LE GOUVERNEMENT
DU GRAND-DUCHÉ DE LUXEMBOURG
Ministère de la Santé

Direction de la santé

FAQ – Vaccination COVID-19

Contents

1. GENERAL INFORMATION

1.1. WHY DO WE NEED A VACCINE TO PREVENT COVID-19 ?

COVID-19 vaccines aim to prevent the disease caused by SARS-CoV-2 by triggering an immune response. The disease can cause severe disease and death, and it may cause yet unknown long-term consequences in people of all ages, even those that do not have any pre-conditions. Therefore, safe and effective vaccines for COVID-19 are needed to protect all of us, especially healthcare professionals and vulnerable populations, such as older people or those with chronic diseases.

1.2. HAVE THERE BEEN OTHER CORONAVIRUSES?

Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS) are two illnesses caused by coronaviruses closely related to SARS-CoV-2. Researchers began developing vaccines for these diseases after their discovery in 2003 and 2012. However, they never made it past the early stages of development and testing, mainly due to a lack of interest as the viruses disappeared. This earlier vaccine research has been very helpful for the COVID-19 vaccine development process.

2. THE TARGET POPULATION

2.1. CAN I GET VACCINATED IF I AM PREGNANT?

Pregnant women have thus far not been included in COVID-19 vaccine trials, but researchers are currently studying potential effects on pregnancy. Until these studies have been concluded, it is unclear if the immunizations would be safe for their use in pregnant women and therefore they are not recommended in this particular case.

2.2. CAN I GET VACCINATED IF I AM BREASTFEEDING?

COVID-19 vaccine trials have thus far excluded people who are breastfeeding. Therefore, it is unclear when the vaccination would be safely available for them.

2.3. CAN CHILDREN GET VACCINATED?

It is very probable that COVID-19 vaccine will only be authorized for adults. Eventually, they will be authorized for adolescents, but this will depend on the data available for these ages groups. Additionally, children are less affected by COVID-19. It is therefore likely that adults and at-risk individuals will be vaccinated first.

2.4. DO I HAVE TO GET VACCINATED IF I HAVE ALREADY HAD COVID-19?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. It is recommended to get vaccinated even if you have had COVID-19 in the past.

2.5. WHAT DISEASES ARE CONTRAINDICATED FOR VACCINATION?

The detailed list of contraindications may differ depending on the different vaccines and will be known at the time of vaccine authorisation, i.e. after finalisation of the scientific evaluation of the data obtained during the clinical trial phases. A scientific evaluation of the contraindications of the vaccine will be carried out when assessing the balance between benefits and risks. Standard contraindications to vaccination in general include known severe allergic reactions (e.g. anaphylaxis) and hypersensitivity to any of the vaccine components, as well as severe febrile illness or acute infection.
According to the data currently available to us, there are very few people who cannot receive the Pfizer-BioNTech vaccine (the first vaccine to arrive in Luxembourg). As soon as we will know when the other vaccines will arrive, we will update this information.
The Pfizer-BioNTech vaccine should not be given to those who have had:

- an anaphylactic reaction (= severe allergic reaction that can be life-threatening) confirmed to a previous dose of a COVID-19 vaccine,
- a confirmed anaphylactic reaction to one of the components of the COVID-19 vaccine

Precautions
Minor illnesses without fever or systemic disorders are not valid reasons to postpone vaccination. If a person is seriously ill, vaccination can be postponed until they have fully recovered. This is to avoid confusing the differential diagnosis of any acute illness (including COVID-19) by mistakenly attributing signs or symptoms to the adverse effects of the vaccine.
To date, there have been no reports of safety problems associated with vaccinating individuals with a history of COVID-19 infection, or with detectable COVID-19 antibodies.

3. YOUR RIGHTS

3.1. WILL VACCINATION BE MANDATORY?

No, vaccination will not be a legal requirement.

3.2. WHO IS RESPONSIBLE IF A PERSON HAS LASTING SIDE EFFECTS?

Due to the strict evaluation procedure for granting marketing authorisations (MA), only safe, effective and high quality vaccines reach the market.
In principle, the responsibility for the vaccine lies entirely with the companies that market the vaccines. Their pharmacovigilance obligations (such as the monitoring of adverse events) remain

in force. These companies always remain liable and are responsible for compensation if they do not comply with good practice requirements or pharmacovigilance requirements or in case of intentional errors.
Purchase contracts concluded by the European Commission may include strict clauses to compensate the company for specific potential liabilities. An example is a "not-for-profit during the pandemic" clause. This means that the company supplies the vaccine at cost price and therefore makes no profit. As candidate vaccines follow a very fast track to market due to the urgent demand for vaccines and exceptional circumstances, participating Member States will in this case exempt the company concerned from certain compensation claims.
This does not change the usual rights of citizens and patients. The liability clauses apply only between the contracting parties, i.e. the authorities (Ministry of Health) and the companies holding the MA. The citizen or the patient can invoke his rights at any time.

3.3. CAN MY EMPLOYER FORCE ME TO GET VACCINATED?

No, your employer will not be able to force you to get vaccinated.

3.4. WILL NON-VACCINATED PEOPLE BE LIMITED IN WHAT THEY ARE ALLOWED TO DO?

There will be no legal consequences for people that have not been vaccinated. However, there might be measures restricting non-vaccinated people's access to venues, events, regions or even countries. At this point, no national or international restrictions have been defined.

3.5. WHY SHOULD I GET VACCINATED IF I CAN JUST KEEP WEARING MY MASK AND KEEP UP PHYSICAL DISTANCING?

To stop this pandemic, we need to use all available tools. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Additional safety measures such as wearing a mask or keeping a 2 meter distance from others help, but not fully reduce your chances of being exposed to the virus or spreading it to others.

4. THE VACCINATION

4.1. HOW MANY INJECTIONS WILL I GET AND HOW MANY DAYS DO THEY HAVE TO BE APART FROM EACH OTHER?

The number of necessary injections will depend on the type of COVID-19 vaccine. The majority of vaccines currently in the final stages of development will require two injections with a 3- or 4-week gap between each injection. Your medical professional will give you all the necessary information once we know what vaccine will be used.

4.2. HOW WILL THE VACCINE BE ADMINISTERED?

The vaccines will be given through an injection into your arm.

4.3. DO I NEED TO WEAR A MASK WHEN I GET VACCINATED?

Yes, everyone needs to wear a mask that covers their mouth and nose when in contact with others outside of their household and when a distance of at least 2 meters cannot be guaranteed. This includes when you are in healthcare facilities and when receiving the vaccine, unless you have a medical certificate explaining that you are exempt from this rule.

4.4. WILL I HAVE A CHOICE BETWEEN DIFFERENT VACCINES?

The choice of vaccine is made on the basis of the medical history and medical tests carried out by the vaccinating doctor. It is important that patients answer the questions asked, when making appointments and during the vaccination, in a detailed and honest manner, to ensure that the doctor can make the appropriate choice.

4.5. WHAT ARE THE BENEFITS OF GETTING VACCINATED IF YOU ARE NOT ELDERLY OR VULNERABLE?

Given the current epidemiological situation, all studies available to date indicate that the best option for preventing morbidity and mortality in the initial phase of the vaccination programme is to protect those most at risk. This includes people over 65 years of age or those who are vulnerable, particularly because of an underlying disease that increases the risk of complications or mortality.
Vaccination is an act of solidarity: When you get vaccinated, you also help to protect those who cannot get vaccinated themselves.

4.6. WHY GET VACCINATED?

- To prevent the vast majority of people from catching the disease
- To help keep as many people healthy as possible
- To help reduce the social and psychosocial burden of disease on people
- To help reduce the burden on hospitals and health systems
- To free up resources from the health system to fight other diseases, such as cancer or Alzheimer's disease

5. LIFE AFTER THE VACCINATION

5.1. IF WE VACCINATE PEOPLE AT RISK AND HEALTH WORKERS, WILL PROTECTIVE MEASURES (E.G., WEARING A MASK, PHYSICAL DISTANCING, ETC.) STILL BE NECESSARY?

Yes, the basic restrictions (wearing a mask, keeping 2 meters physical distance and other safety precautions) will remain. The restrictions are continuously being adapted to the given circumstances. Once at-risk groups and medical professionals have been vaccinated, the restrictions will be adjusted as necessary, closely monitoring the impact of the virus on the population.

It is important to note that even people who do not belong to an at-risk group may develop symptoms or severe complications when contracting the virus.

5.2. DO I NEED TO KEEP WEARING A MASK AFTER I GOT VACCINATED?

Experts still need to better understand the protection that COVID-19 vaccines provide before deciding if vaccinated people no longer need to wear a mask. Until this information is available, everyone will have to keep wearing a mask and follow all other safety restrictions even after having been vaccinated.

5.3. WHEN WILL LIFE GO BACK TO NORMAL?

Unfortunately, it is too early to say when we will be able to get back to “normal”. A vaccine is not a silver bullet, yet it is an extremely important step for us to get back to what it was like before the pandemic.

5.4. IF I DO NOT HAVE ANY PRE-CONDITIONS, IS IT NOT MORE LIKELY FOR ME TO DEVELOP DANGEROUS SIDE EFFECTS FROM THE VACCINATION THAN IT IS FOR ME TO DEVELOP SEVERE SYMPTOMS FROM COVID-19?

Every vaccine undergoes thorough testing processes before it is approved for use in order to limit the risk to develop any negative side effects that could result from vaccination. However, COVID-19 can be deadly even for people who do not exhibit any pre-existing conditions. Therefore, it is recommended that even people without pre-existing conditions get vaccinated.

5.5. WHAT IS HERD IMMUNITY?

Herd immunity, also known as "indirect protection", "community immunity" or "community protection", refers to the protection of susceptible individuals against infection when a sufficiently high proportion of immunized individuals exist in a population.
In other words, herd immunity is the inability of infected individuals to spread an epidemic due to lack of contact with a sufficient number of susceptible individuals.
The threshold for herd immunity is defined as the proportion of individuals in a population who, having acquired immunity, can no longer be part of the chain of transmission. If the proportion of immunized individuals in a population is above this threshold, ongoing outbreaks will be extinguished and transmission of the virus will be interrupted.

6. THE VACCINES

6.1. HOW COULD THE COVID-19 VACCINES BE PRODUCED SO QUICKLY?

Normally, the preliminary studies, preclinical studies, clinical trials and approval of a vaccine take several years. However, the first COVID-19 vaccines are currently on the verge of approval. There are several reasons why the production of these vaccines has been so much faster.
Research on vaccines was already conducted during the outbreaks of SARS (2002) and MERS (2012). These studies are now providing important insights. So there was no need to start from scratch. Moreover, it is relatively easy to develop vaccines against coronaviruses.
Furthermore, very high financial resources have been made available for vaccine development and there has been an exceptionally intensive cooperation between private and public partners. This has resulted in a high quantity of vaccine candidates (currently over 260). As a result, there is an increased likelihood that one or more vaccines will be successful.
In three clinical trials, vaccines are tested on an ever-increasing number of test persons. Normally, the authorities only receive all the results for review at the end of the entire trials. In this case, however, a "rolling review" is used, which makes it possible for the authorities to have access to the data while the trials are still running. The authorities can therefore review the data as soon as they are available, which saves time.
Due to an extraordinarily high number of voluntary study participants and the currently high prevalence in the population, a sufficient number of test persons are quickly infected. This makes it possible to determine efficiency and record possible side effects more quickly. This helps to ensure that this third and usually longest clinical phase progresses faster than usual.
In addition, the costly third phase usually only starts when all data from the previous phases have been evaluated and the risk of failure is low. In the case of the COVID-19 vaccine, the manufacturers did not wait for all the results before initiating the third phase. This represents a financial risk for the manufacturers. However, it does not affect the safety or efficiency of the vaccine.
Even with accelerated vaccine development, the developed COVID-19 vaccines must meet the same safety standards to be licensed in the European Union, just like all other vaccines.
You can find more information on this topic here: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring

6.2. WHAT TYPES OF VACCINES ARE THERE?

There are three different mechanisms of action: live vaccines with vector viruses, dead vaccines with virus proteins, or RNA/DNA vaccines. In all three mechanisms, so-called antigens (viral proteins) are designated, which activate the immune system and thus generate the protective immune response.
Vector vaccines: An attenuated virus serves as a means of transport (vector) for a harmless part of the genetic information of SARS-CoV-2. These parts, which contain the blueprint for one or more antigens, are taken up into a few body cells.

RNA/DNA vaccines: These vaccines contain parts of the genetic information of the virus (RNA or DNA), which provide the blueprint for viral proteins. After vaccination, the genetic information is taken up by human body cells and used as a template to produce the antigens themselves. In the process, only a small component of the virus is formed, thus ruling out the possibility of complete viruses being created that are capable of reproducing or causing an infection.
Dead vaccines with viral proteins: In this method, the genetic information with the blueprint for antigens is introduced into bacteria, yeast or mammalian cells, which then produce the antigen.

6.3. How many vaccines are being developed?

Multiple COVID-19 vaccines are under development. As of 14 December 2020, fifteen vaccines have begun large-scale (Phase 3) clinical trials worldwide.

6.4. Some of the vaccines that are currently being developed are not "traditional" vaccines. Instead, they are using a newer technique based on mRNA. Could this be a problem?

No, mRNA vaccination is a very modern scientific technology that has so far proven to be extremely safe. Even if no mRNA vaccine has been approved yet, research in this area has already been going on for many years and the current "new" vaccines (e.g. mRNA) are undergoing very strict safety tests and will only be approved once they have passed every single test.

6.5. Can an mRNA vaccine alter our DNA ?

mRNA vaccines are not able to enter the human DNA. The necessary enzymes to start this process are not present inside human cells. A number of clinical studies focusing on other viruses (e.g., Ebola, Zika, etc) has confirmed this. Additionally, the human body breaks down the mRNA after a short period.

6.6. What is a conditional marketing authorization?

Both Biontech/Pfizer and Moderna recently applied for a conditional marketing authorization. The European Medicines Agency (EMA) only grants this type of authorization if all of the following requirements are met:

- The medicine (in this case the vaccine) addresses a medical need for which we do not yet have a cure, treatment or vaccine
- The medicine's benefits outweigh its risks
- It is likely that the applicant will be able to provide comprehensive data on the medicine
- The medicine's immediate availability presents a benefit to public health that outweighs the risks that we may face due to the need for further data

The conditional marketing authorization remains valid for one year. Within that time, the applicant provides comprehensive data. Once this data has been reviewed by the EMA, the

agency converts the conditional marketing authorization into a standard authorization when all safety and efficacy requirements have been confirmed.
Between 2006 and 2016, the EMA granted a conditional marketing authorization to 30 medicines. None had to be suspended or revoked after the authorization was given. Reports have shown that the conditional marketing authorization has helped speed up patient access to new medicines.

6.7. ON WHAT CATEGORIES OF PEOPLE HAVE THE VACCINES BEEN TESTED SO FAR?

Vaccines are tested in large clinical studies. The inclusion and exclusion criteria for these studies vary from study to study. However, it can generally be said that the people normally recruited for these studies are physically healthy adults, both men and women (for women: pregnancy and breastfeeding are exclusion criteria, non-pregnant women must use effective contraception), aged at least 18 years.

7. VACCINE EFFECTIVENESS

7.1. HOW LONG WILL I BE IMMUNE TO THE VIRUS AFTER I GOT VACCINATED?

It is not known yet what level of immunity can be reached with the vaccines in development. The final stages of clinical trials will provide information and long-term efficacy studies will show if a booster vaccination will be necessary. All this information will become available as researchers continue to run tests and complete the different phases of the vaccine development process.
You can find more information on how vaccines and other medicines are evaluated and authorized in the EU by clicking the link below:
COVID-19 vaccines: development, evaluation, approval and monitoring

7.2. WILL I BE IMMUNE RIGHT AFTER THE VACCINATION?

Immunity develops over the first weeks following a vaccination. The immune system takes time to react to the vaccine and develop the necessary protection. Therefore, it is important to still follow all safety measures (e.g., wearing a mask) in place. You can find all current safety precautions and restrictions here: https://covid19.public.lu/fr/mesures-sanitaires-en-vigueur.html

7.3. HOW DO WE DEFINE VACCINE EFFECTIVENESS?

Vaccine efficacy is analyzed during the final stages of the clinical trials, which are currently still ongoing. Efficacy is expressed in percent of patients protected against COVID-19 out of the total population vaccinated. A statistical test compares the results from vaccinated patients with patients having received placebo and determines whether there is a “real” difference between those patients.

7.4. IF A VACCINE IS 90% EFFECTIVE, DOES THAT MEAN THAT 10% OF THE PEOPLE WILL NOT BE PROTECTED AT ALL?

Even if a vaccine does not lead to complete immunity, it offers a partial protection also for these 10% and it limits the circulation of the virus in the entire population.

7.5. IS IT POSSIBLE THAT THE VIRUS MUTATES AND THE VACCINES WILL NO LONGER BE EFFECTIVE?

Viruses are constantly mutating, however, in most cases coronavirus mutations are irrelevant abnormalities that cause changes in genetic material (RNA) but they do not impact its composition and structure.

- Mutations are mostly observed in non-essential regions of a virus's genetic material, and it will probably still be able to function perfectly.
- Mutations in critical regions can inactivate a virus, so they do not happen very often.

It is for this reason that vaccines target these critical regions. However, researchers are constantly monitoring the possible emergence of new mutations to make sure that the vaccine remains effective.

7.6. DO VACCINES ONLY PREVENT A "SEVERE" FORM OF COVID-19?

How a vaccine works
The purpose of a vaccine is to help develop immunity to an infectious disease by stimulating the immune system to produce antibodies, thus protecting against future infections.
In the case of the new coronavirus, a vaccine would make the vaccinated person resistant to an infection with the virus and the disease it causes - COVID-19 - or, at the very least, make an infected person have a shorter duration of illness or fewer complications.
First results of vaccines against COVID-19
Currently, two vaccines are in the process of being approved by the European Medicines Agency. The companies behind the two vaccines indicate that they are very effective in preventing COVID-19 in clinical trial participants.
Pfizer / BioNTech announced on November 18 that its two-dose vaccine is 95% effective against COVID-19 from 28 days after the first dose. (In adults 65 years and older, the vaccine has been shown to be 94% effective in preventing COVID-19).
Moderna's Phase 3 clinical trial showed that its vaccine was 94.1% effective against COVID-19 and 100% effective against severe COVID-19. It is important to note, however, that the data from both trials are currently being reviewed by experts of the European Medicines Agency.

7.7. WHICH VACCINE IS THE MOST EFFECTIVE?

At this stage, it is very difficult to say whether one vaccine is more effective than another, since this would require direct comparative studies with several vaccines within the same study.
What we can say today is that the vaccines will only be approved by the European Medicines Agency if they are be deemed sufficiently effective and safe enough to be given to the population.

The best source of reliable information is therefore the European Medicines Agency itself (https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-key-facts).
In addition, as soon as the results are available, we will make them available here: https://covid19.public.lu/fr/vaccination.html and on the website www.sante.lu .

7.8. DO VACCINES PREVENT THE TRANSMISSION OF SARS-COV-2?

Pfizer said its scientists were looking for ways to assess the transmission of the virus in future studies. For now, AstraZeneca and Oxford University may be able to provide the first clues as to whether a vaccine can protect against transmission of the virus. Although they have not yet published full results, their trial has routinely tested participants for SARS-CoV-2, allowing researchers to know whether people were infected without developing symptoms. Early indications show that the vaccine may have reduced the frequency of these infections, suggesting that transmission may also be reduced.

Good to know

It is important to remember that you cannot get COVID-19 directly from the vaccines that will be offered, as none of them contain the full virus.

8. SAFETY AND UNDESIRABLE EFFECTS

8.1. HOW WILL WE KNOW IF THE VACCINES ARE SAFE?

COVID-19 vaccines are being developed following the same legal requirements as other medicines. Like all medicines, COVID-19 vaccines' effects are first tested in laboratories, then, in a later phase, they are tested in human volunteers. There are three stages of human testing. At each stage, they have to pass many tests to enter into the next phase.
What is different for COVID-19 vaccines is the speed of development. Potential approval is much faster due to the public health emergency. However, dedicated expert task forces and rapid review procedures have been put in place to evaluate data from companies in the shortest possible timeframes, while ensuring robust scientific opinions and respecting all necessary safety measures.
You can find more information on how vaccines and other medicines are evaluated and authorised in the EU on:

COVID-19 vaccines: development, evaluation, approval and monitoring
European Vaccination Information Portal
Authorisation of medicines
How EMA evaluates medicines for human use
From laboratory to patient: the journey of a centrally authorised medicine
European Commission: Coronavirus vaccines strategy

8.2. WHAT ARE POSSIBLE SIDE-EFFECTS OF THE VACCINES?

Just like with any other vaccines, there may be side effects. This is completely normal. Each vaccine may have different types of side effects and your health care professional will be able to explain them to you in detail. Potential side effects may include headache, fatigue, muscle and joint pain, pain and redness around the point of injection. However, these side effects also indicate that your immune system is working and that you are developing a protection.