

COVID-19 EU update

European Commission:

- The European Commission issued a [joint statement](#) together with the WHO Regional Office for Europe on “A deeper and result-oriented partnership for health in Europe”. In this statement they underline “a common ambition to achieve the highest level of health and health protection, in line with the Sustainable Development Goals (SDG)”, in particular SDG 3 on health and well-being. It is stated that the recent developments and challenges in form of the COVID-19 pandemic have underlined the importance of the ongoing partnership and shown its benefits for the European region. The aim of the statement is to strengthen the partnership and adapt it to new health priorities and challenges, foster technical and policy synergies, strengthen the voice of citizen’s and trust in health and food authorities and maximise the support to countries and the impact of initiatives. They defined the key priorities and areas as being the strengthening of health security against health emergencies and threats, strengthening effective, accessible, resilient and innovative health systems, the reduction of the impact of NCDs (non-communicable diseases) with a focus on cancer, the promotion of sustainable food systems and health and the promotion of health cooperation with non-EU-countries.

Council:

- On 6 October the Council approved [conclusions](#) on the role of the EU in strengthening the World Health Organization (WHO). The conclusions acknowledge the central role of the WHO as the leading and coordinating authority in addressing global health challenges. As to reform the Council suggests:
 - a revision of the alert system for declaration of a Public Health Emergency of International Concern to allow for differentiated levels of alerts
 - a distinction between travel and trade restrictions under the International Health Regulations (IHR) in order to avoid unnecessary harm to economies
 - the possibility of an independent epidemiological assessment on-site in high risk zones in close collaboration with the state party
 - increased transparency on national compliance with the IHR.

EMA:

- EMA [published](#) the clinical data used to support the conditional authorization of remdesivir for COVID-19, following questions about the drug’s efficacy in light of new data. Gilead’s remdesivir has already secured conditional approval from the EMA, but recent data from the World Health Organization’s trial of the drug found that it had little to no effect on mortality or hospitalization length. Prior to the WHO’s announcement, the European Commission signed a [€1 billion deal](#) for remdesivir. Questions have emerged over the deal, with both the Commission looking into the new data. DG Sante’s Director General Sandra Gallina defended the deal on October 29, telling MEPs that the Commission spent the money “because member states in the joint procurement want the product.”

In addition, the agency published [information on 64 potential coronavirus medicines and vaccines](#) that have so far received scientific advice or guidance. The EMA is set to update the list on a monthly basis.

- EMA's safety committee ([PRAC](#)) has reviewed the guidance developed by EMA for pharmaceutical companies on how to prepare [risk management plans \(RMPs\)](#) for COVID-19 vaccines. As for any medicine, companies are required to submit an RMP for COVID-19 vaccines when they apply for a [marketing authorisation](#). Such a plan explains how the company that markets the vaccine must monitor and report on its safety, and what measures they must put in place to manage any risks. Importantly, RMPs are continually updated throughout the lifetime of the vaccine as new information becomes available. The guidance is for COVID-19 vaccines only and complements the already existing [guidelines on the RMP format in the EU](#), which apply to all medicines. The guidance will now be sent for adoption to EMA's human medicines committee ([CHMP](#)) and will be made public once it is adopted by the [CHMP](#).
- EMA revamped its communication materials on COVID-19 vaccines. The information materials are divided into 'tiers' depending on the level of detail and complexity:
 - Tier 1: Basic facts on COVID-19 vaccines - Q&A in public friendly language for the public published on EMA website ([link](#))
 - Tier 2: Development, evaluation, approval & monitoring - a description of how COVID-19 vaccines are developed, approved and monitored intended for general and (professional) interested audience ([link](#))

In addition, based on this material, text has been developed for the European Vaccines Information Portal (EVIP) <https://vaccination-info.eu/en>, which will be translated into all EU languages for publication.

ECDC:

- ECDC published new [maps](#) in support of the Council Recommendation on a coordinated approach to the restriction of free movement in response to the COVID-19 pandemic. The fourth update informs that 14-day notification rate is higher than 150 cases per 100 000 in the whole Union besides Finland, Norway, and parts of Greece.

WHO/WHO Europe:

- 29.10.2020: [statement by WHO regional director for Europe at emergency meeting of ministers of health from WHO European Region on COVID-19 projections for the winter season](#)
 - Calling for the last epidemiological data to be respected
 - Underlining mental health issues associated with lockdown, financial hardship
 - Stating that data suggests that working from home, restricting large gatherings and proportionately shutting down places where people gather "can go a long way to preserve lives and livelihoods."
 - Confident that children and adolescents are not primary drivers of transmission, which is why school closures are not considered to be an effective single measure and should continue to be a last resort
 - Calling for people not to underestimate the impact that COVID-19 fatigue is having on wellbeing of communities and effectiveness to ongoing response
 - Underlining the engagement of citizens to help create solutions and the importance of communication to manage expectations in coming season with empathy
 - Calling for the protection of health care and essential workers and their needs and wellbeing to be prioritized
 - Calling for the necessity to adapt the system to assess where to focus resources as the testing and tracing can no longer be ramped up.
 - "Adapting testing and tracing so that they are used in a targeted way for maximum impact, focusing on the events that trigger highest spread within communities, may become necessary. But we cannot give up on these critical systems."

- The European Observatory on Health Systems and Policies has just published a **special issue of its journal, [Eurohealth](#)**, in collaboration with WHO/Europe and the European Commission. This issues draws on data from the [COVID-19 Health System Response Monitor](#) to examine health system responses to COVID-19.
- 05.11.2020 the [World Health Assembly charts course for COVID-19 response and global health priorities](#)
- 30.11.2020 WHO issued a [Statement on fifth meeting of International Health regulations Emergency Committee regarding the COVID-19 pandemic](#)