



**2021**

DISCOVERY HEALTH

# COVID-19 VACCINE FREQUENTLY ASKED QUESTIONS

## Frequently asked questions regarding the COVID-19 vaccine

### Vaccine specifications

#### 1. Which COVID-19 vaccination will members have access to?

To date, three COVID-19 vaccines have published evidence from Phase 3 clinical trials and received approval for emergency use in multiple countries. These include the Pfizer–BioNTech, Moderna and Oxford–AstraZeneca vaccines. Several other vaccine manufacturers (such as Johnson & Johnson and Novavax) are expected to release their Phase 3 trial data soon and are likely to be approved soon. The early indications are that the safety and efficacy of these vaccines are excellent, and comparable to the three COVID-19 vaccines that have already released.

China (CoronaVac) and Russia (Sputnik V) have also approved the local use of vaccines developed in their own countries. Due to delays in the release of Phase 3 trial data for these vaccines, they have not yet been registered in many other countries. Brazil recently released Phase 3 clinical trial results for the CoronaVac vaccine, reporting an efficacy of 50.4%, well below that of other recognised vaccines. We are still waiting for efficacy data from clinical trials conducted in Turkey and Indonesia.

In South Africa, all vaccines must be approved by the South Africa Health Products Regulatory Authority (SAPHRA) before they can be used. **Vaccines that SAPHRA has not approved are, by law, not allowed to be used in South Africa.**

How South Africa prioritises vaccines for South Africa will first be based on SAPHRA approval, which takes into account safety and efficacy. This will be determined based on the results of extensive clinical trials on vaccine candidates as well as the clinical experience from rolling out these vaccines in other countries. Since there is a global shortage of COVID-19 vaccines in the short term, it's likely that South Africa will deploy a mix of approved vaccines in the course of 2021. This should not be a concern for medical scheme members and other South Africans as the vaccines being used all have similar safety and efficacy. All vaccines approved for use in South Africa will undergo the same rigorous testing and clinical evaluations.

The Minister of Health and his team secured access to 1 million doses of the AstraZeneca vaccine from the Serum Institute of India to be delivered in January 2021 and a further 0.5 million doses to be delivered in February. The President also noted in a recent statement that an additional 20 million COVID-19 vaccine doses have been secured through the Serum Institute of India.

#### 2. Have the COVID-19 vaccines been properly tested? What are the efficacy and expected side effects?

All vaccines undergo rigorous clinical trials globally before they are approved for use. So far, the clinical trials for COVID-19 vaccines have included over 60 000 participants to ensure that the vaccines are safe and effective.

The results that have been released to date demonstrate high levels of efficacy for the vaccines being rolled out, with reported efficacies of 90% and higher. Vaccine recipients will be monitored closely to track and document any side effects that may arise in the long term. Additionally, all COVID-19 vaccines will undergo extensive review for safety and efficacy before the South Africa Health Product Regulatory Authority (SAPHRA) will approve them for use in South Africa.

SAPHRA has to approve all medicines and vaccines for use in South Africa and conducts an in-depth and extensive scientific and clinical analysis of the safety and efficacy of each medical product before approving the product for use. SAPHRA has also formed close working relationships with pharmaceutical and various global medical regulatory authorities. Therefore, they are leveraging these relationships and experience in evaluating COVID-19 vaccines for use in South Africa.

Common side effects of the three COVID-19 vaccines currently being used worldwide include:

- Pain and swelling on the injection site
- Fever
- Chills
- Tiredness
- Headache

3. **How many doses will each person need?**

The different vaccines have differing dosing regimens. So far, all approved vaccines require two doses, given 21 to 28 days apart, to be effective.

4. **Will medical schemes take full responsibility for side effects or even deaths of their members who take the vaccine?**

The Council for Medical Schemes and National Department of Health have made the COVID-19 vaccine a Prescribed Minimum Benefit from 4 January 2021. This means that all medical schemes in South Africa must fund COVID-19 vaccine for all medical scheme members without using members' day-to-day benefits. Members will also not have to pay extra for the vaccine.

The South Africa Health Product Regulatory Authority (SAPHRA) only approves using vaccines in South Africa after thorough and independent review of the scientific evidence. Vaccines are also closely monitored once they are available in the market and can quickly be removed if safety concerns are identified.

Like any medicine, vaccines can cause side effects. Mechanisms are currently being explored to implement a no-fault vaccine injury support programme similar to what has been implemented in other countries. While it is still in the early phases of development, this programme will likely provide support in the rare instance of a serious adverse reaction to a vaccine approved for use in South Africa. As a healthcare funder, medical schemes are not legally responsible for the side effects and adverse effects of medicine. This also applies to vaccines.

5. **When will the vaccine be available?**

Discovery Health is actively working alongside industry role players and government to secure vaccines for all South Africans.

The South Africa Health Product Regulatory Authority (SAHPRA) has created an expedited approval framework and has taken steps to cooperate with international regulators to ensure that prior research by competent global regulators is recognised. The National Department of Health has secured access to 1 million doses of the AstraZeneca vaccine from the Serum Institute of India for delivery in January 2021 and a further 0.5 million doses for delivery in February. The President also noted in a recent statement that an additional 20 million doses have been secured through the Serum Institute of India. It is not yet clear when these are expected to be delivered. Through COVAX, a further 10% of the population (6 million South Africans, 12 million doses) will be vaccinated against COVID-19; this is expected by the second quarter of 2021.

The National Department of Health and the vaccine acquisition task team continue to engage with various vaccine manufacturers to secure additional COVID-19 vaccine doses for South Africans. South Africa aims to secure sufficient vaccines for 40 million South Africans (67% of the population) to achieve herd immunity.

## Vaccine procurement and funding

6. **Will medical schemes pay for members to receive COVID-19 vaccine?**

Discovery Health Medical Scheme has set aside funding so all members of the Scheme can receive the COVID-19 vaccine when it becomes available in South Africa.

Scheme members will get access to a COVID-19 vaccine in line with national clinical protocols and in the same order as the priority population group guidelines as set by the National Department of Health in collaboration with Discovery's clinical teams. The Council for Medical Schemes has declared funding for the COVID-19 vaccine to be a Prescribed Minimum Benefit. This was formally published in an amendment to the Medical Schemes Act 131 of 1998 Prescribed Minimum Benefit legislation and was signed by the Minister of Health on 4 January 2021.

Therefore, medical schemes have to fund the COVID-19 vaccine as a Prescribed Minimum Benefit for every member of their scheme, no matter the member's health plan, in line with South Africa's vaccine prioritisation guidelines. This medical schemes have to pay for the COVID-19 vaccine for all medical scheme members without using members' day-to-day benefits. Members will also not have to pay extra for the vaccine.

There are conditions and limits to cover for Prescribed Minimum Benefits. Access to the vaccine as a Prescribed Minimum Benefit will be driven by the prioritisation framework as defined by the National Department of Health in consultation with the Ministerial Advisory Committee on COVID-19 Vaccines.

**7. Why are existing medical scheme members subsidising the vaccine for people who are not on Discovery Health Medical Scheme or any other medical scheme? Why is the cost of the vaccine for medical scheme members higher than for the general public?**

For the vaccine to be effective in bringing this pandemic to a halt, a significant proportion of the population needs to be vaccinated against COVID-19. Doing this is called reaching 'herd immunity'. Herd immunity happens when enough people in a community become immune to an infectious disease that it stops or slows the disease from spreading from person to person. To reach this point, many people must be vaccinated.

In South Africa, the infectious disease experts estimate that we will reach herd immunity to COVID-19 when about 40 million South Africans have been fully vaccinated against COVID-19 (received all the necessary vaccine doses). This is the same as 67% of the South African population.

This is a moment in time when solidarity in the healthcare sector is paramount to the country, and is warmly welcomed and supported by both the public and private sectors. All role players – including government, the Solidarity Fund, the business sector and medical schemes – will probably have to work together to secure funding for vaccination.

Medical schemes are in discussions with government and regulators to reach a pricing arrangement for COVID-19 vaccines to support South Africa in reaching herd immunity as quickly as possible. Through this pricing arrangement, medical schemes would pay enough for each member's vaccine doses to subsidise the vaccine doses for one other person who is not a member of a medical scheme.

This will provide funding for 7.1 million adult medical scheme members to be vaccinated as well as another 7.1 million adult South Africans who do not belong to a medical scheme. This approach to medicine pricing is not unusual considering that many medicines are currently sold at a higher Single Exit Price (SEP) to the private healthcare sector than to the public health sector.

**8. How much will it cost medical schemes to buy the vaccine? How does this affect reserves?**

At this stage, the prices of the vaccines range from \$5 to \$36 a dose. The National Department of Health has indicated that it has arranged to buy an initial batch of 1.5 million doses from the Serum Institute of India at \$5.20 a dose.

The cost of procuring vaccines for 7.1 million medical scheme members (all medical schemes, not just Discovery Health Medical Scheme) in South Africa using a pricing mechanism that subsidises vaccines for a further 7.1 million people who are not members of medical schemes as well as the cost of delivering the vaccine to medical scheme members is estimated to cost R7 billion at most. This is around 3% the yearly contributions of all medical schemes in South Africa and; therefore, affordable for medical schemes. It also offers strong health economic return on investment to schemes, considering the cost of treating COVID-19 patients. The final costs will depend on the pricing agreed with manufacturers, the mix of different COVID-19 vaccines, ancillary logistics costs and the prevailing exchange rate when the vaccines are bought.

Discovery Health Medical Scheme has already set funding aside for all members of the Scheme to receive the necessary doses of a COVID-19 vaccine when it becomes available in South Africa.

## Vaccine prioritisation and distribution

**9. Which members will be prioritised?**

The order in which members can receive a COVID-19 vaccine will be based on national protocols as determined by the National Department of Health in consultation with the Ministerial Advisory Committee on COVID-19 Vaccines.

These prioritisation protocols will be based on similar international protocols and on the specific needs of South Africa's population. This is important to protect vulnerable people's health first and to support the South African economy. The

order in which people in South Africa will be able to access COVID-19 vaccines will worked out for the South African population as a whole and it does not make a difference if a person is a member of medical scheme or not.

It is important that groups receive a COVID-19 vaccine in order of need as and when it becomes available in the country. It would be ethically wrong for a young, healthy, low-risk person to receive the vaccine before someone living with a high-risk clinical condition.

As outlined by the President, the priority groups to receive the vaccine are as follows:

- Phase 1: (1.2 million) front-line healthcare workers
- Phase 2: (16 million) essential workers such as teachers, police, municipal workers and other front-line personnel. This phase will include people over 60 years of age and adults with co-morbidities as well as people in institutions like old age homes, shelters and prisons
- Phase 3: (22.5 million) remaining adult population

#### 10. Why can't medical schemes procure and prioritise the roll-out of a COVID-19 vaccine on their own?

The success of each country's vaccination programme depends on making sure that the most vulnerable population groups are vaccinated first, no matter whether they are in the private or public sector, and ensuring that a significant number of people in the country are vaccinated in order to reach herd immunity and halt the spread of infection for the benefit of everyone.

Vaccination against COVID-19 could be considered the most important public health intervention of the century. It is important that priority groups receive the vaccine in order of need as and when it becomes available in South Africa. It would be ethically wrong for a young, healthy, low-risk person to receive the vaccine before someone living with a clinical condition that puts them at high risk of severe COVID-19 infection and possible death.

Discovery Health has been engaging directly with vaccine manufacturers for some time. However, manufacturers have expressed a strong preference for engaging through government leadership in all countries to ensure a coordinated and organised approach to each country's vaccine distribution. This is because of the massive global demand, and the importance of following a coordinated national strategy. It is not sustainable for every stakeholder to have their own approach to vaccine distribution, which would mean losing out on the economic and health benefits of aggregate population immunity.

Considering this critical global and national imperative, medical schemes are collaborating closely with the National Department of Health to ensure access for all South Africans to the vaccine, and especially for the priority groups.

#### 11. How will the private sector be involved in the distribution of the vaccine?

The country has a strong base to work from with both the private and public sectors being renowned for robust vaccination programmes. We also have very good vaccination penetration, especially compared to other developing nations. That said, it will require detailed logistics and planning to get COVID-19 vaccinations to tens of millions of people. This planning is currently underway.

We are proud of the close coordination and cooperation of public and private sector partners to ensure that all South Africans, and especially priority groups, will have access to a COVID-19 vaccine. South Africa has established a national coordinating committee that brings together key government departments, the private sector and other stakeholders to oversee the implementation of our national vaccination strategy. The COVID-19 vaccines will be administered through hospitals, clinics, outreach services and mobile clinics, and in private settings such as doctor's offices, pharmacies, private clinics, and workplaces.

**12. Can employers order or buy vaccines in bulk through Discovery or through MedXpress, and pay for them now?**

We do not know whether this will be possible yet, and are waiting for confirmation of the final distribution plan.

We will make every effort to ensure convenient and expedient delivery and administration of vaccines to members of medical schemes administered by Discovery Health and other Discovery Health products.

**13. Will Discovery administer the vaccines, either at employer wellness days or using the flu campaign approach?**

We do not know whether this will be possible yet, and are waiting for confirmation of the final distribution plan.

We will make every effort to ensure convenient and expedient delivery and administration of vaccines to members of medical schemes administered by Discovery Health and other Discovery Health products.

## Benefit details

**14. If a past laboratory test showed I had COVID-19, will I qualify for a vaccine?**

Yes. All members of Discovery Health Medical Scheme will qualify for a COVID-19 vaccine.

Current scientific evidence shows that, in most people, vaccines make the body produce stronger and more effective antibodies than infection. For this reason, it is important that everyone, regardless of whether they have been previously infected or not, receive a COVID-19 vaccination.

**15. Do I need to test for antibodies before getting vaccinated?**

You don't need antibody testing before getting vaccinated as the vaccine is recommended for everyone who meets the qualifying criteria, no matter if you've had COVID-19 before or not. At the moment, natural immunity after an infection is reported to last at least 90 days.

**16. Can I be vaccinated if I have just been diagnosed with COVID-19 and still have symptoms?**

If you still have symptoms of COVID-19, you should wait until you've recovered and have met the criteria to stop isolating before you are vaccinated against COVID-19.

**17. Will the vaccine be given to children as well? If yes, from what age?**

Children and adolescents outside the approved age groups will not be vaccinated as the approved vaccines have not been tested in younger age groups.

Clinical trials have been approved and are under way to test vaccines in children as young as 12 years. Children younger than 12 years will be included in clinical trials at a later stage, with results expected by 2022.

The Pfizer–BioNTech COVID-19 vaccine is approved for people who are 16 years or older. The Moderna and Oxford–AstraZeneca COVID-19 vaccines are approved for use in people who are 18 years or older.

**18. Are the vaccines safe to use in pregnancy?**

Limited data is currently available on the safety of COVID-19 vaccines in pregnant patients. However, no safety concerns were documented from data from animal studies. Studies on the effect of the vaccine on pregnant people will be carried out. In the interim, pregnant people who are in the prioritised high-risk groups can receive the vaccine.

**19. Would Discovery Health Medical Scheme cover the cost of the vaccine if a member travels to a different country to be vaccinated? (For example, if a member goes to the United States of America and gets vaccinated there, would the Scheme pay the vaccine cost when the member returns to South Africa?)**

This would need to be considered on a case by case basis. Since the vaccine is a Prescribed Minimum Benefit, the Scheme would consider funding for an approved vaccine, according to the recognised protocol, in full at the South African equivalent rate for vaccination in South Africa.

20. **Once I'm vaccinated, do I still need to adhere to non-pharmacological interventions such as wearing a mask when I am in public?**

Yes, until herd immunity is reached, enough people have been vaccinated, and the infection is no longer spreading in communities, this remains an important requirement.