

# COVID-19 Vaccine FAQs

## Vaccine specifications

To date, three vaccine manufacturers have published evidence from Phase 3 clinical trials and received emergency use approval of their COVID-19 vaccines in multiple countries. These include Pfizer-BioNTech, Moderna and AstraZeneca-Oxford vaccines.

Several other vaccines manufacturers are expected to release their Phase 3 trial data imminently, ahead of imminent expedited approval. These include Johnson & Johnson and Novavax. Early indications are that the safety and efficacy of these vaccines is excellent, and comparable to the three that have already been released.

China (SinoVac) and Russia (Sputnik V) have also approved local use of vaccines developed in their own countries but have not yet released publicly available Phase 3 trial data. Consequently, in the absence of sufficient evidence, these vaccines have not yet been registered in many other countries. Brazil has registered the SinoVac vaccine and is reporting efficacy of 50%; well below the other recognised vaccines. These results are dissatisfactory.

In South Africa, all vaccines must be approved by the South African Health Products Regulatory Authority (SAHPRA) before they can be used. Vaccines that have not received approval from SAHPRA are not permitted, by law, to be used in South Africa.

SAHPRA has close working relationships with the pharmaceutical and various global medical regulatory authorities and will, therefore, leverage these relationships and experience in evaluating the vaccines for use in South Africa.

Prioritisation of vaccines for South Africa will be based, first and foremost, on the above regulatory approval, which takes into account safety and efficacy. This will be determined from the extensive clinical trials on vaccine candidates and clinical experience through the rollout in other countries.

### **1. Which vaccines will be available in South Africa and when will they become available?**

Given the shortage of COVID-19 vaccine supply globally in the short-term, it's likely that South Africa will deploy a mix of approved vaccines during the course of 2021. Industry role players are actively working with government to secure vaccines for all South Africans.

The Minister of Health and his team have secured access to 1 million doses of the AstraZeneca vaccine from the Serum Institute India in January 2021, and a further 500 000 doses in February.

Our President has also confirmed in a recent statement that an additional 20 million doses have been secured through the Serum Institute India.

Through COVAX, a further 10% of the population (about 6 million South Africans, 12 million doses) will receive a vaccination; this is expected by Quarter 2 of 2021.

The National Department of Health (NDoH) and the vaccine acquisition task team continue to engage various vaccine manufacturers to secure additional doses for South Africans.

South Africa aims to secure enough vaccines for 40 million South Africans covering 67% of the population in order to achieve herd immunity

**2. Has the vaccine been properly tested and, what is the efficacy and expected side effects?**

All vaccines have undergone rigorous clinical trials globally before they are approved for use. These clinical trials have included up to 60,000 participants to ensure that the vaccines are entirely safe and fully effective.

The results that have been released demonstrate high levels of efficacy for the vaccines that have been approved for use thus far, with most around 90% effective.

Additionally, all vaccines will undergo extensive review of safety and efficacy before they will be approved for use in South Africa. Close monitoring of vaccine recipients will be done in order to track and document any side effects that may arise in the long term and where necessary, vaccines can be quickly removed from the market.

Adverse events and side effects are mild indeed, and include mainly headache, tiredness, body ache and a slight fever in the minority. A small number of recipients of the Pfizer vaccine experienced an allergic reaction, which is immediately treatable.

**3. How many doses will be required for each person?**

The different vaccines have differing dosing regimens. So far, all approved vaccines require 2 doses, roughly 28 days apart.

**4. Will members be covered for any side effects once they take the vaccine?**

Like any medication, vaccines may cause side effects. Mechanisms are currently being explored for implementation of a no-fault vaccine injury support programme, similar to what has been implemented in

other countries. While 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 funder of medicines, medical schemes do not carry liability in law for side effects and adverse effects of medicine administration. This would apply to the vaccine on the same basis.

**5. Will medical schemes pay for members to receive COVID-19 vaccination?**

The Council for Medical Schemes (CMS) 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 PMB legislation, signed by the Minister of Health on 4 January 2021.

Medical schemes are effectively obliged by law to fund the COVID-19 vaccine as a Prescribed Minimum Benefit to every member of the respective scheme, in line with South Africa's vaccine prioritisation guidelines.

We have ring-fenced funding for all members of the Scheme to receive the COVID-19 vaccine when it becomes available in South Africa.

Access to the vaccine for members will be in alignment with national clinical protocols and priority population group guidelines, as set by the NDoH, in collaboration with our clinical teams.

**6. Why is the cost of the vaccine for medical scheme members inflated? Why are existing medical scheme members subsidising the vaccine for people who are not on any other medical scheme?**

For the vaccine to be effective in bringing this pandemic to a halt, a significant proportion of the population need to be vaccinated, allowing any country to reach “herd immunity”. Herd immunity happens when sufficient people in a community become immune to an infectious disease, that it prevents the unconstrained exponential spread of the disease, person to person. Reaching this threshold requires mass vaccination.

In South Africa, the virologists guide us that herd immunity will be reached when approximately 40 million South Africans have received a COVID-19 vaccine; equivalent to 67% of the South African population.

This is a moment in time where solidarity in the healthcare sector is of paramount importance to the country, and is warmly welcomed and supported by both the public and private sectors. Funding for the vaccine will ultimately likely be secured from all role players, including government, the Solidarity Fund, the business sector and medical schemes.

Medical schemes are in discussions with government and regulators to support a pricing arrangement for the vaccines, in order to support SA in reaching herd immunity as quickly as possible.

This pricing arrangement would generate a surplus from the schemes’ purchases of the vaccines for their members, in order to subsidise the vaccination of an equivalent number of non-medical scheme members.

As such, for each vaccine procured for a medical scheme member, sufficient surplus is generated through procurement arrangements for the vaccine to subsidise the vaccination of one non-medical scheme member.

This provides funding for 7.1 million adult medical scheme members to be vaccinated, and another 7.1 million adult South Africans, who are uninsured, which results in aid being provided to government to cover a portion of uninsured South Africans.

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.

**7. How much will it cost medical schemes to purchase the vaccine? How does this affect your medical scheme’s reserves?**

Initial indications on the price of the vaccines range from \$5 to \$36 a dose. The NDoH has indicated that it has procured the initial batch of 1,5 million doses from Serum Institute India at \$5,20 per dose.

The cost of procuring vaccines for 7,1 million medical scheme members in South Africa on a pricing mechanism that allows for procuring vaccine 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 not more than R7 billion. This is around 3% of annual premium contributions and, therefore, affordable for medical schemes. It also offers strong health economic return on investment to schemes, considering the costs medical schemes have incurred in treating COVID-19 patients.

Final costing will depend on the pricing agreed with manufacturers, the mix of different vaccines procured, ancillary logistics costs and the prevailing exchange rate at the time.

The Scheme has already ring-fenced funding for all members of the Scheme to receive the COVID-19 vaccine when it becomes available in South Africa.

## **8. Which members will be prioritised?**

Vaccination will be prioritised based on national protocols as determined by the NDoH in consultation with the Ministerial Advisory Committee on COVID-19 vaccines.

These prioritisation protocols will be based on similar protocols internationally and on specific needs of South Africa's population. This is important in order to achieve the health and economic benefits that the vaccine roll-out aims to achieve.

Prioritisation of the order in which people in South Africa will be able to access COVID-19 vaccination will be done on a population level and will be irrespective of whether the person is a member of medical scheme or not.

It is important that priority groups receive the vaccine in order of need, as and when it becomes available in the country. It would be ethically inappropriate for a young, healthy, low-risk person to receive the vaccine before someone living with a high-risk clinical condition. The public health benefits, economic recovery of the country and the impact on protecting lives is greatest, if this prioritisation assures that the highest risk individuals receive the vaccine first.

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

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

## **9. Why is it not possible for medical aid schemes to procure and prioritise roll out of the vaccine on their own?**

The success of each country's vaccination programme is dependent on prioritisation of the most vulnerable population groups, regardless of whether these are in the private or public sectors, 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 for 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 inappropriate 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.

Vaccine manufacturers, with whom the industry has been engaging directly for some time, 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, in the context of massive global demand, and the importance of a coordinated national strategy. It is not sustainable for there to be isolated approaches to vaccine distribution, which would forego the economic and health benefits of aggregate population immunity.

Considering this critical global and national imperative, the medical scheme industry is collaborating closely with the NDoH to ensure access for all South Africans to the vaccine, and especially for the priority groups.

**10. How will the private sector be involved in the distribution of the vaccine?**

South Africa has a strong base to work from, with both the private and public sector renowned for very 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 the vaccination to tens of millions of people and that planning is currently underway.

We are proud of the close coordination and cooperation of public and private sectors partners to ensure access for all South Africans to the vaccine, and especially for the priority groups.

SA has established a National Coordinating Committee, which brings together key government departments, the private sector and other stakeholders to oversee the implementation of our national vaccination strategy.

The vaccines will be administered through hospitals, clinics, outreach services and mobile clinics, and private settings such as Healthcare Professionals' offices, pharmacies, private clinics, and workplaces.

**11. Can employers order/bulk buy vaccines through the Scheme or another third party, and pay for them now?**

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

We will make every effort to ensure convenient and expedient delivery and administration of vaccines to our members.

**12. Will we administer the vaccines, either at employer wellness days or via the flu-campaign type of approach?**

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

We will make every effort to ensure convenient and expedient delivery and administration of vaccines to our members.

**13. If I have previously tested positive for COVID-19 will I be eligible for the vaccine?**

Yes. All members will be eligible for the COVID-19 vaccine.

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

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

There is no requirement for antibody testing before getting vaccinated as the vaccine is recommended for everyone who meets the eligibility criteria regardless of prior infection.

Natural immunity following an infection is reported to last at least 90 days currently.

**15. Can I be vaccinated if I have just been diagnosed with COVID-19 infection and I am still symptomatic?**

Vaccination of people who are still symptomatic should be deferred until the person has recovered and meets criteria to discontinue isolation.

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

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

Clinical trials have been approved and are under way to trial vaccines in children as young as 12 years.

Younger age groups (< 12 years) will be included in clinical trials at a later stage with results expected by 2022.

The Pfizer-BioNTech vaccine is approved for use in persons aged 16 and older. The Moderna and Astra-Zeneca-Oxford vaccines are approved for use in persons 18 years and older.

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

Limited data is currently available on the safety of COVID-19 vaccines in pregnant women. Available data is only from animal studies and no safety concerns were documented from this data. Studies in pregnant women will be carried out. In the interim, pregnant women who are in the prioritised high-risk groups can receive the vaccine, subject to guidance from their treating Healthcare Professional.

**18. Would the Scheme cover the cost of the vaccine if a member travels to a different country to be vaccinated? For example, a member travels to the US to get vaccinated there. Would the Scheme pay the vaccine cost upon the member's return to South Africa?**

This would need to be considered on a case-by-case basis. Considering this is a Prescribed Minimum Benefit, should a member be vaccinated with an approved vaccine, according to the recognised protocol, we would consider funding this in full at the SA-equivalent rate for vaccination locally.

**19. Once 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.