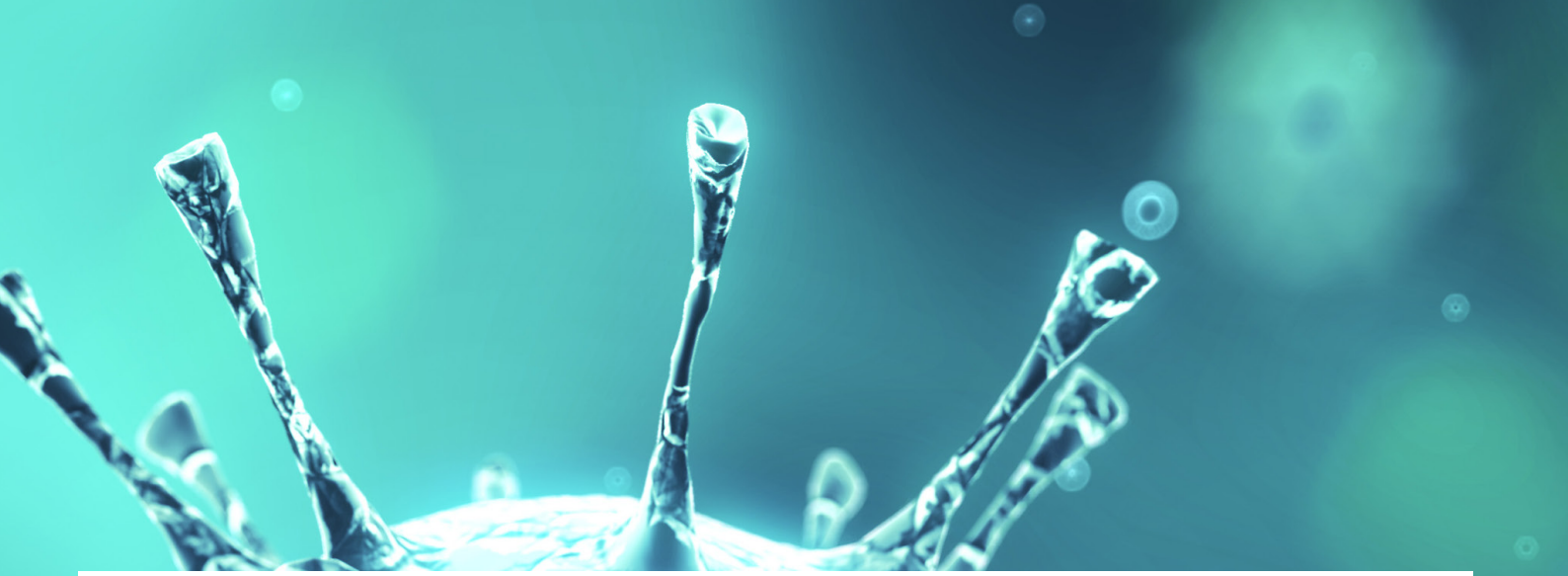

COVID-19 Vaccines

An overview prepared by EAHP

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This is a summary compiled by the European Association of Hospital Pharmacists (EAHP) on publicly available information on the main COVID-19 vaccines which are currently being developed. Some of these vaccines candidates are at this time under rolling review by the European Medicines Agency (EMA).

This document will be regularly updated to reflect any decisions that have been made by EMA.

Should you have any comments on this overview you can contact the EAHP Secretariat via info@eahp.eu

Pfizer/BioNTech vaccine

Manufacturer: BioNTech/Fosun Pharma/Pfizer
RNA-based vaccine called BNT162b2/ Comirnaty
Date of availability: (Vaccination started across the EU in late December 2020/early January 2021)
On 18 November 2020, Pfizer announced that the critical clinical tests required before approval had been completed. As already indicated in an interim analysis, the vaccine shows a high level of effectiveness. In addition, it has so far proven to be safe, the companies said in a joint statement. BNT162b2 therefore meets the conditions for an application for an emergency approval in the USA. Shortly afterwards, the company announced that they had initiated the application. Even before the final studies were completed, the European Medicines Agency (EMA) had already taken the first steps towards the approval of BNT162b2. In a so-called rolling review process, the previously available data on the vaccine were checked, while the final results of the studies will be submitted later. The application for a conditional marketing authorisation in the EU was submitted on 1 December 2020. NHS hospitals started on 8 December 2020 to administer 800,000 doses of the Pfizer/BioNTech vaccine.
EMA authorisation process: On 21 December EMA's Committee for Medicinal Products for Human Use (CHMP) recommended Comirnaty for authorisation in the EU. The conditional marketing authorisation was granted by the European Commission on the same day as the recommendation by the CHMP.
This vaccine has already been approved by the UK.
Dosage: two dosages intramuscular
Intervals between doses: The vaccine should be administered in 2 doses, a minimum of 21 days apart.
Quantity: 200 million doses + 100 million doses
Storage and handling specifics: EMA's human medicines committee (CHMP) has recommended updating the product information for Comirnaty to clarify that each vial contains 6 doses of the vaccine. In order to extract six doses from a single vial, low dead-volume syringes and/or needles should be used. The low dead-volume syringe and needle combination should have a dead volume of no more than 35 microliters. If standard syringes and needles are used, there may not be enough of the vaccine to extract a sixth dose from a vial. If the amount of vaccine remaining in the vial after the fifth dose cannot provide a full dose (0.3 ml), the healthcare professional must discard the vial and its contents. There should be no pooling from multiple vials to make up a full dose, and any unused vaccine should be discarded 6 hours after dilution. Further information on all the steps for using Comirnaty is available in the updated product information.
Production information: The product information of Comirnaty is available in all 24 EU languages on the website of EMA: https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty#product-information-section
Other information: In their ongoing Phase 3 study, their mRNA-based COVID-19 vaccine candidate, BNT162b2, met all of the study's primary efficacy endpoints. Analysis of the data indicate a vaccine efficacy rate of 95% ($p<0.0001$) in participants without prior SARS-CoV-2 infection (first primary objective) and also in participants with and without prior SARS-CoV-2 infection (second primary objective), in each case measured from 7 days after the second dose. The first primary objective analysis is based on 170 cases of COVID-19, as specified in the study protocol, of which 162 cases of COVID-19 were observed in the placebo group versus 8 cases in the BNT162b2 group. Efficacy was consistent across age, gender, race, and ethnicity demographics. The observed efficacy in adults over 65 years of age was over 94%.
Price: Price: 15-19,50 $

Moderna vaccine

Manufacturer: Moderna Therapeutics
The vaccine mRNA-1273 (COVID-19 Vaccine Moderna) is a genome-based vaccine.
Date of availability: (Vaccination with the COVID-19 Vaccine Moderna started across the EU in January 2021) mRNA-1273 met its their first efficacy endpoint on 16 November 2020 in the first interim analysis of the Phase 3 COVE study with a vaccine efficacy of 94.5%.
EMA authorisation process: On 6th January 2021 EMA' CHMP has recommended granting a conditional marketing authorisation for COVID-19 Vaccine Moderna to prevent Coronavirus disease (COVID-19) in people from 18 years of age.
Dosage: two doses intramuscular
Intervals between doses: The vaccine should be administered in 2 doses, a minimum of 28 days apart.
Quantity: 80 million doses + 80 million doses
Storage and handling specifics: For shipping and longer-term storage, Moderna expects that mRNA-1273 will be maintained at -20°C (-4°F), equal to most home or medical freezer temperatures, for up to 6 months. Using standard freezer temperatures of -20°C (range of -25° to -15°C or -13° to 5°F) is an easier and more established method of distribution and storage than deep freezing and most pharmaceutical distribution companies have the capability to store and ship products at -20°C (-4°F) worldwide. After thawing, to facilitate storage at points of administration, Moderna expects that mRNA-1273 will remain stable at standard refrigerated conditions of 2° to 8°C (36° to 46°F) for up to 30 days within the 6-month shelf life. The stability at refrigerated conditions allows for storage at most pharmacies, hospitals, or physicians' offices. Once the vaccine is removed from the refrigerator for administration, it can be kept at room temperature conditions for up to 12 hours. The vaccine will not require onsite dilution or special handling, which facilitates vaccination across a range of settings including pharmacies and physicians' offices.
A risk management plan for the COVID-19 Vaccine Moderna is also in place and contains important information about the vaccine's safety, how to collect further information and how to minimise any potential risks. A summary of the RMP is available. Safety measures will be implemented for COVID-19 Vaccine Moderna in line with the EU safety monitoring plan for COVID-19 vaccines to ensure that new safety information is rapidly collected and analysed. The company that markets COVID-19 Vaccine Moderna will provide monthly safety reports.
Production information: The product information of the COVID-19 Vaccine Moderna is available in English on the website of EMA: https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-moderna
Other information: After the first vaccination, antibody responses were higher with higher dose (day 29 enzyme-linked immunosorbent assay anti–S-2P antibody geometric mean titre [GMT], 40,227 in the 25-µg group, 109,209 in the 100-µg group, and 213,526 in the 250-µg group). After the second vaccination, the titres increased (day 57 GMT, 299,751, 782,719, and 1,192,154, respectively). After the second vaccination, serum-neutralizing activity was detected by two methods in all participants evaluated, with values generally similar to those in the upper half of the distribution of a panel of control convalescent serum specimens. Solicited adverse events that occurred in more than half the participants included fatigue, chills, headache, myalgia, and pain at the injection site. Systemic adverse events were more common after the second vaccination, particularly with the highest dose, and three participants (21%) in the 250-µg dose group reported one or more severe adverse events.
Price: Price: 32 $ - 37 $

Oxford/AstraZeneca vaccine

Manufacturer: AstraZeneca

The vaccine called AZD1222, known in studies as ChAdOx1, works on the principle of a vector vaccine. In this case, the vehicle used is an adenovirus, which is often used as a vector and is known to trigger cold-like symptoms in humans, among other things
AZD1222
Date of availability: early 2021
EMA authorisation process: EMA has recommended granting a conditional marketing authorisation for COVID-19 Vaccine AstraZeneca to prevent coronavirus disease 2019 (COVID-19) in people from 18 years of age.
Dosage: two doses intramuscular
Intervals between doses: The vaccine should be administered in 2 doses, the second between 4 to 12 weeks after the first.
Quantity: 300– 400 million doses
Storage and handling specifics: AstraZeneca's COVID-19 vaccine candidate, dubbed AZD1222, can be stored and transported at normal refrigerated temperatures of 2 degrees to 8 degrees Celsius (36 degrees to 46 degrees Fahrenheit) for at least six months and can be administered in "existing healthcare settings," giving the shot a major logistics leg up over a leading mRNA-based competitor that requires ultra-cold storage.
Other information: The COVID-19 Vaccine AstraZeneca is expected to work by preparing the body to defend itself against infection with the coronavirus SARS-CoV-2. This virus uses proteins on its outer surface, called spike proteins, to enter the body's cells and cause disease.
COVID-19 Vaccine AstraZeneca is made up of another virus (of the adenovirus family) that has been modified to contain the gene for making the SARS-CoV-2 spike protein. The adenovirus itself cannot reproduce and does not cause disease. Once it has been given, the vaccine delivers the SARS-CoV-2 gene into cells in the body. The cells will use the gene to produce the spike protein. The person's immune system will treat this spike protein as foreign and produce natural defences – antibodies and T cells – against this protein. If, later on, the vaccinated person comes into contact with SARS-CoV-2, the immune system will recognise the virus and be prepared to attack it: antibodies and T cells can work together to kill the virus, prevent its entry into the body's cells and destroy infected cells, thus helping to protect against COVID-19.
Price: 2.5 €

Sanofi GSK vaccine

Manufacturer: Sanofi
Viral vector, protein subunit
Date of availability: The vaccine has entered the third phase of the clinical trial, probably first half of next year
EMA authorisation process: No evaluation process is currently ongoing for this vaccine at the EMA.
Dosage: a two-dose recombinant protein vaccine with an adjuvant
Quantity: 300 million doses
Storage and handling specifics: The vaccines can be stored between 35.6 to 46.4 degrees Fahrenheit (2 to 8 degrees Celsius)
Price: <10€

Johnson & Johnson vaccine

Manufacturer: Johnson & Johnson/ Janssen-Cilag International N.V
Ad26.COV2.S, a non-replicating viral vector vaccine
Date of availability: Spring 2021
EMA authorisation process: On 11 of March 2021 EMA recommended granting a conditional marketing authorisation for COVID-19 Vaccine Janssen to prevent COVID-19 in people from 18 years of age.
Dosage: COVID-19 Vaccine Janssen is administered as a single dose of 0.5 mL by intramuscular injection only. One dose (0.5 mL) contains: Adenovirus type 26 encoding the SARS-CoV-2 spike glycoprotein (Ad26.COV2-S), not less than 8.92 log10 infectious units (Inf.U).
Storage and handling specifics: The vaccine vials may be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) until the expiration date before the vials are punctured. After puncturing the multidose vial seal, the vaccine can be stored in the refrigerator between 2°C and 8°C (36°F and 46°F) for up to 6 hours or at room temperature (up to 25°C/77°F) for 2 hours.
Other information: COVID-19 Vaccine Janssen works by preparing the body to defend itself against COVID-19. It is made up of another virus (an adenovirus) that has been modified to contain the gene for making the SARS- CoV-2 spike protein. This is a protein on the SARS-CoV-2 virus which it needs to enter the body's cells. The adenovirus passes the SARS-CoV-2 gene into the vaccinated person's cells. The cells can then use the gene to produce the spike protein. The person's immune system will recognise the spike protein as foreign and produce antibodies and activate T cells (white blood cells) to target it. Later, if the vaccinated person comes into contact with the SARS-CoV-2 virus, the person's immune system will recognise the spike protein on the virus and be ready to defend the body. The adenovirus in the vaccine cannot reproduce and does not cause disease.
Price: 10 $

CureVac vaccine

Manufacturer: CureVac (mRNA)
Date of availability: The vaccine has entered phase 2 of the clinical trial.
EMA authorisation process: No evaluation process is currently ongoing for this vaccine at the EMA.
Dosage: two dosages (TBC)
Quantity: 225 million doses + 180 million doses
Storage and handling specifics: CureVac mentioned that its candidate could remain stable at refrigerator temperatures for up to three months and at room temp for upward of 24 hours.
Price: 10 to 15 €

Disclaimer for materials included in EAHP's COVID-19 Resource Centre

The document "COVID-19 Vaccines - An overview prepared by EAHP" provides interim information that was put together based on publicly available information. Updates will be made once the vaccines listed therein are authorised in the EU and the final summary of product characteristics SmPC can be obtained.

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