



**2021**

DISCOVERY HEALTH

# COVID-19 VACCINE FREQUENTLY ASKED QUESTIONS

## Frequently asked questions about the COVID-19 vaccine

### Vaccine specifications

**1. Which COVID-19 vaccination will members get?**

All vaccines must be approved by the South Africa Health Products Regulatory Authority (SAHPRA) before they can be used in SA. By law, no one in South Africa may use vaccines that SAHPRA have not approved.

Prioritisation of vaccines for South Africa is first based on the above regulatory approval that takes into account safety and efficacy. The safety and efficacy is determined from the extensive clinical trials on the vaccines and clinical experience through the rollout of vaccinations in other countries.

Given the global shortage of COVID-19 vaccine supply in the short-term, it's likely that South Africa will use a mix of approved vaccines in 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. Have the COVID-19 vaccines been properly tested, and do we know what the efficacy and expected side effects are?**

All vaccines have undergone rigorous clinical trials globally before they have been approved for use. These clinical trials have included over 60 000 participants to make sure that the vaccines are safe and effective. There is ongoing research focusing on vaccine efficacy against new variants of COVID-19 and this research is used to guide the vaccine roll-out plan.

Vaccine recipients will be closely monitored to track and document any side effects that may arise in the long term. All vaccines will also undergo extensive review of safety and efficacy before they will be approved for use in South Africa.

The South Africa Health Products Regulatory Authority (SAHPRA) is responsible for approving all medicine and vaccines for use in South Africa. They do an in-depth and extensive scientific and clinical analysis of the safety and efficacy of a medical product before approving it for use in SA.

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

Common side effects that have occurred include the following:

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

There have been very few severe adverse reactions.

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

The doses differ for the different vaccines. So far, most approved vaccines need two doses, given 21 to 28 days apart. The Johnson & Johnson vaccine (administered under a research approval and the first vaccine administered in South Africa on 17 February 2021) needs only one dose.

**4. Will medical schemes take full responsibility for the side effects or even death of their members who 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 from 4 January 2021. This means that all medical schemes in South Africa must pay for the COVID-19 vaccination for all their scheme members at no extra cost to the 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 the market if safety concerns are identified.

Like any medicine, vaccines may cause side effects. South Africa is looking into the option of a 'no-fault vaccine injury support programme' like other countries have implemented. While still in the early phases of development, this programme will likely give support in the rare instance of a serious adverse reaction to a vaccine approved for use in South Africa.

As a funder of medicine, 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 Health is actively working with government alongside other industry role players to secure vaccines for all South Africans. SAHPRA has created a faster approval framework and has taken steps to work with international regulators to make sure they recognise earlier research by competent global regulators.

The National Department of Health had already secured 1 million doses of the AstraZeneca vaccine from the Serum Institute of India which arrived in South Africa on 1 February 2021 with a further 0.5 million doses due for delivery during February.

However, results of the South African arm of the Astra-Zeneca vaccine trial of 2 000 participants were recently released showing 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 stopping the roll-out of the AstraZeneca vaccine while waiting for more clinical efficacy data. The Johnson & Johnson vaccine, while it showed a slightly reduced efficacy in protecting against mild to moderate disease from 72% to 57%, is also the only vaccine with data against severe disease. The efficacy of the Johnson & Johnson vaccine against severe disease is currently 85%.

The South African Government has, therefore, decided to work on a new roll-out approach prioritising the Johnson & Johnson and Pfizer vaccines towards the end of February and early March. Through COVAX, South Africa will get vaccines for a further 10% of the population (6 million South Africans, 12 million doses). The National Department of Health and the vaccine acquisition task team continue to talk to various vaccine manufacturers to get extra doses for South Africans.

South Africa is trying to get vaccines for 40 million South Africans covering 67% of the population to achieve population immunity.

## Buying and paying for vaccines

#### 6. Will medical schemes pay for members to get the COVID-19 vaccine?

Discovery Health Medical Scheme has set aside funding for all members of the Scheme to get the COVID-19 vaccine when it becomes available in South Africa. Scheme members will have access to the vaccine in line with the national clinical protocols and priority population-group guidelines as set by the National Department of Health in collaboration with Discovery's clinical teams.

The Council for Medical Schemes (CMS) has declared that the COVID-19 vaccine must be paid as a Prescribed Minimum Benefit (PMB). This was published in an amendment to the Medical Schemes Act PMB legislation, signed by the Minister of Health on 4 January 2021. Medical schemes must – by law – pay for the COVID-19 vaccine as a Prescribed Minimum Benefit for every member of their scheme. They must do this in line with South Africa's vaccine prioritisation guidelines.

#### 7. Why is the cost of the vaccine for medical scheme members inflated and why are existing medical scheme members subsidising the vaccine for people who are not on Discovery Health Medical Scheme or any other medical scheme?

For the vaccine to stop this pandemic, a significant part of the population needs to be vaccinated, thereby achieving population (herd) immunity. Population immunity happens when enough people in a community become immune to an infectious disease so that the virus can no longer spread from one person to the next. To reach this threshold, as many people as possible must get vaccinated.

In South Africa, the infectious disease experts estimate that we will reach population immunity when about 40 million South Africans have had a COVID vaccine – equivalent to 67% of the South African population.

This is a moment in time where solidarity in the healthcare sector is very important to the country. As a result, all role players need to play their part. Payment for the vaccine programme will, therefore, come from all role players, including:

- Government
- Donors
- Business sectors
- Medical schemes

Medical schemes are in discussions with government and regulators to support the quicker rollout of the vaccine. They are discussing a pricing arrangement for the vaccines that would make this quicker rollout possible.

This arrangement could allow for each vaccine the scheme buys for a medical scheme member to be matched with the buying of one vaccine for a person who is not a member of a medical scheme. This could potentially unlock money for an extra 7.1 million adult South African's to be vaccinated, besides the 7.1 million medical scheme members who will already have access to vaccination.

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

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

The cost of buying vaccines for 7.1 million medical scheme members in South Africa (at the single exit price) is estimated to be less than R6-7 billion. This is about 2-3% of the yearly 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 had in treating COVID-19 patients.

Final costing will depend on:

- The pricing agreed with manufacturers
- The mix of different vaccines bought
- Ancillary logistics costs
- The prevailing exchange rate at the time

Discovery Health Medical Scheme has already ring-fenced funding for all members of the Scheme to get the COVID-19 vaccine when it becomes available in South Africa. Vaccine prioritisation and distribution

**9. Does Discovery have any comment on government considering a 'vaccine tax' to raise money for the state's vaccine rollout?**

Discovery recognises 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 co-ordinated approach to paying for vaccines and we are contributing constructively to these deliberations.

The vaccine project for South Africa is a massive task that needs collaboration across and between government and the private sector so that the country can get the benefits of achieving population (herd) immunity.

**10. Is there a possibility for the private sector to supplement government's procurement and distribution of vaccines? In other words, can companies that have more than 1 000 staff members buy for themselves, and perhaps donate on a one-for-one basis (or more) to the wider community?**

At this stage, the national buying of vaccines is centralised. The public and private sectors are working closely together to assure the most efficient and effective vaccine roll-out and are looking into ways for employers to get involved in distribution.

## Vaccine prioritisation and distribution

### 11. Which members will be prioritised?

Vaccination will be prioritised 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 protocols internationally and on the specific needs of South Africa's population. This is important 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 get the COVID-19 vaccination, will be done on a population level and will be irrespective of whether the person is a member of a medical scheme or not.

It is important that priority groups get 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 get the vaccine before someone living with a high-risk clinical condition. The public health benefits, economic recovery of the country and the effect on protecting lives is greatest if this prioritisation assures that the individuals with the highest risk get the vaccine first.

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

- Phase 1: (1.2 million) frontline health workers
- Phase 2: (16 million) essential workers, such as:
  - Teachers
  - Police officers
  - Municipal workers
  - Other frontline personnel
  - People in institutions, like old age homes
  - People in shelters
  - People in prisons
  - People over 60 years of age
  - Adults with co-morbidities
- Phase 3: (22.5 million) remaining adult population

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

The success of each country's vaccination programme depends on:

- Prioritising the most vulnerable population groups, regardless of whether they are in the private or public sectors and
- Making sure that a significant number of people in the country are vaccinated to reach population immunity and stop 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 get 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 get 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 Discovery Health has been engaging directly for some time, have expressed a strong preference for engaging through government leadership in all countries. This is to guarantee 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 risk the economic and health benefits of aggregate population immunity.

Considering this critical global and national necessity, the medical scheme industry is working closely with the National Department of Health to guarantee access for all South Africans to the vaccine, and especially for the priority groups.

### 13. 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 for having very robust vaccination programmes. We also have very good vaccination penetration, especially compared to other developing nations. That said, it will call for 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 guarantee access for all South Africans to the vaccine, and especially for the priority groups.

SA 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 vaccines will be administered through:

- Hospitals
- Clinics
- Outreach services and mobile clinics
- Private settings, such as:
  - Doctor's offices
  - Pharmacies
  - Private clinics
  - Workplaces

**14. 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 guarantee convenient delivery and administration of vaccines to members of medical schemes administered by Discovery Health and clients with other Discovery Health products.

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

Discovery Health Medical Scheme members who are healthcare workers need to register on the National Department of Health's Electronic Vaccination Data System (EVDS) for their vaccination. They will then be notified of where and when they will be scheduled for their vaccinations. This can be done through the Discovery registration system circulated to healthcare providers. Vaccination of healthcare workers will be at private and public hospitals and at select retail pharmacies. The list of these accredited vaccination sites is being compiled and should be available soon.

## Vaccine clinical questions

**16. 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, get a COVID-19 vaccination.

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

No. There is no need for antibody testing before getting vaccinated as the vaccine is recommended for everyone, if they have had a COVID-19 infection or not.

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

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

No. People who are still symptomatic must delay their vaccination until they have recovered and meet the criteria to stop 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 (younger than 12 years) will be included in clinical trials at a later stage with results expected by 2022.

Currently:

- Pfizer-BioNTech vaccine is approved from ages 16 and above
- Moderna vaccine is approved for use in people who are 18 years and older
- Johnson & Johnson has been tested 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 prioritised high-risk groups can get the vaccine.

**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 we have reached population immunity, enough people have been vaccinated and the infection is no longer spreading in communities, this is still an important requirement.

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

The Pfizer-BioNTech vaccine is authorised for people who are 16 years old and older while Moderna is authorised for people who are 18 years old and older. Johnson & Johnson has been tested in people who are 18 years and older. Aside from this age difference, there is no target population better suited to one vaccine or the other.

**23. Will the vaccine cover or 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 AstraZeneca vaccine trial showed a reduction from 66% efficacy down to 22% efficacy resulting in a decision by government to stop the national roll-out with the AstraZeneca vaccine.

At the same time, the Johnson & Johnson vaccine, while it showed a slightly reduced efficacy in protecting against mild-to-moderate disease from 72% to 57%, it is also the only vaccine with data against severe disease. The current efficacy of the Johnson & Johnson vaccine against severe disease is 85%. 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 prioritising Johnson & Johnson and Pfizer vaccines towards the end of February and early March.

**24. Will people with autoimmune diseases be able to take the vaccine? Has it been tested for people with autoimmune disease or other comorbidities?**

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

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

At this stage, we need more evidence to determine the duration of immunity after vaccination. This 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, trials or approved use of ivermectin?**

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

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

There is early evidence that immunity may not last and we have seen repeat COVID-19 infections over 90 days apart, within Discovery Health Medical Scheme's member base. This shows a re-infection rate that is statistically significant.

**28. How accurate is the antibody test in detecting previous infection? Would it pick up if an individual has had the virus when it first hit SA 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 the antibody response depends on several factors, including:

- Age
- Nutritional status
- Severity of disease
- Certain medicine or infections, like HIV, that suppress the immune system

Nevertheless, early signs show that being naturally infected with COVID-19 may not produce lasting immunity through antibodies. This means an individual who have previously had a COVID-19 infection, 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. 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. So, it is best to isolate after exposure to COVID-19. Experts need to understand more about the protection that COVID-19 vaccines give in real-world conditions.

## Discovery and benefit details

30. **Will Discovery administer the vaccines, either at employer wellness days or through the flu-campaign type of approach?**

We do not know whether this will be possible yet, and we wait for confirmation of the final distribution plan. We will make every effort to guarantee convenient delivery and administration of vaccines to members of the medicals schemes Discovery Health administers.

31. **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 US and gets vaccinated there, would Discovery Health Medical 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 at the Scheme's discretion.

32. **Can I choose which vaccine to get? Will Discovery Health Medical Scheme members have the option to purchase the higher efficacy vaccine (Pfizer), even if it is with a co-payment?**

Given the limited supply of vaccines globally at this stage, it is advisable that all people use the vaccine that is made available. Studies are currently underway to test the safety and efficacy of using one vaccine for the first dose and a different vaccine for the second. At present, there is no supporting data for switching.

33. **Will people need to carry proof of vaccination in the future and what will this proof be? Who will give this proof to persons? What form will this take, card, digital or other?**

There will be a form of a vaccine certificate issued to persons who had had the vaccine. This will be common across Discovery Health Medical Scheme and for all South Africans.

The South African government announced that they are in the process of developing an electronic vaccination data system (EVDS) to help with the roll-out of COVID-19 vaccines across the country. Issuing the vaccine certificate will form part of this process.

34. **Please elaborate on Discovery's involvement in the government distribution plan for vaccines**

Discovery is taking part in the Business for South Africa (B4SA) work streams that are planning the roll-out of the national COVID-19 vaccination programme alongside the National Department of Health. We are contributing skills and expertise to support this national effort. Discovery Group CEO, Adrian Gore, has also been working with the Task Team appointed by the Minister of Health to support vaccine procurement.

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

Vaccinations will be free of charge for medical scheme members. Vaccinations will also be free of charge for all other adult South Africans across all public sector health facilities.

36. **Can you tell us what the costs of the COVID-19 vaccine will be?**

Government will define the cost of the vaccines once the vaccines are registered. The full cost of vaccination includes the cost per vial (container with the vaccine), 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.

37. Can employers force employees to take the vaccine? (In other words, make employees get vaccinated when the employee would prefer not to)

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