investing in health on the opinion: the organisation of resilient health and social care following the COVID-19 pandemic" on 20 October from 10.00 12.00 CET Brussels time. Find here the agenda and technical details to participate. The aim of this hearing is to provide stakeholders with an opportunity to share their views on the draft opinion of the Expert Panel on the above-mentioned subject.
- Dr Martin Balzan co-written three scientific papers on the COVID-19 pandemic development in Malta and in Southern Europe. You may find the links to the articles below:
 - Malta tourism losses due to second wave of COVID-19
 - Mass Events Trigger Malta's Second Peak After Initial Successful Pandemic Suppression
 - Low Incidence and Mortality from SARS-CoV-2 in Southern Europe. Proposal of a hypothesis for Arthropod borne Herd immunity
- CPME participating in webinar on COVID-19: "mental health support network- Addressing mental health needs of healthcare workers" 16 October 2020 10h30-12h CET Brussels. The objective of this webinar is to share knowledge and practices related to supporting mental health and wellbeing of healthcare professionals in the time of health crisis. Dr Jacques des Haller, Rapporteur on mental health and the Latvian and British Medical Associations will share experience and relevant examples. Find the registration link and the streaming link here.
- CPME participating in 16th World Congress on Public Health 2020, in a one-hour workshop around the theme of "Incentivising vaccination uptake in Europe" on 15 October 14:30-15:30. The workshop will bring together policy-makers, experts and health professionals to showcase recent policy initiatives, good practices and innovative collaborations aiming at increasing coverage rates

for key vaccines and taking a life course approach. Dr Jacques de Haller, Rapporteur on vaccination will present the Coalition for Vaccination, CPME is co-chairing.