COVID-19 EU update

European Commission:

- On 7 December 2020, the Commission welcomed an agreement on crucial VAT relief for vaccines and testing kits to
  - enable member states to relive hospitals, medical practitioners and individuals of VAT when acquiring covid vaccines and testing kits.
  - give better and cheaper access to the tools needed to prevent, detect and treat COVID.
- On 8 December 2020, the Commission published the Expert Panel opinion on the organisation of resilient health and social care following the COVID-19 pandemic. The opinion identifies the building blocks of resilient health and social care, explores the elements and conditions for capacity building to strengthen health system resilience, addresses healthcare needs of vulnerable patients at times of crisis, and defines a blueprint for resilience testing of health systems. Please find the Panel's recommendations here.

Council:

- On 09.12.2020 the Council released an update on COVID-19: how the EU is promoting research on vaccines.

European Council:

- On 10. – 11.12.2020 the European Council discussed the COVID-19 situation, including overall coordination effort in response to pandemic, work on vaccines and testing and gradual lifting of restrictions.
- European Council President Charles Michel has called for an international treaty on pandemics within the framework of the World Health Organisation. This could cover risk monitoring, financing and coordination of research, the system of alerts and information sharing, improving access to healthcare, and building resilience of systems and supply chains. The proposal will be put to G20 and G7 leaders with the aim of ensuring involvement of a broad range of international bodies.

EMA:

- **E**MA published its updated guidance for the antiviral drug remdesivir, recommending that its use be restricted to patients with COVID-19 who are receiving oxygen without invasive ventilation. Previously, the drug, developed by U.S. drugmaker Gilead, was recommended for all patients receiving supplementary oxygen, regardless of whether they were intubated. The new guidance will be reflected in a changed marketing authorization for remdesivir, which still needs to be confirmed by the Commission. More information from EMA on remdesivir can be found here.
- EMA Question & Answer on what type of studies are needed to approve a COVID-19 vaccine.
- EMA receives application for conditional marketing authorisation of Moderna COVID-19 vaccine: EMA has received an application for conditional marketing authorisation for a COVID-19 mRNA vaccine by Moderna. The assessment of the vaccine known as Moderna Covid-19 vaccine (also referred to as mRNA1273) will proceed under an accelerated timeline. An opinion on the marketing authorisation could be issued within weeks, depending on whether the data submitted are sufficiently robust and complete to show the quality, safety and effectiveness of the vaccine. Such a short timeframe is only possible because EMA has already reviewed some data on the vaccine during a rolling review. During this phase, EMA assessed data from laboratory studies and also started assessing data

on immunogenicity (how well the vaccine triggers a response against the virus) and safety from an early study.

- EMA receives application for conditional marketing authorisation of COVID-19 mRNA vaccine BNT162b2: EMA has received an application for conditional marketing authorisation for BNT162b2, a COVID-19 mRNA vaccine developed by BioNTech and Pfizer. The assessment of BNT162b2 will proceed under an accelerated timeline. An opinion on the marketing authorisation could be issued within weeks, depending on whether the data submitted are sufficiently robust and complete to show the quality, safety and effectiveness of the vaccine.
- EMA starts rolling review of Janssen's COVID-19 vaccine Ad26.COV2.S: EMA's human medicines committee has started a rolling review of Ad26.COV2.S, a COVID-19 vaccine from Janssen-Cilag International. The CHMP's decision to start the rolling review is based on preliminary results from laboratory studies and early clinical studies in adults. These studies suggest that the vaccine triggers the production of antibodies and immune cells that target the SARS-CoV-2 coronavirus. The company is currently conducting trials in people to assess safety and immunogenicity (how well the vaccine triggers a response against the virus), and effectiveness. EMA will evaluate data from these and other clinical trials as they become available.
- EMA has also updated information on its exceptional transparency measures to cover post-authorisation procedures. You may consult them here.

ECDC:

- ECDC provides an overview of COVID-19 vaccination strategies and vaccine deployment plans. It outlines the initial developments regarding vaccine deployment plans and national vaccination strategies for COVID-19 vaccines, including interim considerations for priority groups, evidence to be considered for the prioritisation of target groups, logistical considerations and monitoring systems for post-marketing surveillance (e.g. vaccine coverage, safety, effectiveness and acceptance). This overview is based on results from an ECDC survey and meeting among members of the EU/EEA National Immunisation Technical Advisory Groups (NITAG) Collaboration.
- Testing and quarantining air travellers not 'effective,' as such measures only work if the coronavirus transmission rate is very low, according to new European guidelines on health measures in air travel released Wednesday. The guidelines, written by the European Union Aviation Safety Agency (EASA) and the ECDC, state that in the current epidemiological situation, imported cases account for just a small proportion of detected cases. Coronavirus prevalence in travelers is "estimated likely to be lower than the prevalence in the general population or among contacts of confirmed cases,". Systematic testing or quarantines for air travelers is therefore currently "not recommended."
- ECDC updated its report on COVID-19 and supply of substances of human origin (SoHO). It integrates the experience of maintaining safe and sufficient supply of SoHO gained in the course of the COVID-19 pandemic and through recent scientific developments in understanding the evolution of the disease. The document reassesses the risk posed by COVID-19 and revises management options for the safe and sustainable supply of SoHO. It also includes information relating to the safety of staff in SoHO establishments and recipients of SoHO products.

WHO/WHO Europe:

- WHO's Emergency Medical Teams inspire countries and colleagues during the COVID-19 pandemic: WHO-Europe reports on progress made in training Emergency Medical Teams in Europe which can then be deployed to provide urgent assistance in case of pandemics, natural disasters and other situations. In 2020, 8 teams from 6 different countries were deployed to help with the COVID-19 response. Thanks

to twinning, mentorship programmes and information sharing, this capacity is set to increase in the coming years.

- Call for Action: Managing the Infodemic Manifesto: WHO continues its action to improve communication and dispel false information by inviting interested parties to co-sign a manifesto developed during the 3rd Virtual Global WHO Infodemic Management Conference. There is also a complementary statement from the 'civil society' track of the conference.

OECD:

- Testing for COVID-19: How to best use the various tests?: This policy response discusses how to create a testing strategy that balances capacity restraints with effectiveness and reliability of test results, looking in particular at the relative advantages and disadvantages of PCR tests and rapid antigen testing.
- Asia-Pacific countries have managed COVID-19 crisis relatively well but major challenges remain in low-middle-income countries: the Health at a Glance reports for the Asia/Pacific region show a wide variety of approaches, capacities in outcomes in pandemic management. Australia, Japan, Korea and New Zealand are presented as successful examples, which is due i.a. to effective testing, tracing and isolation systems, as well as a high level of citizens' trust in and compliance with containment measures.

Webinars/Other Reports:

- On 10 December, the European Health Policy Platform hosted a webinar on "Protecting vulnerable populations from Covid-19" which included presentations by Commissioner Stella Kyriakides, ECDC, Medecins Sans Frontieres, UNICEF, the Red Cross and Stemm vun der Strooss. A recording is available here.
- COVID-19 impact on employment income: Eurostat has published a report which estimates a 5.2% decrease of median employment income in the EU in 2020 compared to 2019. There are large variations both between countries and socio-economic group within the same country.