COVID-19 EU update

European Commission
- On 4 March, the Commission published a new factsheet on the EU Global response to COVID-19.

EMA
- EMA publishes clinical data used to support their authorisations of the Moderna COVID-19 vaccine: The decision, taken together with Canada’s regulator, was made “to ensure the public has as much information as possible to make decisions regarding vaccination”, according to the press release. The package of information, which is available on the EMA online portal, includes Moderna’s safety and efficacy data from three clinical studies. The Agency expects to publish the clinical data for BioNTech/Pfizer’s vaccine shortly.
- EMA announced that it has launched a rolling review of Russia’s Sputnik V vaccine. The vaccine, created by Russia’s Gamaleya National Centre of Epidemiology and Microbiology, has prompted confusion after its funders, the Russian Direct Investment Fund, continually claimed they sent data for a rolling review to the EMA. But the agency denied that claim, saying it was only providing scientific advice to the developers. So far, Hungary has been using the vaccine after approving it on a national basis, and Slovakia has already received orders of the vaccine. The agency is also currently undergoing a rolling review of the Novavax vaccine from the U.S. and CureVac from Germany, and it should make a decision on whether to recommend the Johnson & Johnson vaccine next week. Besides, EMA is conducting a review of Celltrion’s monoclonal antibody regdanvimab to support national authorities who may decide on the use of this medicine for COVID-19 prior to authorization, the Agency announced on Tuesday. This review is in addition to the ongoing rolling review of regdanvimab for the treatment of confirmed COVID-19 in patients who do not require supplemental oxygen therapy and are at high risk for progressing to severe COVID-19 and/or hospitalisation.
- EMA publishes monthly safety updates on Comirnaty and Moderna vaccine. The safety updates summarise the data that have become available since the vaccine’s authorisation. They also indicate whether any safety information requires further investigation.

ECDC
- ECDC provides a report on methods for the detection and identification of SARS-CoV-2 variants. It includes a guidance to laboratories, microbiology experts and relevant stakeholders in making decisions on establishing or scaling up capability and capacity to detect and identify circulating SARS-CoV-2 variants, and in making decisions on which technologies to use and for which objective.

WHO-Europe
- New WHO expert group to identify gaps and solutions to the mental health impacts of COVID-19: WHO-Europe’s new technical advisory group has launched its activities. It brings together scientists, service providers and managers on the front line, mental health service users, family advocates, and COVID-19 survivors to examine the available evidence from research, policy and patients and produce recommendations for the WHO-Europe Regional Committee.