

## COVID-19 Vaccine FAQs

### 1. Which COVID-19 vaccination will be given to members?

All vaccines must be approved by the South Africa Health Product Regulatory Authority (SAHPRA) before they can be used in SA. Vaccines that have not received approval from SAHPRA are not permitted by law to be used in South Africa.

Prioritization 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.

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. This should not be a concern for medical scheme members and the people in South Africa as the safety and efficacy of these vaccines will be similar and all vaccines approved for use in South Africa would have undergone the same rigorous testing and clinical evaluations.

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

All vaccines have undergone rigorous clinical trials globally before they have been approved for use. These clinical trials have included tens of thousands of participants to ensure that the vaccines are safe and effective. Research focusing on vaccine efficacy against new variants of COVID-19 is ongoing and is used to guide the vaccine roll-out plan.

Close monitoring of vaccine recipients will be done in order to track and document any side effects that may arise in the long term.

Additionally, all vaccines will undergo extensive review of safety and efficacy before they will be approved for use in South Africa.

The South Africa Health Product Regulatory Authority (SAHPRA) is responsible for approving 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 medical products before approving products for use in SA.

SAHPRA also 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.

Common side effects that have been documented include the following:

- Pain and swelling on the injection site
- Fever
- Chills
- Tiredness
- Headaches
- Muscle pains
- Nausea

The prevalence of severe adverse reactions has been very low. No deaths related to vaccines have been reported.

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

The different vaccines have differing dosing regimens as per below:

- Johnson and Johnson vaccine – single dose
- Pfizer vaccine – 2 doses separated by a minimum of 28 days
- Moderna Vaccine – 2 doses separated by a minimum of 28 days
- Astra-Zeneca -Oxford Vaccine – 2 doses separated by a minimum of 28 days

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

The Council for Medical Schemes and National Department of Health have made the provision of COVID-19 vaccination a Prescribed Minimum Benefit as of 04 January 2021. This means that all medical schemes in South Africa will be obliged to fund COVID-19 vaccination for all Scheme members at no additional cost to Scheme members.

Vaccines are only approved in South Africa after thorough and independent review of the scientific evidence. They are also closely monitored once on the market and can quickly be removed from market if safety concerns are identified.

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. This programme will provide support in the rare instance of a serious adverse 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. When will the vaccine be available?**

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

SAHPRA has created an expedited approval framework and has taken steps to cooperate with international regulators to ensure recognition of prior research by competent global regulators. The NDoH had already secured 1 million doses of the AstraZeneca vaccine from the Serum Institute India which arrived in South Africa on the 1st of February 2021 with a further 0,5 million doses due for delivery during the course of the month of February.

However, results of the South African arm of the Astra-Zeneca vaccine trial of 2000 participants showed only a 22% efficacy against mild to moderate COVID-19 disease. Current data has not assessed efficacy against severe disease. This has resulted in the government halting the roll-out of the Astra-Zeneca vaccine while awaiting more clinical efficacy data.

At the same time, the Johnson and Johnson vaccine, while it showed a slightly reduced efficacy in protecting against mild-to moderate disease from 72% to 64%, it is also the only vaccine with data against severe disease. The current efficacy of the J & J against severe disease is currently 82%.

The South African Government has therefore decided to work on a new roll-out approach prioritizing introduction of the J & J and Pfizer vaccine towards the end of February and early March. Through COVAX a further 10% of the population (~6m South Africans, 12 million doses). The National Department of Health and the vaccine acquisition task team continue to engage with various vaccine manufacturers to secure additional doses for South Africans. South Africa aims to secure sufficient vaccines for 40 million South Africans covering 67% of the population in order to achieve herd immunity.

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

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

Access to the vaccine for Scheme members will be in alignment with national clinical protocols and priority population group guidelines as set by the National Department of Health.

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 the 4th of 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 prioritization guidelines.

### **7. Why is the cost of the vaccine for Medical Scheme members inflated? AND Why are existing medical scheme members for the 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, thereby achieving herd immunity. Herd immunity happens when sufficient people in a community become immune to an infectious disease so that the virus can no longer spread from one person to the next. Reaching this threshold requires that as many people as possible get vaccinated.

In South Africa, the infectious disease experts guided us that herd immunity will be reached when approximately 40 million South Africans have received a COVID 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. As a result, all role players need to play their part. Funding for the vaccine programme will therefore come from all role players, including government, donors, the business sector and medical schemes.

Medical schemes are in discussions with government and regulators to support the accelerated rollout of the vaccine programme with a view to agreeing a pricing arrangement for the vaccines that enables this accelerated rollout.

This principle of this pricing arrangement would be to generate a surplus from the schemes' purchases of the vaccines that could then be used to subsidize the vaccination people who don't have the benefit of being a member of a medical scheme.

As such, mechanism could allow for each vaccine procured for a medical scheme member to be matched with the purchase of one vaccine for a person who's not a member of a medical scheme.

Conceptually, this could then potentially unlock funding for an additional 7.1 million adult South African's to be vaccinated, in addition to the 7,1 million medical scheme members who will already have access to vaccination.

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

The cost of procuring vaccines for 7,1 million medical scheme members in South Africa on an SEP pricing mechanism is estimated to cost not more than R6-7 billion. This is around 2-3% of annual contributions and will therefore be affordable for most 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.

**9. What is the "vaccine tax" being considered by government to raise funds for the state's vaccine rollout?**

We recognize that tax mechanisms can have knock-on effects on economic activity. Given the current position of the South African economy, this needs to be carefully balanced. There needs to be a holistic and coordinated approach to vaccine funding.

The vaccine project for South Africa is a massive task that requires collaboration across and between government and the private sector in order for the country to derive the benefits of achieving population (herd) immunity.

**10. Is there a possibility for private sector to supplement Government's procurement and distribution of vaccines, i.e., companies with large staff complements (<1000) to procure for themselves, and perhaps donate on a 1 for 1 basis (or more) to the wider community?**

At this stage vaccine procurement is being centralized nationally. The mechanisms for employer involvement in distribution are being determined, the public and private sectors are working closely together to assure the most efficient and effective vaccine roll-out.

**11. Given the recent announcement that the Private sector can procure COVID vaccines, does the Scheme plan to procure vaccines independently?**

Our administrator remains in regular contact with vaccine manufacturers while making every effort, in coordination with the Department of Health, to avail vaccines quickly to members of the medical schemes that we administer. We have completed detailed analytics and modelling for the schemes, and understand the economics, prioritization of member segments and have prepared the requisite distribution plans. The schemes have the money ready and waiting for disbursement to fund vaccination in full for all members. We are expecting expanded registration of vaccines by SAHPRA in the near future, increasing the availability for distribution in the country. We understand the anxiety around the rollout of the vaccine, and with the appropriate prioritisation of risk groups as a leading principle, we are doing everything we can to accelerate the rollout.

## Vaccine prioritization and distribution

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

Vaccination will be prioritized based on national protocols as determined by the National Department of Health in consultation with the Ministerial Advisory Committee on COVID-19 Vaccines.

These prioritization 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

Prioritization 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 prioritization assures that the highest risk individuals receive the vaccine first.

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

- Phase 1: (1.2 million) front line 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, shelters and prisons, people over 60 years of age and adults with co-morbidities
- Phase 3: (22.5 million) remaining adult population

The above prioritization plan is currently being reviewed in order to further split phase 2 into various priority groups. The aim is to prioritize the population firstly by age and then by underlying comorbidities.

### **13. 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 prioritization 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 the country. 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 our administrator 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 organized 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 National Department of Health (NDoH) to ensure access for all South Africans to the vaccine, and especially for the priority groups.

### **14. 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 sector being renowned to have 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 sector 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 mass vaccination sites, pharmacies, private clinics, and workplaces.

### **15. Can employers order/bulk buy vaccines and pay for them now?**

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

## **Vaccine clinical questions**

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### **16. If I have previously tested positive for COVID-19 will I be eligible for the vaccines?**

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

### **17. 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 regardless of prior infection.

### **18. 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 have met criteria to discontinue isolation.

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

Vaccines are typically tested first in adults before researchers begin tests in children, once the drug has been found to be relatively safe.

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.

Pfizer-BioNTech- approved from ages 16 and above. Moderna and Astra-Zeneca-Oxford- approved for use in people who are 18 years and older

### **20. Are the vaccines safe to use in pregnancy?**

Limited data is currently available on the safety of COVID-19 vaccines in pregnant patients. 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 prioritized high-risk groups can receive the vaccine.

No reports of significant side effects from the preliminary data collected from thousands of pregnant women who have already received the COVID-19 vaccine globally have been shared. In early reports, antibodies have been identified in babies born to vaccinated mothers, which may indicate protection for these babies

**21. 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.

**22. Is one vaccine preferable to the other for specific patients?**

All approved vaccines are suitable for everyone.

**23. Will the Vaccine cover/protect us from the new variant?**

Preliminary data has shown reduced efficacy of the various vaccines against the new variant. Recent results from the South African arm of the Astra-Zeneca vaccine trial showed a reduction from 66% efficacy down to 22% efficacy resulting in a decision by government to halt the national roll-out with the Astra-Zeneca vaccine.

At the same time, the Johnson and Johnson vaccine, while it showed a slightly reduced efficacy in protecting against mild-to moderate disease from 72% to 64%, it is also the only vaccine with data against severe disease. The current efficacy of the J & J against severe disease is currently 82%. Data from the Moderna and Pfizer vaccines are limited to lab studies that have also observed reduced efficacy.

The South African Government has therefore decided to work on a new roll-out approach prioritizing introduction of the J & J and Pfizer vaccine and this is currently underway.

**24. Will people with auto immune diseases be able to take the vaccine? Has it been tested with people with AI disease, or comorbidities?**

There is currently no published data on the safety and efficacy of the COVID-19 vaccines in people with autoimmune conditions but may still be offered the vaccine weighing the benefits of protection against severe COVID-19 infection versus potential harms which are currently very rare.

**25. How long will the protection from the vaccine last?**

At this stage, more evidence is required to determine the duration of immunity after vaccination which will be established once there is more data on how well the COVID-19 vaccines work in real-world conditions. Experts are working to learn more about vaccine-induced immunity.

**26. Can you share any developments on the studies / trails / approved use of Ivermectin?**

Clinical trials are still underway to determine the safety and efficacy of Ivermectin in the prophylaxis and treatment of COVID-19 infection. Mixed results from small studies have been observed. This data is still very limited and cannot be used for regulatory approval of Ivermectin which is why it currently has not received any approval by any regulatory authority in the world for the use in prophylaxis and treatment of COVID-19 infections.

### **27. Is there any evidence of people getting infected twice?**

There is evidence that immunity may not be enduring. Despite having been infected previously, there is a strong possibility an individual could be reinfected. This could be aggravated by the continued emergence of COVID-19 variants that are capable of immune escape as we have seen happening in South Africa and around the world.

### **28. How accurate is the antibody test in detecting previous infection? Would it pick up if an individual had the virus when it first hit SA in for example a year ago and that individual did not get tested at the time?**

Antibodies are produced over days to weeks after infection with the virus. The strength of antibody response depends on several factors, including age, nutritional status, severity of disease, and certain medications or infections like HIV that suppress the immune system. Nevertheless, early indications show that being infected with COVID-19 naturally may not produce enduring immunity through antibodies, thus a previously positive COVID-19 individual may not have antibodies.

### **29. Is it necessary to isolate if you have had contact with a COVID-19 positive person if you have already had COVID-19 or have been vaccinated?**

Yes. At this stage experts are not yet certain whether getting a COVID-19 vaccine will prevent individuals from spreading the virus that causes COVID-19 to other people, thus it is best to quarantine following a COVID-19 Exposure. Experts need to understand more about the protection that COVID-19 vaccines provide in real-world conditions. If you were infected within the past 90 days, it is not necessary to quarantine as you may still have some remaining protection.

### **30. Can you actually prevent COVID-19 with a simple flu shot?**

The influenza and COVID-19 are not part of the same virus family. While the symptoms may be similar, their origins are different. It is possible to be exposed to both viruses and then develop one or both of these illnesses.

The flu vaccination provides protection for the strain of flu that is expected in each year's flu season. It will not protect you against COVID-19. Only vaccines created for COVID-19, will be effective at protecting individuals from COVID-19.

### **31. Should I get a flu shot or wait for the COVID-19 vaccine?**

Since the flu season and COVID-19 are likely to overlap, the National Institute for Communicable Diseases (NICD) in South Africa has recommended that every South African citizen receive a flu vaccination ahead of influenza season this year. If a person becomes unwell with any kind of viral infection, their immune systems typically become weakened for a while. This makes a person even more susceptible to any other infectious condition that may be prevalent at the time.

By protecting yourself against one contagious infection – the flu – you should be able to reduce your level of risk somewhat against the other. The vaccination won't prevent COVID-19 infection, it will protect you against flu related complications. If you are in the position to get both vaccines, the guideline is to ensure that vaccines are administered two weeks apart.



### **32. Are there ways to tell the difference between COVID-19 and Flu infections?**

It's not easy to differentiate between the two based on symptomatic presentations alone. With similar signs and symptoms, the general preventative measures for reducing the risk of spread and transmission work for both and COVID-19. A healthcare professional is likely to ask questions when assessing a patient and where appropriate request a PCR or antigen test for confirmation of active COVID-19 infection.

### **33. How long after recovering from COVID-19 infection can I get my flu shot?**

You can get your flu vaccination as soon as you have met criteria for deisolation (i.e., no longer experiencing symptoms or completed 10 days of isolation if asymptomatic)

## **Benefit details**

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### **34. Would the scheme cover the cost of the vaccine if a member travels to a different country to be vaccinated? (e.g., A member goes to the US, and gets vaccinated there?)**

This would need to be considered on a case-by-case basis at the Scheme's discretion.

### **35. Can I choose which vaccine to get?**

Given the limited supply of vaccines globally at this stage, it is advisable that members/citizens make use of the vaccine that is made available. All approved vaccines have met the required clinical efficacy standards.

### **36. Will people need to carry proof of vaccination in the future and what will this proof be? Who will provide this proof to members/citizens? What form will this take, card, digital, other?**

There will be a form of a vaccine certificate issued to members/citizens. This will be common for all South Africans.

The South African government has developed an electronic vaccination data system (EVDS) to assist with the roll-out of COVID-19 vaccines across the country, of which the vaccine certificate will form a part.

### **37. Will vaccinations be free of charge to all South Africans?**

Vaccinations will be free of charge for all eligible South Africans across both the private and public health sectors.

### **38. Can you advise on the costs of the COVID-19 Vaccine?**

The cost of the vaccines will be defined by Government once the vaccines are registered. The full cost of vaccination includes the cost per vial, import costs, health professional fees for administering the vaccine and the cost to distribute the product in South Africa. Each vaccine will have a different cost structure given different manufacture and logistics costs.

**39. Can employers "force" employees to take the vaccine? E.g., oblige employees to get vaccinated when employee would prefer not to.**

The President has indicated that vaccination will not be mandatory. It is recommended that as many people as possible should be vaccinated for South Africa to reach herd immunity. Employer approaches to vaccination will depend on factors such as the industry and workplace safety requirements.

**i. Vaccine rumors debunked: Microchips, 'altered DNA' and more**

<https://www.bbc.com/news/54893437>

**ii. The New England Journal of Medicine: Covid-19 Vaccine Frequently Asked Questions**

<https://www.nejm.org/covid-vaccine/faq>

**iii. Which is the best COVID vaccine to get? It's complicated**

<https://techcentral.co.za/which-is-the-best-covid-vaccine-to-get-its-complicated/105747/>