

COVID-19 EU update

European Commission

- The European Commission has [extended](#) the transparency and authorization mechanism for exports of COVID-19 vaccines until the end of June. The export authorization mechanism only applies to exports from companies with which the EU has concluded Advance Purchase Agreements.
- The European Commission [authorized](#) a fourth vaccine against COVID-19 on March 11th. A conditional marketing authorization has been granted for the COVID-19 Vaccine developed by Janssen Pharmaceutica NV. The Janssen Vaccine will be given in one dose to adults aged 18 years and older.
- On 4 March, the Commission published a new [factsheet](#) on the EU Global response to COVID-19.

EMA

- The info-card for healthcare professionals on how to report suspected side effects with medicines is now available in all EU languages. You can find them [here](#).
- EMA's CHMP has [started](#) a rolling review of two monoclonal antibodies from Eli Lilly for the treatment of COVID-19.
- EMA [published](#) the clinical data supporting the authorisation of Comirnaty. Health Canada also published these data at the same time.
- The Commission authorised the fourth COVID-19 vaccine: Following the [advice](#) from the EMA that Johnson & Johnson's single-shot coronavirus vaccine is safe and effective to use in everyone over the age of 18, the Commission granted the vaccine a conditional marketing authorization later Thursday. It is the fourth vaccine approved in the EU after BioNTech/Pfizer, Moderna and Oxford/AstraZeneca. The Commission has already secured 200 million doses of the Johnson & Johnson vaccine, with the option to purchase 200 million more. However, the company won't deliver doses to EU countries until the second quarter of the year — possibly not until mid-to-late April. Once delivered, the jab could be much easier to use than the three other approved vaccines because only one dose is required and it can be stored in a normal refrigerator for three months. The vaccine proved to be 67 percent effective in preventing cases of COVID-19, according to the EMA. The vaccine was approved in the U.S. at the end of February and the company has submitted for approval in the U.K. The EMA has rolling reviews of three other vaccines ongoing: CureVac, Novavax and Sputnik V.
- EMA [confirmed](#) that COVID-19 Vaccine AstraZeneca's can continue to be administered while investigations are ongoing. EMA is aware that the Danish Health Authority has paused its vaccination campaign with COVID-19 Vaccine AstraZeneca. This was decided as a precautionary measure while a full investigation is ongoing into reports of blood clots in people who received the vaccine, including one case in Denmark where a person died. Some other Member States have also paused vaccination with this vaccine. However, there is currently no indication that vaccination has caused these conditions, which are not listed as side effects with this vaccine. The position of EMA's safety committee PRAC is that the vaccine's benefits continue to outweigh its risks and the vaccine can continue to be administered while investigation of cases of thromboembolic events is ongoing. PRAC is already reviewing all cases of thromboembolic events, and other conditions related to blood clots, reported post-vaccination with COVID-19 Vaccine AstraZeneca.
- EMA [concludes](#) safety signal of anaphylaxis with COVID-19 Vaccine AstraZeneca. Following the assessment of a safety signal regarding cases of anaphylaxis (severe allergic reactions) with COVID-19 Vaccine AstraZeneca, the Pharmacovigilance Risk Assessment Committee has recommended an

update to the product information to include anaphylaxis and hypersensitivity (allergic reactions) as side effects in section 4.8, with an unknown frequency, and to update the existing warning to reflect that cases of anaphylaxis have been reported. The update is based on a review of 41 reports of possible anaphylaxis seen among around 5 million vaccinations in the United Kingdom³. After careful review of the data, PRAC considered that a link to the vaccine was likely in at least some of these cases.

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.
- WHO has launched a [COVID-19 vaccine introduction toolbox](#), including guidance, tools, and training to equip all countries to prepare for and implement COVID-19 vaccination. This toolbox is organized in line with the [Guidance on Developing a National Deployment and Vaccination Plan for COVID-19 vaccines](#) and will be updated as new resources become available.