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FAQ: COVID-19 vaccination

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Contents

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Is it possible to get vaccinated against COVID-19?

Free vaccination will be available for everyone in Austria who wants it. The state is purchasing the vaccines centrally and will distribute them to the many places where vaccination will be carried out. At present, (09.12.2020), no COVID-19 vaccine is yet available in Austria. However, people are working very hard all over the world to develop vaccines.

Will the COVID-19 vaccine be free of charge?

Free vaccination will be available for everyone in Austria who wants it.

Will COVID-19 vaccination be voluntary?

Yes. The federal government and other government representatives have repeatedly emphasised that there will be no compulsory vaccination for all. The government is relying on a voluntary system based on public information. Everyone who wants to be vaccinated will be able to have the vaccine. Because there will initially not be enough vaccine available to vaccinate everyone at the same time, those people will be vaccinated first who are at the greatest risk. After that, everyone else will be vaccinated in stages. We are confident that sufficient vaccine will be available from the second quarter onwards for everyone to be vaccinated who wants it. We are confident that many people will accept this free, voluntary service and will be vaccinated, without it being made compulsory. The vaccine is an enormous step forward in the battle against the worst pandemic for a hundred years and we can all help to improve the situation by getting vaccinated.

Who will accept responsibility and be liable for any adverse events after a COVID-19 vaccination?

The Vaccine Damage Act covers this kind of harm to health. The state is obliged to pay compensation for health damage caused by vaccinations which are recommended under the directive on recommended vaccines to avert a threat to the general state of public health, in the interests of the health of the nation. Work is currently underway to include the COVID-19 vaccine in this directive.

If a relevant health event occurs in a timeframe associated with vaccination, the individual concerned can apply to have this recognised as vaccine damage. Such an application leads to an administrative process by the Ministry of Social Affairs. The process includes obtaining expert opinions and holding a hearing for the parties concerned. The legal eligibility requirements under the Vaccine Damage Act require a lower level of proof than procedures under civil law, and no proof of causality between the vaccination and the health damage has to be provided. Furthermore, a procedure for transferring the legal action from the Ministry of Social Affairs to the Federal Administrative Court or the Higher Administrative Court and the Constitutional Court for free also exists. The harm to health is recognised as vaccine damage if the process establishes a probable connection with vaccination. In order to assess whether the vaccine that was administered was a significant factor in the individual's current state of health, the process entails checking for the existence of a clear temporal connection, the lack of any other (more probable) explanation for the symptoms that occurred, and any similarity between the alleged harm caused by the vaccination and the complications caused by infection with the pathogen against which the vaccine is intended to offer protection. If a connection is recognised, social security assistance is available in the form of a one-off payment or regular benefit payments.

Who can carry out COVID-19 vaccinations?

All doctors, regardless of whether they are specialists or trained in general practice, are entitled to carry out COVID-19 vaccination. The same applies to occupational health practitioners and school doctors. Foundation doctors in the final years of medical training (junior doctors), retired doctors and foreign doctors can also administer COVID-19 vaccines in cooperation with doctors who are authorised to practise independently. Medical students are also allowed to do so in a structured setting (e.g. a vaccination

"pathway" operated on behalf of a regional public health authority) and under medical supervision and direction. Qualified nurses and care staff are also allowed to administer COVID-19 vaccines subject to written instruction from a doctor. Paramedics and ambulance workers should also be mentioned in this context, because the legal principles for them are currently being put in place. Once the legislative process has been successfully completed, and members of these occupations have been given appropriate training, they will be entitled to administer COVID-19 vaccination under medical supervision and direction. Everyone who is entitled to give vaccinations may also prepare the vaccine in accordance with the relevant requirements, although such preparatory work can also be carried out by appropriate pharmaceutical personnel.

The professional conduct requirements for carrying out COVID-19 vaccinations are defined in the "Ordinance on the professional conduct requirements for carrying out COVID-19 vaccinations" dated 03.12.2020 and can be found here: https://www.sozialministerium.at/Informationen-zum-Coronavirus/Coronavirus---Rechtliches.html

FAQ: Vaccine development and approval

Which COVID-19 vaccines are currently being studied?

At present, (8.12.2020), researchers are working hard around the world to develop a vaccine against COVID-19. There are currently over 52 candidate vaccines in clinical development and some candidate vaccines are already in Phase 3 of testing, the stage that is most significant in the approval process. Over 150 other vaccine projects are undergoing trials but have not yet been tested on people. Different vaccine technologies are being used, for example vector-based vaccines, mRNA vaccines and protein-based subunit vaccines. An overview of the current status of vaccine development is available from the World Health Organization (WHO) at https://www.who.int/publications/m/item/draft-landscape-of-covid-19-candidate-vaccines .

When will a COVID-19 vaccine be available in Austria?

The first valid, safe and effective vaccines in relevant quantities could be available in Austria from the start of 2021. The deciding factor is the centralised granting of approval for the European Union. It is only then that the vaccines are deemed to meet the legal quality requirements. Applications have already been submitted for limited approval for the vaccines from BioNTech/Pfizer and Moderna. Finding a suitable vaccine is always a complex process. The huge importance for global health has led to unprecedented efforts being made and significant public funding provided, resulting in scientific, technical and administrative/official partnerships that have enabled vaccines to be developed rapidly.

Why hasn't a COVID-19 vaccine been developed yet?

SARS-CoV-2 is a novel pathogen. It was only identified as causing COVID-19 in January 2020. Research began immediately around the world to develop a vaccine. By the end of 2020, the first promising clinical trial data is already available. That is a scientific success

story. Because numerous trials are being run concurrently, as opposed to one after the other as is normally the case, it has been possible to obtain relevant data more quickly. Producing a vaccine for use in humans is always complex and the process is subject to the highest level of quality control and strict monitoring. New drugs or vaccines must be tested for their effectiveness, side effects and safety before they can be authorised in the European Union, and COVID-19 vaccines have to meet the same high quality standards as any other vaccine.

How are the clinical trials conducted?

Before clinical trials are carried out on people, pre-clinical trials have to be carried out. This takes place in the laboratory, using cell cultures and/or animal trials. Pre-clinical research delivers initial information about how the new drug works, how well tolerated it is and the correct dosage. Only if no dangerous side effects occur and the product is effective will clinical trials on people be approved. All clinical trials on people have to be presented to the relevant (research) ethics committee for approval and licensing before they begin. Both the pre-clinical and clinical trials take time in order to analyse in detail the safety (tolerability) and effectiveness of any vaccine product. That is why a promising candidate for a vaccine cannot be made available immediately.

What are ethics committees?

Ethics committees are legally established, independent and autonomous advisory panels, made up of experts and lay people, men and women, whose job is to test whether research projects on humans are safe – before they start. The members include experts from different fields of medicine, social care, ethics (or institutional spiritual welfare), pharmacy or pharmacology, the law, biometrics and so on. There must also be members representing the disabled and the elderly and one independent patient representative. Ethics committees are established on a legal basis. They have existed in Austria since the 1970s in individual federal Länder, at hospitals and at medical schools. There are also ethics committees in every country in the world where clinical research is carried out. Multi-centre clinical trials that are conducted in more than one country around the world have to be assessed and approved by the relevant ethics committees in all those countries. A distinction needs to be made between those ethics committees and ethics councils or bioethics committees such as the Bioethics Committee in the Federal

Chancellery in Austria. They advise parliaments or governments on general ethical questions relating to life sciences, such as stem cell research or artificial intelligence.

What is the role of ethics committees? What do they guarantee?

Ethics committees assess clinical trials of drugs or medical products and the use of new medical methods. They have to examine the scientific content and relevance of such research projects. They also have to carry out a risk-benefit analysis and judge whether the rights and integrity of the volunteers taking part in the clinical trial will be preserved during the trial. The information provided to the participants and the confidentiality of the data that is obtained also form part of the assessment. In addition to protecting individuals, their purpose is also to ensure that public confidence in clinical research is maintained.

Are databases accessible by the public, in the interests of transparency in clinical research?

All clinical trials must be registered in a publicly accessible database before the trial starts and before it is assessed by an ethics committee. This is essential in order to guarantee that medical science is as transparent as possible and be confident that no data is suppressed or selectively excluded.

The main database in the European Union is that maintained by the European Medicines Agency, the EMA: the EU Clinical Trials Register https://www.clinicaltrialsregister.eu/

What steps are involved in developing a vaccine against a new unknown virus like SARS-CoV-2 or COVID-19?

First, the pathogen is analysed and tested to find out which components of the virus the human immune system reacts to, and against which protection (antibodies and specific T-cells) can be built up. This is followed by development of the vaccine design – which vaccine platform is suitable and which additives are needed. 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). The EMA evaluation of the vaccine is carried out by experts from Europe's various national competent authorities. In the event that the vaccine meets all scientific and regulatory requirements, and the benefits it offers outweigh the risks, a recommendation for authorisation will be issued to the European Commission as soon as the authorisation procedure has been concluded. The vaccine can then be marketed and used in humans. Each batch must, however, be approved by a recognised test laboratory before entering the market.

How does the approval procedure for vaccines work?

An authorisation 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 their vaccine to be authorised by the relevant authority for medicines. The application is accompanied by a dossier containing information of a regulatory nature (e.g. type of application, intended product information), data on the manufacture of the vaccine, data on animal testing and, finally, data on clinical trials involving humans, together with 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 COVID-19 vaccines, so far four (as of 9.12.2020) vaccine developers have applied to the European Medicines Agency (EMA) for a concomitant review process known as a "rolling review". This means that the agency is not simply notified about progress 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 happen more quickly because large parts of the data have already been assessed in detail.

How safe is a new COVID-19 vaccine?

A vaccine will only be made available on the market after it has been adequately examined. 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 authorisation has been granted, the vaccine will be constantly monitored to record possible adverse reactions, and the risk-benefit ratio will be continuously assessed to judge its effectiveness. In the case of vaccines, including COVID-19 vaccines, conditional approval is granted at first which can be withdrawn or suspended at any time, should any problems relating to its production, safety or effectiveness emerge when it is in use.

Will vaccine safety continue to be monitored even after approval?

The purpose of pharmacovigilance (or drug safety) is to monitor vaccines constantly, not only before and during the approval process but also for as long as they are available on the market. Pharmacovigilance involves a variety of methods and activities designed, among other things, to detect, assess, understand and prevent adverse reactions.

One element of pharmacovigilance is the reporting obligation for members of the healthcare professions who are involved in using vaccines, as is the case for all other drugs under the requirements of Section 75g of the Medicines Act (AMG). It applies to suspected adverse reactions or the failure of the expected effectiveness of medicines used in humans. Not only healthcare staff but also patients and their relatives are able to report suspected adverse reactions (section 75h, AMG). Any such reports must be made electronically or in writing to the Austrian Federal Office for Safety in Health Care (BASG), Traisengasse 5, 1200 Vienna. Further details available here: www.basg.gv.at/pharmakovigilanz/meldung-von-nebenwirkungen/.

When a suspected adverse drug reaction is reported to the BASG, the person reporting it receives confirmation of receipt of the notification. 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 recorded and, where applicable, the necessary details have been added, the BASG will carry out an inspection. 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 the national and European level (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 approval for a drug, where necessary.

Why are COVID-19 vaccines being evaluated and authorised so quickly?

In the case of COVID-19 vaccines, the quality, nature and scope of the regulatory assessment does not differ in any way from the "conventional" authorisation process, nor are any corners being cut. However, the procedure as a whole is being accelerated in order to bring urgently needed vaccines, which have also been shown to be safe and effective, to the market. For this purpose the so-called rolling review process has been applied, under which, in the case of promising vaccines, the medicines authorities can begin assessing them in parallel, while they are still being developed. The "actual approval process" which follows can then be made much shorter, because significant components of the dossier have already been examined in detail. The EMA also offers an "accelerated assessment" process, another greatly shortened approval process, but based on submission of a complete dossier. In that case, no assessment by the authorities takes place in parallel to the development process. In both cases, the risk-benefit analysis by the EMA's committee of experts (made up of representatives from the EU member countries, Norway and Iceland) determines whether approval can be recommended or not. The procedure is then as usual: if the EMA gives a positive assessment and recommendation

for approval, the European Commission gives the final order for the vaccine to be approved.

What is done to ensure that no compromises are made when it comes to safety?

Testing is first carried out on animals and then in trials 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. Very large trial populations comprising over 30,000 test subjects are usually needed for this purpose. As is the case with other drugs, even large-scale trials are only able to detect adverse reactions that occur very frequently, frequently or occasionally. Rare or very rare adverse reactions can only be observed after approval, as much larger populations are required to be able to show this with any degree of reliability. However, tools used in pharmacovigilance to ensure safety mean that, even after drugs have been approved, more rarely occurring adverse reactions can be identified. Where applicable, official steps are then taken promptly to avoid or minimise any risk. In exceptional cases, the approval may even be revoked if the risk-benefit ratio changes adversely after approval.

How is it possible to know that there will be no long-term side effects after such a short phase of testing?

This cannot be said with 100% certainty, but that is also the case for other drugs when they are approved. To identify all possible long-term side effects, very large trials would have to be carried out over many years, if not decades. However, during that time, 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. Close attention is therefore paid to information gleaned from the animal experiments that formed part of the trial, and all evidence arising from the clinical development programme is carefully examined in order to identify potential long-term side effects. Suspicious symptoms are identified and closely monitored, with regular reporting by the approval-holder to the authorities at shorter than usual intervals being one of many potential measures available here. Approval-holders may also be required, where appropriate, to conduct post-approval long-term trials to investigate both safety and efficacy in greater depth, with an obligation to provide these results within a specified period of time. No drug can be said to be 100%

risk-free, but the benefits must always outweigh the potential risks. The risk-benefit analysis is carried out as part of the approval process but it is also regularly reviewed – even after approval – to take account of any newly received additional data or information (see also " Will vaccine safety continue to be monitored even after approval?“)

FAQ: Procurement of COVID-19 vaccines

Why is it important that an EU-wide approach is taken to the distribution of COVID-19 vaccines?

The EU strategy on COVID-19 vaccines aims to ensure the manufacture of high-quality, safe and effective vaccines in Europe and to ensure that member states and their populations have swift access to them. Pursuing a common approach at EU level is the safest, fastest and most efficient way to achieve these objectives. No member state alone would be able to provide the investment to develop and produce a sufficient number of vaccines. Only if the EU and its member states act quickly and together can an adequate and rapid supply of safe and effective vaccines be guaranteed.

How does the joint vaccine procurement process work?

The joint procurement process has seen the 27 EU member states, together with the European Commission, commit to entering into advance purchase agreements with the manufacturers of promising COVID-19 vaccines not separately but together as 27 countries. 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. This coordinated process to procure vaccines can be considered one of the EU's great successes in the field of healthcare. EU member states, together with the European Commission, have been working since mid-June to put together a procurement programme that ensures that European citizens will have access to promising COVID-19 vaccines – without any long-drawn-out disputes. This joint approach makes it possible for risks to be shared and for investment and know-how to be pooled with a view to benefitting from economies of scale and association, as well as acting with the required speed.

The 27 countries of the European Union have established a working mechanism with the European Commission for this purpose. This includes a steering group in which all 27 member states are represented, together with the European Commission. This steering

group is co-chaired by Austria together with the European Commission. A joint negotiating team explores and negotiates with the manufacturers and reports to the steering group on a regular basis.

How is an advance purchase agreement set up?

Before an advance purchase agreement (APA) is negotiated, the joint negotiating team conducts exploratory talks with the manufacturer to determine whether it makes sense to enter into detailed contract negotiations. If this is the case and agreement is reached on what is referred to as a term sheet, a request for a quotation is sent to the company.

An advance purchase agreement is signed when both parties have completed the contract work. The finalised elements of the contract are discussed and decided upon in the steering group. Forming 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 become available.

Will the European Commission publish the advance purchase agreements signed with the pharmaceutical companies?

Protecting public health and securing the best possible conditions with companies to ensure that vaccines are affordable, safe, effective and actually available are key priorities for the European Commission. The contracts are protected by confidentiality clauses, something which is justified in view of the fierce competition in this global market. The purpose is to protect both sensitive negotiations and business-related information, such as financial information as well as development and production plans. All companies require sensitive business information to remain confidential and only available to the signatories of the agreement, which means that the European Commission must therefore respect the contracts it forms with the respective companies. Ultimately, the European Commission is accountable to the other European institutions and to the citizens of the European Union. The European Commission acts in full compliance with all the applicable regulations for financial management and these may be subject to investigation at a later date.

What are the advantages of this EU-wide approach over a purchasing strategy where each country buys its own vaccines?

The risk associated with entering into advance purchase agreements with manufacturers and sharing the research and production costs is borne by the EU as a whole and not by each individual country. The European Union has allocated a budget of EUR 2.7 billion here. One major administrative advantage is that Austria does not have to negotiate with potential manufacturers alone. The market power of all EU countries combined is greater than that of Austria alone when it comes to agreeing on the price and legal contractual conditions. As soon as the first quantities become available, all EU member states will have access to them at the same time and in accordance with their respective share of the EU population.

What contribution is Austria making to the development of a vaccine against COVID-19?

Austria is at the forefront of efforts to research and manufacture potential COVID-19 vaccines. Several domestic companies are working on developing or researching potential vaccines or vaccine components. The ultimate aim of these and other activities is to have several vaccines ready for approval and subsequent use as soon as possible. Austrian companies are therefore playing a key role in efforts to bring the COVID-19 pandemic under control.

FAQ: Distribution of COVID-19 vaccines

How many vaccine doses will Austria receive?

The European Commission adopted the European Vaccine Strategy on 17 June 2020 with a view to securing the supply of high-quality, safe, effective and affordable vaccines. This involves the European Commission, on behalf of the member states, entering into advance purchase agreements with vaccine manufacturers to give the member states the right to purchase a certain number of vaccine doses at a certain price as soon as they become available. The reserved quantities are divided up among EU member states in accordance with the number of inhabitants, meaning that Austria is entitled to receive approximately 2 percent of the available vaccine doses. Overall, there will be enough vaccine doses available in Austria to vaccinate anyone who wants it. What must be remembered here, however, is that the available vaccines may have specific areas of use; it will in all likelihood not be possible for all vaccines to be used for all groups of people.

How will the new COVID-19 vaccine be distributed in Austria and where can people get vaccinated?

The various COVID-19 vaccines will be purchased centrally by the federal government and then distributed throughout Austria. They will be distributed according to the quantities available, which will be confirmed following European marketing authorisation. It is safe to assume that the first batch will only have a limited number of doses. Vaccination should generally take place at places where people work, live or spend time, thereby ensuring a high degree of accessibility. As far as the vaccine's properties permit, vaccination will begin in places where there is the greatest risk to people and key systems. Work is therefore currently under way to prepare and plan all the organisational and logistical measures needed to facilitate an efficient vaccination process. Care must be taken to ensure that vaccines can be properly stored, transported, distributed and administered. It is also necessary to create ways to document vaccinations in a systematic and timely way. To achieve a high rate of vaccination, it must be easily accessible. For that reason, it will

be a high priority to offer vaccination in special settings such as in the workplace: "We bring the vaccine to the people, not the people to the vaccine."

When will the vaccines be approved for release?

Provided sufficient data on the safety and efficacy of the vaccine are available and the risk-benefit analysis is positive, initial approvals may be granted around the turn of 2020/2021. It is not currently known exactly which vaccine will be approved or when, or for which indication and age group it can be used. It is also not yet known whether the vaccines will only protect against contracting the disease or whether they can also prevent virus transmission, and what the epidemiological situation will be at the time when the vaccine becomes available.

Who will be given the COVID-19 vaccines that are available in future?

Current expectations are that there will not be enough vaccine doses available at the beginning to vaccinate everyone in Austria who wants to be vaccinated at once. It is also likely that some vaccines will not be approved for all groups of people.

It is the stated goal of the federal government, however, to provide a fully tested, safe, effective and approved COVID-19 vaccine to anyone who wishes to be vaccinated. This was also considered in the strategy to purchase vaccines. It can therefore be assumed that any prioritisation will only be required temporarily, i.e. in principle there will be sufficient vaccine available.

How will it be decided who can get vaccinated first against COVID-19?

Fortunately, we can assume that – provided that the vaccine can be used and recommended for all groups of people – anyone in Austria wishing to be vaccinated against COVID-19 will be able to do so. The plan is, in view of the limited availability at first, to start administering the vaccine where the personal and systemic risk is greatest, provided the vaccine’s properties allow this. This relates in particular to people who are at

risk of suffering serious illness or dying from a COVID-19 infection, as well as for healthcare and nursing staff. An expert medical recommendation will be provided by the National Vaccines Committee in accordance with the properties of the vaccine and the epidemiological situation.

FAQ: COVID-19 vaccines

How often do people need to be vaccinated?

The vaccines that are at the most advanced stage of development, those from BioNTech/Pfizer, Moderna and AstraZeneca, are currently all being tested with two doses of the vaccine, according to the companies. This means that vaccination is likely to be carried out by administering two doses several weeks apart.

Which vaccine technologies are being used for COVID-19 vaccines?

All vaccines are based on the principle that the body reacts to the active ingredient in the vaccine, the antigen, and produces active antibodies and specific T-cells. That is why this is referred to as "active immunisation". Our immune system is presented with molecules (antigens) or a blueprint for antigens to the pathogen that causes COVID-19, the coronavirus, SARS-CoV-2, and thereby builds up immunity to the pathogen. However, the various candidate vaccines use very different antigen molecules and techniques. There are three main lines of development: live vaccines using a vector virus, dead vaccines (using virus proteins or complete virions) and mRNA vaccines.

How do mRNA vaccines work?

In the case of mRNA vaccines, the human body cells are provided with the blueprint (in the form of "messenger RNA") for virus proteins. This information is read in the cells and the coded protein is produced. It is a process that goes on continuously in the body's cells in order to produce the necessary proteins for the cell. This means, for example, that the spike protein on the coronavirus SARS-CoV-2 can be produced by the human cells themselves. Because it is an alien protein that is of no use to the cell, it is transported to the surface of the cell and presented there with the help of specific immunocomplex proteins. It is recognised by special immune cells and this subsequently triggers the immune system to produce antibodies to SARS-CoV-2 and generate T-cells specifically targeted at molecules of this alien protein.

So, like all other vaccines, an mRNA vaccine also introduces a pathogen or a component of one into the human body so that the immune system is stimulated to produce antibodies. What is different about it is how the pathogens (or components of them) are transported into the body: whereas, with other vaccine technologies, they are administered directly, with mRNA vaccines only the blueprint is provided, so that the human cells produce the pathogens (or components) themselves.

The mRNA that is used to administer the vaccine is soon broken down by the cells. It is not built into the DNA (the carrier of genetic information) and does not affect human genetic information, either in the body's cells or in reproductive cells. Once the mRNA has been broken down, no further production of the virus protein occurs. Video: https://www.youtube.com/watch?feature=youtu.be&v=GBq_l2llyzo

How do vector-based vaccines work?

Vector vaccines are based on the principle of reconstructing a virus that is infectious to humans but completely harmless so that it does not lose its harmless properties but looks to our immune system like a completely different pathogen, in our case a SARS-CoV-2 virus. In simple terms, it looks to our immune system like a "sheep in wolf's clothing": our immune system reacts to this vector virus as though it was a SARS-CoV-2 virus, but with the difference that there are no symptoms of the illness. The spike protein of the SARS-CoV-2 virus is produced by the cell itself and then presented to the immune system on the surface of the cell, so that antibodies and T-cells are created to attack that protein and these are designed to provide protection from future illness. The COVID-19 vector vaccine candidates use safe, well-documented carrier viruses which are controlled and eliminated by the human immune system. In non-replicating vector-based vaccines, the viruses used as the vector are altered by gene technology so that they can no longer multiply in the host cell but serve only as the means of transport for the genetic blueprint for the surface proteins of the virus that is to be attacked.

Is it possible to choose which vaccine one receives?

In principle, COVID-19 vaccination is voluntary. Because of the properties of the vaccines, they are likely to be offered in different settings. For example, it is probable that it would be logistically difficult for a vaccine that has to be stored at -70°C to be made widely

available at doctors' surgeries. The situation is entirely different with vaccines that can be stored at normal fridge temperatures. It is also a question of the quantities in which the various vaccines are available. The different vaccines will also come on to the market at different times, so a free choice will not be available because of the availability at the time, in a similar situation to the one with which we are familiar from the seasonal flu vaccines. Nor will every vaccine be equally suited to everyone, so there will be different indications and target groups for each vaccine. As far as we know at present, there is no reason to expect any difference in the quality of the vaccines in terms of their effectiveness and safety.

Can people who have already had a SARS-CoV2 infection be vaccinated?

Since, as far as we know, the vaccine is well tolerated, regardless of whether or not someone has already had a SARS-CoV2 infection, vaccination can still take place even after someone has already been ill, or had a positive test. At the moment it is also not fully known whether, and for how long after a SARS-CoV2 infection, immunity and protection against falling ill again will last. It is therefore recommended that vaccination is offered to everyone in the relevant target groups, even if they have already had the infection. In such cases it can be expected that vaccination will refresh existing immunity and therefore extend the period of protection. If a shortage of vaccine should occur, it is possible that people who have not yet been infected by SARS-CoV-2 will be vaccinated before those who have already had the infection.

Can COVID-19 vaccines cause side effects?

Yes. It is important to distinguish here between reactions to the vaccine and genuine side effects. Reactions to the vaccine are symptoms that may accompany the actual effect of the vaccine and reflect the (desired) immunological defensive reaction. They are not dangerous but may be uncomfortable and generally occur at the vaccination site in the form of reddening, possibly swelling or pain of varying degrees. Systemic reactions to the vaccine are also possible and encompass a wide range of sensations such as fatigue, headache, slight fever, general flu-like feelings and others. RNA vaccines are known for activating the immune system very well, which is why they are said to be more reactogenic than other vaccines. As part of a strong immune response, the body produces

a lot of messenger substances and some of these messenger substances could also lead to the secondary symptoms referred to above. These possible symptoms are not unexpected and potentially dangerous adverse reactions but a sign that the body is interacting normally with the vaccine and this is producing the protective effect. This kind of reaction to the vaccine normally disappears without trace in a few days and is significantly less harmful than the possible symptoms and consequences of the infection that is being prevented by the vaccine: vaccines are only approved if the benefits significantly outweigh any possible risk from the vaccine.

Any genuine adverse reactions that can be expected are recorded during the trials before approval, and the vaccine is tested on at least 10,000 people. It is possible that very rare adverse reactions (very rare means fewer than 1 case in 10,000 people vaccinated) may only be recorded after the vaccines have been approved. That is why, even after marketing authorisation has been granted, the vaccine will be continuously and meticulously monitored to record possible adverse reactions, and the risk-benefit ratio will continue to be assessed. These possible adverse reactions are listed in detail in the technical information and user information for the vaccine.

On the subject of adverse reactions, it is important to be aware that not every sign of illness that occurs a short time after a vaccination can be attributed to the vaccine. Especially when vaccines are administered to a great many people, the probability increases that symptoms will occur after vaccination which were caused not by the vaccination but for other reasons that occur regularly in the population even if they have not been vaccinated, for example by an illness that occurred at the same time as, or shortly after the vaccination ("background incidence"). In order to enable all reactions and side effects that occur after vaccination to be evaluated as accurately as possible, people who have been vaccinated and healthcare staff administering the vaccine are urgently requested to report all such symptoms. Details can be found at: www.basg.gv.at/pharmakovigilanz/meldung-von-nebenwirkungen/.

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