Federal Ministry
Republic of Austria
Social Affairs, Health, Care
and Consumer Protection

FAQ coronavirus vaccination

Version: 07.05.2021

FAQ coronavirus vaccination

FAQ: General questions about the coronavirus vaccination

General information

All persons who are resident in Austria can also receive a coronavirus vaccination free of charge in Austria and thus be vaccinated against COVID-19. This also applies to persons who have no Austrian social security number. The national COVID-19 vaccination schedule regulates the order in which all persons willing to be vaccinated in Austria are vaccinated. The organisation as well as implementation of the vaccinations is carried out by the Federal States (Bundesländer). The coronavirus vaccination is voluntary.

Who receives a coronavirus vaccination and when?

The national COVID-19 vaccination schedule regulates the order in which persons in Austria get a coronavirus vaccination. This COVID-19 vaccination schedule was determined by the Federal Ministry of Social Affairs, Health, Care and Consumer Protection based on the recommendations of the National Vaccination Committee. The schedule is implemented in three phases. According to the availability of vaccines, consideration will primarily be given to vulnerable groups of people, i.e. people at increased risk of severe COVID-19 courses of disease and people at increased risk of infection. The COVID-19 vaccination schedule is the binding guideline for all vaccinating centres in Austria.

The top priority is to make the best possible use of available vaccines and to vaccinate every available dose. The disposal of unused vaccine should in all cases be avoided.

You can find the current COVID-19 vaccination schedule here.

The Federal States are responsible for the specific implementation of the COVID-19 vaccination schedule. They regulate the concrete planning, organisation and implementation of the coronavirus vaccinations.

Is it possible to deviate from the order within the prioritised groups as defined in the COVID-19 vaccination schedule?

Yes. Within the prioritised groups, certain people may be vaccinated earlier if the available scientific evidence, the current recommendation of the National Vaccination Committee or the epidemiological situation in the respective area makes this necessary.

In addition, the order of the given prioritisation may be deviated from in individual cases if this is necessary for the efficient organisation of the coronavirus vaccination and to avoid the short-term disposal of vaccines. Any remaining vaccine doses should be administered as soon as possible, even if in individual cases this means that vaccines are administered to persons who do not belong to the target group to be vaccinated at the applicable time.

Due to the complex storage conditions of the vaccines and multi-dose containers, organisation and logistics may also deviate slightly from the COVID-19 vaccination schedule.

How can I register for a coronavirus vaccination?

Registration for the coronavirus vaccination is via the registration platforms of the respective Federal States (Bundesländer): Coronavirus Vaccination – Register Now! (sozialministerium.at)

Which documents or papers should I bring to the vaccination appointment?

Please bring the following documents with you to your arranged vaccination appointment:

- Your social security number (e-card) (if available)
- Your vaccination certificate (if available)
- Your allergy certificate (if available)
- Optional: completed "COVID-19 Vaccination Information and Documentation Form"

Who is allowed to carry out a coronavirus vaccination?

- General practitioners and specialist doctors
- Occupational doctors and school doctors
- Interns in cooperation with doctors authorised to practise independently
- Retired doctors in cooperation with doctors authorised to practise independently

- Foreign doctors in cooperation with doctors authorised to practise independently
- Medical students under medical supervision and guidance (e.g. in a vaccination line on behalf of the Regional Sanitary Directorate [Landessanitätsdirektion])
- Qualified health care staff and nursing staff according to written doctor's orders
- Paramedics and emergency paramedics with suitable training, on doctor's orders and under medical supervision.

All persons entitled to vaccinate may prepare the vaccine under the generally applicable and customary conditions. Preparation may also be carried out by appropriate pharmaceutical personnel.

The legislative professional requirements for carrying out the coronavirus vaccination are regulated in the "Ordinance on the Professional Requirements for the Performance of COVID-19 Vaccinations" of 03.12.2020 (which, however, does not yet include the vaccination authorisation of paramedics). This ordinance is available here.

How many inoculations (doses) does a coronavirus vaccination consist of?

The vaccine Comirnaty from the manufacturer BioNTech/Pfizer is administered in two doses at intervals of 19 to 42 days in accordance with the product information.

The COVID-19 Vaccine Moderna from the manufacturer Moderna is administered in two doses at intervals of 21 to 42 days in accordance with the product information.

Due to the current epidemiological situation in Austria and current vaccination progress, the National Vaccination Committee recommends extending the vaccination intervals for the two available mRNA vaccines from BioNTech/Pfizer and Moderna: The second vaccination should take place in the 6th week after the first vaccination. Currently arranged vaccination appointments do not have to be postponed.

The vaccine Vaxzevria from the manufacturer AstraZeneca is administered in two doses, and the National Vaccination Committee recommends an interval of 11 to 12 weeks.

The COVID-19 Vaccine Janssen from the manufacturer Johnson&Johnson (Janssen) is administered as a single vaccination.

How long does the duration of protection from a coronavirus vaccination last? Are further booster injections needed in the future?

The duration of protection after a coronavirus vaccination is not conclusively known for any approved vaccine at the present time. For this reason it is not yet known when or if boosters are necessary. Appropriate recommendations will be made available from the results of further studies.

Who is protected by the coronavirus vaccination?

According to current scientific knowledge, the coronavirus vaccination provides individual protection. On a personal level, vaccination means minimising the risk of contracting SARS-CoV-2 and becoming severely ill or even dying from COVID-19. If, in exceptional cases, COVID-19 disease occurs despite vaccination, the course of the disease is much milder and complications and deaths are avoided.

It can also be assumed that the coronavirus vaccination leads to a lower viral load and that vaccinated persons are therefore less contagious. Based on previous experience, it is assumed that a coronavirus vaccination also results in less virus transmission.

More details can be found in COVID-19 Vaccinations: Application Recommendations of the National Vaccination Committee (PDF, 289 KB).

At what point after a coronavirus vaccination can full protection against SARS-CoV-2 be assumed?

From the 22nd day after the first dose, a certain protective effect can be expected to start with all available vaccines. However, this circumstance does not apply to all persons, and may vary in individual cases. Therefore, it is very important that all recommended vaccinations are administered at the recommended interval to gain complete protection via the vaccination.

A second dose of the respective vaccine must be administered according to the vaccine and product information to ensure a complete and durable protective effect. If, in exceptional cases, infection with SARS-CoV-2 or COVID-19 occurs despite vaccination, the course of the disease is much milder and complications and deaths are avoided to the greatest possible extent.

What measures must be observed after a coronavirus vaccination?

According to the current state of knowledge, the coronavirus vaccination definitely provides individual protection. There is also increasing evidence from the use of COVID-19 vaccines that vaccinated individuals have a lower viral load and reduced viral shedding, and are therefore less infectious than unvaccinated individuals. This effect cannot yet be definitively determined (is not yet quantifiable), and is also likely to depend on the specific vaccine and the infecting SARS-CoV-2 variant.

In contrast, individuals who have experienced symptomatic SARS-CoV-2 infection may also become re-infected, but here again it is assumed that these individuals do not have a significant role in disease transmission. This was taken into account within the context of contact person management in cases of contact with a person who tested positive for SARS-CoV-2. If vaccinated individuals have close contact with an individual who has tested positive for SARS-CoV-2, these can be considered as Category II contact persons (from the 22nd day after the 1st dose until 6 months after the 2nd dose).

The protective measures in force, such as the compulsory wearing of respiratory masks of protection class FFP2 (FFP2 masks) without an exhalation valve, or masks of at least an equivalent standard, or general exit restrictions, must be complied with until a sufficient number of people have received a coronavirus vaccination.

Vaccinating special groups of persons

The decision on the use of a coronavirus vaccination should always be made in consultation with the attending doctor while taking into account the individual risk and disease situation.

Especially in the case of vaccinations of persons with underlying diseases, an individual decision must be made according to the specific case.

Please consult your attending doctor prior to your vaccination appointment to discuss issues such as pre-existing or underlying medical conditions, any medications you are taking, possible risk factors and other medical issues. Your doctor can also advise you on rare cases in which a coronavirus vaccine is not recommended.

Is it permitted to get a coronavirus vaccination if I have allergies?

Individuals with known allergies, e.g. allergies to aeroallergens such as pollen or house dust, can and should be vaccinated against COVID-19. Any allergies will be discussed in your clarifying consultation with the attending doctor. Allergy passports should therefore be brought to the vaccination appointment, as these contain information on possible allergens. After the coronavirus vaccination, allergy sufferers are advised to wait at least 30 minutes at the vaccination site under medical supervision.

If an allergic shock (anaphylaxis) ever occurred after a vaccination in the past, you must tell the doctor before the coronavirus vaccination.

Should pregnant women get a coronavirus vaccination?

Up to now, there is only limited experience with the use of COVID-19 vaccines in pregnant women; without exception, these showed no abnormalities.

In particular, data on mRNA vaccines have now been published, which is why mRNA vaccines should be favoured when vaccinating pregnant women. Pregnant women are at high risk for severe disease progression of COVID-19. Accordingly, after a careful individual benefit-risk evaluation, vaccination against COVID-19 with an mRNA vaccine can be administered to pregnant women. This is an off label use, which should be pointed out to the person concerned in a documented manner. Postponing the vaccination to the 2nd or 3rd trimester as a precautionary measure is indicated to counter theoretical concerns.

A routine pregnancy test is not necessary before vaccination. In the case of a pregnancy occurring during the period of a vaccination, this does NOT result in an indication for abortion. The pregnancy is also not classified as a risk pregnancy.

Will there be a separate vaccine for children?

Numerous studies are currently being conducted to investigate the efficacy of COVID-19 vaccines in children. BioNTech/Pfizer has now applied in April 2021 for approval of the Comirnaty vaccine for over-12 year olds, and this application is currently under review by the European Medicines Agency.

Can I get a coronavirus vaccination if I have another concurrent illness (e.g. a flu-like infection)?

Individuals who are ill with an acute infection should only be vaccinated against COVID-19 when they have completely regained their health and have recovered.

Should I also get a coronavirus vaccination even though I was already infected with SARS-CoV-2?

Vaccination against COVID-19 within the next 6 to 8 months is not necessary if an infection with SARS-CoV-2 has already occurred and the infection was also confirmed by a molecular biological test (e.g. PCR test). In the case of a positive neutralisation test (no correlates), the vaccination should be postponed for 3 months. After that, in both cases, administering one dose of vaccine is recommended.

If a molecularly confirmed infection with SARS-CoV-2 occurs in the interval between the 1st dose and the 2nd dose, the 2nd dose should be delayed for 6 to 8 months according to current knowledge.

How should residents of nursing homes and homes for the elderly behave after a coronavirus vaccination? Are these residents fully protected against SARS-CoV-2?

The coronavirus vaccination definitely reduces the risk of contracting SARS-CoV-2 and becoming severely ill or even dying from COVID-19. In addition, it can be assumed that the vaccination leads to a lower viral load and that vaccinated individuals are therefore less contagious.

However, since for medical reasons a certain proportion of residents in nursing homes and homes for the elderly cannot be vaccinated, the continued upkeep of certain testing and hygiene measures is also necessary during the current pandemic to protect these persons, in order to avoid an uncontrolled spread of infections with SARS-CoV-2 among the non-vaccinated residents.

Pending further information, it is therefore necessary to maintain the existing testing programmes and hygiene measures.

Reactions to vaccination and side effects

After the coronavirus vaccination, the body may have expected reactions to the vaccine, which however usually stop by themselves within a few days. These symptoms indicate the body's normal exposure to the vaccine, which leads to the protective effect. However, these reactions are more harmless than the possible symptoms and future consequences of the disease, which can be prevented by the vaccination!

If a health-relevant event or permanent health impairment occurs near in time with a coronavirus vaccination, an application for the recognition of vaccination damage can be filed. If a correlation is recognised, social security assistance is available in the form of a one-off payment or regular benefit payments.

Please monitor your state of health, as you do after other vaccinations or the taking of medication. If you have any side effects that last more than three days after the vaccination or are new (e.g. dizziness, severe and persistent headache, visual disturbances, nausea/vomiting, shortness of breath, acute pain in the chest, abdomen, arms or legs, swelling of the legs or small blood spots under the skin), contact your doctor, who should carry out a medical diagnosis to clarify thromboembolic events (blood clots)/thrombopenia (reduction of blood platelets).

Important investigations for newly occurring symptoms are:

- Blood count with determination of the platelet count,
- Blood smear,
  D-dimers and, if necessary, further imaging diagnostics (e.g. cMRI, ultrasound, CT of the thorax/abdomen).

For the further medical procedure, you can find information in the current statement of the Society for Thrombosis and Hemostasis Research.

Can the coronavirus vaccination cause vaccination reactions or side effects?

Yes. Known reactions often occur after the coronavirus vaccination, but they usually subside on their own within a few days. Pain, redness and swelling may very frequently

occur at the injection site. Symptoms such as tiredness, headache, muscle or joint pain, swelling of the lymph nodes, nausea/vomiting, shivering or fever are also experienced very frequently. Very frequent means that more than one in ten vaccinated persons are affected.

The doctor responsible for you or you yourself can report any suspected adverse reactions via https://nebenwirkung.basg.gv.at/. Further information on reporting suspected adverse reactions is available at

http://www.basg.gv.at/marktbeobachtung/meldewesen/nebenwirkungen

Who assumes responsibility and liability for vaccination damage after a coronavirus vaccination?

The Vaccine Damage Act (Impfschadengesetz) covers this kind of harm to health. Here, the Federal Government must provide compensation for damages caused by vaccinations. The scheme covers those vaccinations which are recommended in the interests of public health in accordance with the regulation on recommended vaccinations to prevent a risk to the general state of health of the population. The coronavirus vaccination has been added to this regulation.

Effectiveness

The coronavirus vaccination is currently the most effective protection against COVID-19 and severe COVID-19 disease, which can be fatal in worst cases. It is to be expected that deaths also occur close in time to the coronavirus vaccination, but these deaths have nothing to do with the coronavirus vaccination that was previously administered. Especially when vaccinating elderly persons or members of high-risk groups who generally have a higher risk of mortality, it is possible that a death occurs coincidentally shortly after the coronavirus vaccination, without there being a causal connection with the vaccination. This requires close examination on a case-by-case basis before jumping to conclusions about the effect of the vaccines.

Are the available vaccines sufficiently effective?

Yes. Each approved vaccine is effective, extensively tested, and well suited to prevent severe courses of disease and deaths. In the discussion about 'percentages of protection', it should be considered that there is no vaccination that guarantees 100% protection.

Does the coronavirus vaccination prevent symptomatic infections with SARS-CoV-2 and severe courses of COVID-19 disease?

Complete coronavirus vaccination minimises the risk of becoming severely ill or dying from COVID-19. The coronavirus vaccination currently offers the most effective individual disease protection. If, in exceptional cases, infection with SARS-CoV-2 and COVID-19 disease occurs despite vaccination, the course of the disease is much milder and complications and deaths are avoided to the greatest possible extent.

Does the coronavirus vaccination also protect against the transmission of SARS-CoV-2 to unvaccinated persons?

It is currently not conclusively known whether the available vaccines can influence the transmission of an infection with SARS-CoV-2 or only provide self-protection (individual protection). Studies have shown that people who become ill despite vaccination exhibit a reduced viral excretion load and are therefore less infectious, and that a coronavirus vaccination results in less transmission of the virus. This effect cannot yet be conclusively determined and is probably also dependent on the vaccine and the infecting variant of SARS-CoV-2. Thus protective measures, such as the compulsory wearing of respiratory masks of protection class FFP2 (FFP2 masks) without an exhalation valve or masks of at least an equivalent standard, or compulsory quarantine after entry into Austria, or general exit restrictions, must be maintained until a sufficient number of people have received a coronavirus vaccination and until corresponding findings are available.

FAQ: Vaccines and vaccine development:

Vaccines

The COVID-19 vaccines currently approved by the European Medicines Agency (EMA) are, on the one hand, so-called mRNA vaccines, and on the other, so-called vector vaccines. The exact functioning of these two types of vaccines is explained in more detail below.

How do mRNA vaccines work?

In the case of mRNA vaccines, a blueprint (in the form of so-called 'messenger RNA') for viral proteins is made available to the human body cells. This information is read directly in the cells and the coded protein is produced. The process runs continuously in the cells of the body to produce the proteins necessary for the cell. For example, the spike protein of SARS-CoV-2 can be produced by the human cells themselves. Since the spike protein is a foreign protein that is unusable for the cell, it is transported to the cell surface and presented there with the help of specific immune complex proteins. This process is identified by special immune cells and subsequently stimulates the immune system to produce antibodies against SARS-CoV-2 and to generate specific T cells directed against parts of this foreign protein.

More information on how mRNA vaccines work can be seen in the following video.

How do vector vaccines work?

With vector vaccines, a virus that is capable of infection but is completely harmless to humans is modified in such a way that it does not lose its harmless properties but appears to our immune system as if it were a completely different pathogen.

In simple terms, our immune system reacts to this vector virus as if it were SARS-CoV-2, with the difference that symptoms and consequences of the disease are absent. Thus, similar to mRNA vaccinations, only the blueprint for viral surface proteins is provided. Based on this blueprint, the SARS-CoV-2 spike surface protein is produced by the human cells themselves and then transported to the cell surface. There it is recognised as being foreign by special immune cells and stimulates the immune system to produce antibodies

and specific T cells against SARS-CoV-2. These should subsequently protect against disease. The COVID-19 vector vaccines contain harmless, well-researched carrier viruses that are controlled and eliminated by the human immune system. In the case of vector vaccines, the viruses used as vectors are genetically modified in such a way that they cannot further reproduce in the host cell, but merely serve as a means of transport for the genetic blueprint of the surface proteins of the virus to be combated.

More information about how vector vaccines work can be seen in the following video.

Is it possible to choose which vaccine I receive?

From today's perspective, individuals cannot choose which vaccines are used for performing the coronavirus vaccination, since for organisational reasons (e.g. multiple-dose containers, short shelf life) only one type of vaccine is available at most vaccination sites.

Vaccine development

The following COVID-19 vaccines are currently approved in the European Union (as of spring 2021):

The vaccine Comirnaty from the manufacturer BioNTech/Pfizer is approved from the age of 16 years.

The COVID-19 Vaccine Moderna from the manufacturer Moderna is approved from the age of 18 years.

The vaccine Vaxzevria from the manufacturer AstraZeneca is approved from the age of 18 years.

The COVID-19 Vaccine Janssen from the manufacturer Janssen is approved from the age of 18 years.

The development of COVID-19 vaccines is progressing at an accelerated rate due to the current pandemic. Normally, approval studies are conducted one after the other. However, in order to accelerate development, numerous studies are currently being conducted in parallel worldwide. At the same time, vaccine

manufacturers can have data analysed and evaluated by the European Medicines Agency (EMA) on an ongoing basis even before submission for approval. This is called a 'rolling review' process. The subsequent, actual approval procedure can thus be greatly shortened in time, because essential parts of the study data have already been reviewed in detail.

However, the requirements for the vaccine in terms of quality and safety stay the same. All vaccines are tested for safety and efficacy in extensive studies involving tens of thousands of test persons.

How does development of a vaccine proceed against a new unknown virus such as SARS-CoV-2?

Initially, the relevant pathogen is analysed and it is determined to which components of the virus the human immune system reacts and can build up protection against (antibodies and specific T cells).

The vaccine's efficacy and tolerability are tested in cell cultures (e.g. using human immune cells) and in animal experiments. Only once the vaccine has undergone extensive testing and it has been demonstrated that it can be manufactured to the requisite standards and to a level that meets very exacting criteria is it then tested on informed and consenting volunteers in the course of Phase I to Phase III clinical trials.

Once all the results from pre-clinical and clinical trials, and a tried and tested production method, are available, an application for approval can be submitted. In Europe's case, the approval procedure for COVID-19 vaccines is coordinated by the European Medicines Agency (EMA).

What is the basic procedure for the approval of vaccines?

An approval procedure sets particularly strict requirements for modern vaccines while they are being manufactured and monitored (referred to as a risk-benefit analysis): the applicant submits an application for approval of its vaccine to the Medicines Agency. The application is accompanied by a dossier consisting of regulatory information (e.g. type of application and intended product information), data on the manufacture of the vaccine, data on studies in animals and, lastly, data on the clinical trials in humans, as well as

relevant literature. It also contains information on how pharmacovigilance can be performed for this particular product.

It can take up to two years for the vaccine to be evaluated by the experts of the relevant authorities, i.e. to review the entire dossier to ensure compliance with all strict scientific and regulatory standards, as well as to assess the quality, safety and efficacy of the vaccine. This is particularly the case if the dossier is incomplete or if any shortcomings need to be remedied. This period of time may be shortened in the interests of public health. A risk-benefit analysis based on all the data that has been submitted is then carried out to ensure a high-quality, effective and, above all, safe vaccine.

In the case of the COVID-19 vaccines, several vaccine developers have so far applied to the European Medicines Agency (EMA) for a rolling review. This means that the agency is not simply notified when all the trials have been completed but instead is kept constantly informed while they are going on and can continuously check and evaluate the datasets that are already available. The subsequent 'actual approval procedure' can then be completed in less time, as large parts of the data have already been reviewed in detail.

How safe can a rapidly approved vaccine be against a novel virus such as SARS-CoV-2?

A vaccine will only be made available on the market after it has been sufficiently tested. As with any other vaccine, a new vaccine to protect against COVID-19 is tested intensively.

The various candidate vaccines each undergo strictly controlled processes, for which there are clear legal and scientific guidelines that must be met before any vaccine can be used on healthy people. The vaccine will only be approved for the market if the risk-benefit ratio is positive.

Even after marketing approval, continuous monitoring is carried out to identify possible side effects and to check the effect, as well as ongoing further evaluation of the risk-benefit ratio. In the case of COVID-19 vaccines, conditional marketing approval is initially granted, which may be revoked or suspended at any time should production, safety or efficacy issues arise during use.

Will vaccine safety continue to be monitored after the vaccines have been approved by the EMA?

Within the framework of pharmacovigilance (drug safety monitoring), vaccines are continuously monitored not only before and during their approval but also as long as they are on the market. Drug safety monitoring is understood to mean a range of methods and activities which, among other things, should make it possible to detect, evaluate, understand and prevent further adverse reactions.

Part of drug safety monitoring is the obligation to report for health care professionals in connection with the use of vaccines, which, as for all other drugs, follows the requirements in accordance with Section 75g of the Medicines Law (Arzneimittelgesetz). In the case of medicinal products for human use, this applies to suspected adverse reactions and the absence of expected efficacy. However, not only health care workers, but also patients and their relatives can report suspected adverse drug reactions according to Section 75h of the Medicines Law. Reports should be submitted electronically or in writing to the Federal Office for Safety in Health Care (BASG), Traisengasse 5, 1200 Vienna. Find more details here: https://www.basg.gv.at/pharmakovigilanz/meldung-von-nebenwirkungen/.

What happens after suspected and reported side effects?

After reporting a suspected adverse reaction to the BASG, the reporting person receives a confirmation of receipt. The person making the report may be contacted by BASG staff on a case-by-case basis, for example, to ascertain the course or outcome of a suspected adverse reaction.

Once the report has been documented and, where applicable, the necessary details have been added, the BASG will carry out an assessment. This notification is then forwarded to the European Union Drug Regulating Authorities Pharmacovigilance (EudraVigilance) database, where all suspected adverse reaction reports from throughout the EU are collected. Analysing the data collected here makes it possible to identify a potentially new risk at national and European levels (signal detection), to examine it in detail and thereby help improve drug safety for all patients. If a signal is detected, it is evaluated and discussed in a European context by the PRAC (Pharmacovigilance Risk Assessment Committee) of the EMA (European Medicines Agency). This may then result in new warnings, contra-indications and adverse reactions being included in the prescribing

information/package information leaflet, in new measures to reduce the risk in future or even in restricting or revoking the approval for a drug, where necessary.

After such a short testing period, how do I know that there will be no long-term side effects with the vaccines?

There is no such thing as one hundred percent certainty. However, this is also the case for the approval of other drugs.

To record as many possible long-term side effects as possible, very large studies would have to be carried out over many years. During that time though, an effective medicine would be withheld from the general public, which could lead to damage to public health or even deaths caused by untreated illnesses. Therefore, in order to identify possible long-term side effects, attention will be closely paid to information from the submitted animal studies and any evidence arising from the clinical development programme. Suspicious symptoms are identified and closely monitored, with regular reporting by the marketing approval holder to the authorities at shorter than usual intervals being one of many potential measures available in such cases.

In addition, approval holders may also be required to conduct long-term studies after marketing approval has been granted. These will be used to further investigate safety and efficacy. The results of these studies must be obligatorily submitted within a certain period of time.

No drug can be said to be 100% risk-free, but the benefits must always outweigh the potential risks. Although the risk-benefit assessment is carried out as part of the approval procedure, it is the subject of regular review, even after approval, as further data are collected and new information is received.

Further information on vaccine development and approval can also be found here.

FAQ: Procurement of vaccines

Procurement

The procurement of vaccines in the European Union can be significantly accelerated in coming weeks due to the expansion of production capacities. There are currently four approved vaccines for all 27 EU Member States. The EU Commission has secured a broad portfolio of 2.6 billion vaccine doses for the European population, of which 1.8 billion are from the already approved vaccines.

How does European vaccine procurement work?

As part of the joint procurement process, the 27 EU Member States together with the European Commission have committed themselves, not separately but together, to entering into advance purchase agreements with the manufacturers of promising vaccines. This enables quantities to be reserved which are divided among EU member states by population numbers, with Austria's population making up around 2% of the EU's total population.

Vaccine contracts and transparency

An Advance Purchase Agreement (APA) comes into existence when both parties have completed the contract work. The finalised elements of the contract are discussed and decided upon in the steering group. Concluding an advance purchase agreement requires the approval of the European Commission, which signs it on behalf of the member states. The Member States of the European Union are then responsible for purchasing the vaccines as soon as they are available.

What are the advantages of the European procurement process compared to a national purchasing strategy in which each country buys its own vaccines?

The advantage of the common European approach is that the risk of concluding advance purchase agreements with manufacturers and contributing to research and production costs is borne by the European Union rather than each individual Member State. Another enormous administrative advantage is that Austria does not need to negotiate by itself with potential manufacturers. The market power of all EU states together is greater than that of Austria alone in terms of price and legal contractual conditions.

Can vaccine that has not been officially procured via the European Union also be vaccinated in Austria?

Vaccines procured through the European procurement procedure are purchased centrally by the Austrian Federal Government and then distributed to the vaccination centres in the Federal States in compliance with their respective needs. They can therefore not be ordered privately on the Internet. The Federal Office for Safety in Health Care (BASG) even warns against such offers.

An import permit must be applied for with vaccines that are not approved in the EU/Austria. Furthermore, there is no entitlement to compensation under the Vaccine Damage Act if vaccines are used that are not approved in the EU. The administering doctor bears liability for the vaccination of non-authorised vaccines in Austria.

FAQ: Distribution of vaccines

Distribution

The various vaccines are centrally purchased by the Federal Government via the European Union and then distributed within Austria. Distribution is carried out in accordance with the respective number of inhabitants and in proportion to the delivery quantities available.

On behalf of the EU Member States, the European Commission has so far made advance purchase agreements or purchase agreements with six manufacturers (BioNTech/Pfizer, Moderna, AstraZeneca, Sanofi/GSK, Johnson & Johnson and

CureVac). Further agreements with Novavax and Valneva are currently under negotiation.

Vaccination progress and the latest figures for vaccines can be found on the Ministry of Health dashboard: coronavirus vaccination in Austria – Dashboard (gesundheitsministerium.at)

Which COVID-19 vaccines have already received marketing approval?

Until now, vaccines from the following manufacturers have been approved in the European Union: BioNTech/Pfizer ('Comirnaty'), Moderna, AstraZeneca ('Vaxzevria') and Johnson&Johnson (Janssen).

Current figures on vaccines available in Austria can be found on the dashboard of the Ministry of Health: coronavirus vaccination in Austria – Dashboard (gesundheitsministerium.at)

Vaccination

Once an approval has been granted, not enough vaccines are immediately available for all people willing to be vaccinated.

The first quarter of 2021 was marked by vaccine shortages. The reasons for this are the high global demand and the limited supply capacities. This is why it was, and still is, necessary to prioritise certain groups of people with respect to coronavirus vaccinations. The updates of the national COVID-19 vaccination schedule are based on available supply quantities and the marketing approvals.

How long will it take for a majority of the Austrian population to get a coronavirus vaccination?

An approved vaccine must be produced, distributed and administered. It is expected that further COVID-19 vaccines will be approved during 2021. Depending on how many vaccine doses are available in Austria and the organisation of its distribution and administration,

the target may be achieved sooner or later. However, when the majority of the population will have received a coronavirus vaccination also depends on how many people wish to be vaccinated in Austria. The objective is to ensure that every person for whom vaccination is recommended is vaccinated. High vaccination participation within the population will significantly reduce the disease burden, prevent severe cases and deaths, and reduce the burden on the health care system.

FAQ: Medical questions

Is a coronavirus vaccination possible even if antibodies are detected?

Yes. Large-scale approval studies have included both individuals with pre-existing antibodies to SARS-CoV-2 and study participants without antibodies. According to results so far, it is assumed that the presence or absence of antibodies makes no difference regarding the safety of the vaccination. An increased rate of reactions to vaccination is not to be expected in individuals in whom antibodies have been detected.

Studies have demonstrated that individuals have high antibody levels for six to eight months following molecularly confirmed infection with SARS-CoV-2, and that these individuals require only one dose to achieve comparable protection to uninfected, regularly vaccinated individuals. During or after molecularly confirmed infection with SARS-CoV-2, it is therefore recommended to postpone the coronavirus vaccination for six to eight months and then, according to current knowledge, to administer only one dose. In case of a positive neutralisation test (no correlates), the coronavirus vaccination should be postponed for three months. If a molecularly confirmed infection with SARS-CoV-2 occurs in the interval between the 1st and 2nd inoculation, the second dose should be postponed for six to eight months according to current scientific knowledge.

Should an antibody test be performed before a coronavirus vaccination?

Antibody testing is not required before a coronavirus vaccination because it has no consequence for vaccination. Large-scale approval studies have included both individuals with pre-existing antibodies to SARS-CoV-2 and study participants without antibodies. According to results so far, it is assumed that the presence or absence of antibodies does not make any difference regarding the safety of the vaccination. An increased rate of reactions to vaccination is not expected in individuals with antibodies.

Possible interactions of the coronavirus vaccination

Autoimmune diseases or chronic inflammatory diseases are in principle no contraindication for vaccinations. Until now, studies have not been able to prove a causal relationship between a vaccination and a new autoimmune disease, or chronic inflammatory disease, or relapse of an already existing disease.

Vaccine-preventable infections, on the other hand, can increase morbidity and mortality in non-vaccinated persons with autoimmune diseases or chronic inflammatory diseases as well as e.g. triggering an attack. These individuals also have an increased risk of a severe course due to the underlying disease and/or its therapy. Vaccinations can thus reduce the risk of symptomatic disease caused by the respective pathogens and reduce the risk of infection-triggered relapses of the underlying disease.

With regard to the indication for vaccination, a differentiation must be made between courses of disease with and without immunosuppressive therapy.

Do autoimmune diseases or other impairments of the immune system limit vaccination?

To date, COVID-19 vaccines have only been partially studied in individuals with autoimmune diseases or weakened immune systems due to disease and/or medications. Empirical data is already available on HIV, cancer (without chemotherapy), diabetes mellitus, stable autoimmune diseases and diseases affecting the cardiovascular system or the lungs. No negative effects on tolerability, safety or efficacy were found in such cases. There are still insufficient empirical values for other medical conditions. Whether vaccination is recommended for people with autoimmune diseases should therefore be clarified individually with the attending doctor.

Does a coronavirus vaccination interact with medications and other vaccinations?

No interactions are currently known. However, immunosuppressive medications can presumably reduce (inhibit) the effectiveness (immune response) of the vaccination.

Since mRNA vaccines and vector vaccines are vaccines that are to be assessed as inactivated vaccines (dead vaccines), the principles for the use of inactivated vaccines are initially applicable to the respective groups of persons and medications.

As regards the taking of medication, this means that people who can receive other vaccines, such as influenza vaccines or the tick vaccine, can also receive COVID-19 vaccines. The main issue here does not concern the issue of possible adverse reactions from the vaccination, but rather whether the vaccination also works properly, i.e. whether protection is built up. However, this is ultimately a decision according to the specific case and must be discussed with the vaccinating doctor.

With regard to possible interactions with other vaccines, a minimum interval of 14 days from the COVID-19 vaccination is recommended for better correlation of adverse reactions to inactivated vaccines, because COVID-19 vaccines are novel vaccines. The interval to live vaccines should be 28 days. However, if there is another urgent vaccination indication close in time to a COVID-19 vaccination, this can be taken without hesitation.

FAQ: Rumours and facts

Rumours and facts

An increased need for information exists in connection with the coronavirus vaccination. Unfortunately however, there is much misinformation around that also spreads quickly. False reports about the coronavirus pandemic, the course of the disease and the virus itself make people feel uneasy. This sense of uncertainty leads to circulation of the corresponding (false) information. In order to counteract this and to provide everyone with correct information, you can find answers to the most common rumours in connection with the coronavirus vaccination below.

Dependable sources about the coronavirus vaccination

To provide you with comprehensive information about COVID-19 and the coronavirus vaccination, you can find an overview of professional and reliable sources here:

Austrian Agency for Health and Food Safety GmbH/AGES

Federal Office for Safety in Health Care/BASG

Gesundheit.gv.at [Health]

Österreich impft Initiative ['Austria vaccinates' initiative]

Austrian Medical Association

Robert Koch Institute

If you prefer videos, visit the YouTube channel of Österreich impft

Rumour: "The coronavirus vaccine makes me infertile."

These are the facts: No. Animal studies do not suggest any direct or indirect adverse effects regarding the possibility of becoming pregnant. Neither vector vaccines nor mRNA vaccines alter the genetic make-up. They have no effect on fertility.

There is currently only limited experience with the use of vector vaccines and mRNA vaccines in pregnant women. The administration of COVID-19 vaccine during pregnancy should be considered if the potential benefits outweigh all potential risks to the mother and foetus.

Rumour: "Coronavirus vaccination puts a microchip into people."

These are the facts: No, this information is false and is based on a conspiracy theory.

As with any other vaccine, a new vaccine designed to protect against COVID-19 is tested intensively. The various candidate vaccines each undergo strictly controlled processes, for which there are clear legal and scientific guidelines that must be met before any vaccine can be used on healthy people. In Austria there are also several domestic companies involved in the development and research of vaccine candidates or components of these. The common objective of all these and other activities is to get vaccines approved and then used as soon as possible to be able to control the pandemic.

Rumour: "After the coronavirus vaccination the immune system is shut down for 7 days."

These are the facts: That is wrong. Vaccines do not turn off the immune system.

The opposite is true: vaccines stimulate the immune system to build up protection against possible diseases.

Rumour: "The vaccine is radioactive."

These are the facts: No. All safety standards and scientific standards are adhered to in the development of the vaccines.

A vaccine will only be made available on the market after it has been sufficiently tested. As is the case for any other vaccine, a new vaccine to protect against COVID-19 will be rigorously tested. The various candidate vaccines each undergo strictly controlled processes, for which there are clear legal and scientific guidelines that must be met before any vaccine can be used on healthy people. The vaccine will only be approved for the market if the risk-benefit ratio is positive.

Even after marketing approval, continuous monitoring is carried out to identify possible side effects, and ongoing further evaluation of the risk-benefit ratio is performed to assess the effect. In the case of vaccines, including COVID-19 vaccines, conditional approval is granted at first which can then be withdrawn or suspended at any time, should any problems relating to its production, safety or effectiveness emerge during its use.

Rumour: "Deaths occur after the coronavirus vaccination."

These are the facts: There are health events such as autoimmune diseases, cancer, and even death, that occur in every population even without vaccinations.

It must therefore be assumed that if a large number of individuals are vaccinated, such health events will also occur in vaccinated persons close in time to the vaccination. However, these are not necessarily related in cause to the previously administered vaccination. Since, especially at the beginning of the vaccination campaign, mainly very elderly persons are vaccinated, it is to be expected that naturally caused although not vaccine-related health events occur close in time with the vaccination.

The expected number of deaths one week after vaccination in at-risk persons aged 80 years and over is 3.5 per 1000. Based on a background incidence (= expected number of deaths in > 80-year olds of 3.5/1000 persons/week), one in 290 persons in this age group can be expected to die within one week, regardless of vaccination.

Rumour: "People have only become ill with COVID-19 due to the coronavirus vaccine."

These are the facts: No. The available vaccines do not contain live coronavirus, which means that no infection can result from the vaccine.

However, protection via vaccination does not immediately exist upon vaccination because this protection must first be built up. Therefore, it can happen that a disease occurs even after a vaccination, but which would also have occurred without the vaccination. For complete protection via vaccination, a complete (1- or 2-part, depending on the vaccine) series of vaccinations with the identical vaccine is required. Getting vaccinated means you develop disease protection and do not need to worry about getting seriously ill. No vaccination protects 100%. If, in exceptional cases, COVID-19 disease occurs despite vaccination, the course of the disease is much milder and complications and deaths are avoided.

Rumour: "Vector vaccines are not as effective as mRNA vaccines."

These are the facts: Data and results on the individual vaccines cannot be directly compared due to different study protocols. The vector vaccines currently available from AstraZeneca and Janssen are effective and very good at preventing severe courses of disease and death.

The available vector vaccines, as with any other approved vaccine designed to protect against COVID-19, were also tested intensively before being granted approval. In the approval trials, this vaccine demonstrated greater than approx. 60% efficacy in preventing symptomatic, laboratory-confirmed COVID-19 disease in individuals aged 18 to 64 years.

It can also be assumed in the case of vector vaccines that persons who, in exceptional cases, fall ill with COVID-19 despite vaccination, will in such cases experience a milder course of disease and that complications and deaths can be avoided.

Rumour: "The new vaccines are not safe because of the accelerated approval process."

These are the facts: The existing vaccines are safe.

The development of COVID-19 vaccines is progressing at an accelerated pace due to the severe impact of the pandemic. Extensive, already existing knowledge about coronaviruses and vaccine development is a part of this. In order to accelerate development, companies and research institutions are deploying considerably more personnel and financial resources in a shorter period of time compared to conventional development cycles. Manufacturers are also expanding their production facilities at a much earlier stage of development than usual, so that large quantities of vaccine quickly become available after approval.

In addition, the European Medicines Agency (EMA) offers scientific advice to vaccine developers in order to drive development forward in a focused and targeted manner. In the case of COVID-19 vaccines, the quality, nature and scope of the regulatory assessment does not differ in any way from 'conventional' approval processes.

Rumour: "Vaccination doesn't make any sense because the coronavirus is constantly changing."

These are the facts: The coronavirus vaccine also protects against mutations by preventing severe courses of the disease or death.

Viral variants formed by spontaneous mutations are nothing unusual, but are a natural process that occurs to some extent in almost all viruses. It is important to observe where within the virus these mutations occur and what effects they have. Thus, the circulating viruses are closely monitored and analysed. The currently available vaccines cause the human body to produce a large number of neutralising antibodies. It can be assumed that the higher the antibody titres, the more effective is the defence against variants of the virus.

With the new mRNA vaccine or vector vaccine technologies, it is also possible that vaccines can be adapted to new virus variants within a few weeks. At the same time, there are already other vaccine candidates that are currently under discussion where, in

principle, several variants/strains are contained in a single vaccine in order to increase coverage, a principle that is familiar from influenza vaccines for example.

Vaccination efficacy may be somewhat lower for the virus variants from the UK, South Africa and Brazil. Despite the virus mutations, vaccination protects against contracting COVID-19 or can prevent severe courses of the disease and death.

Rumour: "The vaccine is ineffective because people can still get infected."

These are the facts: The coronavirus vaccination means you are protected yourself.

Based on preclinical data, it is also assumed that coronavirus vaccination results in less transmission of the virus, although this has not yet been conclusively proven clinically.

Data until now show that vaccination leads to a lower viral load. It can thus be assumed that vaccinated persons are less infectious. For complete protection via vaccination, a complete (1- or 2-part) series of vaccinations with the same vaccine is required according to the product information.

For you yourself, vaccination means that the risk of becoming severely ill or dying from COVID-19 is significantly reduced. Vaccination is able to prevent many symptomatic COVID-19 diseases. If, in exceptional cases, COVID-19 disease occurs despite vaccination, the course of the disease is much milder and complications and deaths are avoided. The objective is therefore to ensure that every person for whom vaccination is recommended is vaccinated. High vaccination participation within the population will significantly reduce the disease burden, prevent severe cases and deaths, and reduce the burden on the health care system.

Rumour: "The vaccine causes long-term damage to health."

These are the facts: That is wrong. All vaccines authorised in Europe are marketed only after very extensive vaccine safety testing.

At the beginning of every vaccine development, testing is carried out on animals and only then in studies on humans. It has been agreed in Europe (as well as in the USA) that large-

scale trials must show convincingly that the vaccines are both safe and effective. This usually involves very large study populations.

The quality, type and scope of the regulatory review for COVID-19 vaccines are also identical to 'conventional' approval processes, i.e. no less data on the safety and efficacy of the vaccines must be submitted than in other approval processes.

The Medicines Agency is working at full speed to review the applications for marketing approval, taking into account all the regulatory, scientific and legislative requirements applicable in the EU. The following situation serves as an illustration: a car needs an MOT inspection for testing its vehicle safety. The inspection usually takes two days in the garage. If the car is needed urgently within 24 hours though, the garage uses more staff to get the job done more quickly. However, the MOT criteria remain the same.

Even after marketing authorisation, continuous monitoring is carried out to identify possible side effects and to check the effect, as well as ongoing further evaluation of the risk-benefit ratio. In the case of COVID-19 vaccines, conditional marketing approval is initially granted, which may be revoked or suspended at any time should production, safety or efficacy issues arise during use.

Rumour: "Vaccines against pneumonia and influenza (flu) do NOT protect against COVID-19."

These are the facts: Correct. Only the coronavirus vaccine provides protection against COVID-19.

Vaccines against pneumonia such as the pneumococcal vaccine or the vaccination against 'real' flu (influenza) do not provide protection against the novel coronavirus SARS-CoV-2. This virus is new and different, so that separate vaccines have been and continue to be developed for protection against COVID-19 or SARS-CoV-2. Although the above vaccines are not effective against COVID-19, vaccines that prevent other respiratory diseases and their consequences are particularly important during the COVID-19 pandemic. The vaccinations against e.g. pneumococci, pertussis (whooping cough) and influenza ('real' flu), in accordance with the specifications of the Austrian vaccination schedule, are therefore urgently recommended to protect your health.

Federal Ministry of
Social Affairs, Health, Care
and Consumer Protection
Stubenring 1, 1010 Vienna, Austria
+43 1 711 00-0
sozialministerium.at