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MEDIA STATEMENT

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South Africa commences early access vaccine rollout to Healthcare Workers - Sisonke! Let's work together to protect our Healthcare Workers

Day One of the first phase of COVID-19 Vaccine Rollout to health workers was a huge success today. South Africa secured the single dose Johnson & Johnson (JnJ) vaccine for use in the Sisonke ('Together') programme. Sisonke will be rolled out to up to 500,000 healthcare workers starting in 18 public sector hospitals across all nine provinces.

As a demonstration of confidence in the **safety and efficacy of the vaccine ... of organised labour leadership will be taking their shots at Steve Biko Academic Hospital from 14:00. These are leaders who are health workers themselves. They are from:** DENOS, HOSPERSA, NEHAWU, NAPSU, NUPSAW, YNURSES INDABA, PSA, PHSDSBC, SAEPU, SAMATU.

Protecting our healthcare workers is an urgent priority. Phase 1 of the vaccine programme is focused on healthcare workers. This is the first step in rolling out a comprehensive vaccine distribution strategy for the nation. Healthcare workers are the frontline of the country's COVID-19 response and are 3-4 times more likely to contract COVID-19 than the general population. To date 40,000 South African health workers have contracted COVID-19, 6,473 have been hospitalised and 663 of our colleagues have passed on.

Phase 1 of South Africa's three phase vaccine rollout strategy was paused temporarily earlier this month following concerns regarding the efficacy of the Oxford-AstraZeneca (also known as CoviShield) vaccine against mild-moderate COVID caused by the 501.V2 variant. CoviShield may still play a role in the National Programme, however more research is needed to determine how and when it will be used. **Vaccination using a safe and efficacious vaccine must start without delay to protect healthcare workers during a likely 3rd wave this winter.** The switch to the JnJ vaccine allows for the country to restart Phase 1 vaccine rollout to keep our health workers safe.

The single dose JnJ vaccine protects against severe COVID-19 in South Africa. The safety and efficacy of the vaccine was assessed in the international Phase 3 study, ENSEMBLE, which was conducted across Latin America, USA and South Africa with more than 43 000 participants. South Africa contributed around 7,000 participants to the trial between October 2020 and February 2021, including participants who were exposed to the 501.V2 variant. The long-term follow-up of study participants is still ongoing, as is required for the process of regulatory approval by the South African Health Products Regulatory Authority (SAHPRA) for commercial or emergency use. However, since the safety and efficacy of the vaccine has already been proven, the current rollout is being conducted under *The Sisonke Open Label Program*, **to assess real world effectiveness among health care workers**, who

have already been prioritised for vaccination by the South African Government's Covid-19 Vaccination Strategy.

The JnJ vaccine has been shown to be safe, with no safety concerns reported from past trials or rollouts. The ENSEMBLE trial showed excellent protection of a single-dose vaccine against severe COVID-19, including in South Africa, and as such a delay in rolling out the vaccine would be unethical.

There is a clear process for vaccine rollout to healthcare workers. To receive the vaccine, healthcare workers must: (1) register on the South Africa Electronic Vaccination Data System, (2) respond to an SMS invitation, and (3) provide informed consent to take part. Healthcare workers will receive a vaccination voucher and communication once a vaccination centre is open to render the service. To register, follow this link: <https://vaccine.enroll.health.gov.za/#/>

The Sisonke rollout will include meaningful collaboration between the original team who were involved in the ENSEMBLE trial, JnJ, and the NDoH and the SAMRC. The partners will closely monitor, track and assess the real-world rollout of the vaccine. They will measure: (1) the occurrence of hospitalizations and deaths, (2) the incidence of severe SARS CoV-2 infections, (3) the diversity of breakthrough infections; and (4) evaluate vaccine uptake among healthcare workers in South Africa.

This experienced team will utilise their trained and qualified staff including pharmacists, clinicians and others to receive, store and oversee the dispensation of the JnJ vaccine. Sisonke staff will work very closely with national and provincial health public and private vaccine centres to ensure that the vaccination of healthcare workers is done safely and carefully managed.

The protection of our healthcare workers through the rollout of the safe and efficacious vaccine is an urgent priority for South Africa.

As a demonstration

MEDIA ENQUIRIES:

Mr. Popo Maja
Spokesperson
National Department of Health
Cell: 072 585 3219/082 373 1169
E-mail: Popo.maja@health.gov.za

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Sisonke Vaccine Programme

Protecting Healthcare Workers

Fact Sheet - 16 February 2021

Why is the JnJ vaccine a good first choice for the National Vaccination Programme?

The JnJ vaccine was tested in a large trial of almost 44 000 people from four continents, of whom 7000 participants came from South Africa. The follow-up time corresponded with our second wave, so the study was able to provide a good picture of how the JnJ vaccine works against the new 501Y.V2 variant, which is dominant in South Africa. This variant has been responsible for around 9 in 10 of all COVID-19 infections detected during the second wave and it is known to spread more rapidly than previous variants.

The South African part of the trial showed that while the JnJ vaccine is not going to prevent mild symptoms, it provides 57% protection against moderate-severe disease, 85% protection against severe disease and 100% protection against death.

By way of comparison the Oxford-AstraZeneca vaccine provided only 27% protection against mild to moderate COVID-19 caused by the new 501Y.V2 variant. The Oxford-AstraZeneca trial was not designed to investigate protection against severe COVID-19 and it remains unknown how effective it will be in doing this. As such, the Oxford-AstraZeneca vaccine may still play a valuable role in our Vaccination Programme in the future. The Oxford-AstraZeneca vaccine is additionally in the process of being updated to make it more effective against the new variants emerging all over the world.

In the meantime, it is wise to start with a vaccine that we know protects against severe COVID-19 caused by the 501Y.V2 variant dominant in South Africa.

How does the JnJ vaccine compare with other COVID-19 vaccines?

Like all COVID-19 vaccines, the JnJ vaccine contains instructions for the spike protein on the coronavirus. These instructions are delivered to our immune system by a modified adenovirus that has also been used in other vaccines, such as the Ebola and Zika vaccines. The adenovirus is safe to use in vaccines as it has been modified so that it cannot cause disease or replicate in humans.

Nonactive ingredients in the JnJ vaccine include sodium chloride, citric acid monohydrate buffer, polysorbate 80, 2 hydroxypropyl- β -cyclodextrin (HBCD), ethanol (absolute), sodium hydroxide and water for injection. All of these ingredients are safe for human consumption.

The vaccine does not contain any animal products and is halal.

How does the vaccine protect you against COVID-19?

When injected, the vaccine trains your immune system to fight the virus that causes COVID-19. The vaccine does not contain the coronavirus and will not give you COVID-19. People often develop some mild side-effects like tenderness at the injection site, feeling unwell, feverish and a headache for a few days. These are positive signs that the body is mounting an immune response to the coronavirus. The technical term for this is 'reactogenicity'. When you encounter real coronavirus particles in future, your immune system will be able to disarm the virus so that you either do not fall ill at all, or if you do, the symptoms are mild and your chances of being hospitalised or dying are much lower.

How is the JnJ vaccine stored?

The vaccine has a long shelf life of 2 years at -20 degrees Celsius and can be safely stored in a domestic fridge for 1 month. This makes it suitable for widespread rollout in warmer countries like South Africa as ultra-cold freezers are not needed.

How is the vaccine given and when does protection start?

The JnJ vaccine is given as a single dose into the upper arm. Protection starts around 10-14 days after vaccination, and even as early as 7 days for severe disease. Protection rises to good levels around a month after vaccination. The JnJ vaccine is the only COVID-19 vaccine currently available that only uses a single dose. Other COVID-19 vaccines currently require two doses.

No vaccine provides 100% protection. The JnJ vaccine is thought to provide 57% protection against moderate-severe disease, 85% protection against severe disease, and 100% protection against death. We are still waiting for further results on how effective the vaccine is at preventing asymptomatic transmission. It is important you continue to use masks, practise social distancing and good hand hygiene. If you are a healthcare worker, you still need to wear your PPE and stay vigilant, even after you are vaccinated.

Why is a research programme being used to make the vaccine available?

Manufacturers apply for vaccines to be licensed after trials show them to be safe and effective. The JnJ trial results were released in early February and applications for licensing are underway in the US, Europe and South Africa.

The Sisonke Programme allows the government to make this safe and effective vaccine immediately available to healthcare workers using a research programme. Sisonke is not the same as a clinical trial. Rather it is a way that research can help to make it available while the licensing process takes place. The South African government has chosen to move ahead with this programme because it would be unethical to withhold a vaccine known to be safe and effective. The South African Health Products Regulatory Authority (SAHPRA) has approved the use of the JnJ vaccine for the Sisonke Programme while it processes the full licensing. It is important to understand that the fact that it is not yet licenced does not mean that it is not safe or effective.

A third wave of COVID-19 is predicted to begin in South Africa this winter. Protecting healthcare workers is a priority and so we must start vaccinating our healthcare workers before the third wave arrives.

How is the Sisonke rollout going to work?

The South African government has secured half a million doses of the vaccine from JnJ, enough to vaccinate half a million health workers. The first batch of 80,000 doses arrived on the 16th of February and further deliveries will follow every two weeks. Vaccines will be available at 17 hospitals throughout the country where teams of researchers and vaccinators will work together to deliver the vaccine to health workers up to 10 hours a day, 7 days a week.

Research staff will be responsible for ensuring the cold chain and drawing up the correct amount of vaccine. Vaccinators will complete assessment checks, administer the vaccine and monitor you for a few minutes.

I am a health worker. How can I access the programme?

The first step to accessing a vaccine is to register on the country's Electronic Vaccination Data System (EVDS). You can access the system by visiting this website: <https://vaccine.enroll.health.gov.za>

In general, patient-facing health workers will receive priority access to vaccines. Non-clinical staff and traditional healers are also eligible to register on the EVDS system. You will receive a SMS alert with a vaccination voucher and details on what vaccination centre to attend and when. You will also be asked to read an information sheet and provide advanced consent for vaccination before your visit.

On the day of your vaccination, you will need to arrive with your voucher and an identity document.

Why do I need so sign consent for the vaccine?

Consent to be vaccinated against COVID-19 is being sought in most national vaccination campaigns around the world. This is common when vaccines are provided under Emergency Use Authorisation mechanisms.

You will also be asked to provide consent for the JnJ vaccine as part of the early access arrangement through the Sisonke programme. Information regarding the JnJ vaccine has been loaded on the EVDS system, and you will need to read it and agree to receive it before you attend your vaccination visit. Staff will also recheck this with you attend your vaccination.

It also includes consent to access your medical records to monitor any future episodes of COVID-19 or hospitalisations. This information will include where appropriate, your ID number, name, date of birth, postcode and contact details. This information will be kept safe and secure. Anonymised data will be accessed only by Sisonke researchers to monitor the effectiveness of the vaccination programme. A summary version of the consent form is available and you will be able to receive hard copies of these when you attend your appointment.

Are there any reasons why you will not be able to access the programme?

The vaccine is not available to pregnant women during this initial stage. This is common practice when vaccines are not yet fully licensed, such as during clinical trials. This is done because at this stage there is very little information on the safety of the JnJ vaccine in pregnancy. It is highly expected that the JnJ vaccine will be found to be safe in this population and that pregnant women will become eligible for vaccination in the coming months. Similar vaccines to the JnJ COVID-19 vaccine have shown no safety concerns in pregnancy. Access to COVID-19 vaccination for pregnant women is likely to be made available in the coming months. The JnJ vaccine can be safely used in breastfeeding women.

I have had a severe allergic reaction or anaphylaxis to a medicine in the past and am worried. What should I do?

A small number of severe allergic reactions or anaphylaxis have been reported mainly in response to the RNA COVID-19 vaccines, such as the BioNTech-Pfizer and Moderna vaccines. These events are very rare, at approximately 2.5 cases per million doses of vaccine administered. No-one has died from anaphylaxis following administration of any COVID-19 vaccine.

No cases of anaphylaxis have been reported with the JnJ vaccine. If you have suffered a severe allergy or anaphylaxis to a medication or food in the past, please talk to your doctor before receiving the vaccine. You will either be observed for slightly longer than normal (30 minutes instead of 15 minutes) or referred to a specialist for review.

Can I stop general COVID-19 protection measures once I have the vaccine?

No, you should continue to use general COVID-19 protection measures (such as wearing a mask and practising social distancing) after being vaccinated.

Even though you will be protected from getting severely ill and dying, studies have not yet shown enough data to prove that vaccinated people cannot spread the virus to others. Thus it remains possible that a vaccinated person could spread the virus to others, even if they are not showing any symptoms.

Do I need the vaccine if I have already had COVID-19?

Yes, you should still be vaccinated if you have had COVID-19 previously or if you have a positive antibody test. So far, it has been found that the natural immunity you may gain from having COVID-19 does not last. The vaccine would boost your built-in immunity and will not harm you in any way.

Can I have the vaccine if I have symptoms of COVID or am in quarantine or isolation?

If you are in quarantine following close contact with someone with COVID-19, you should finish your ten-day quarantine period before receiving the vaccine. There is no data available to show that vaccination immediately post-exposure will prevent disease as it is unlikely that the vaccine would elicit an immune response quickly enough to protect you from developing COVID-19.

If you currently have COVID-19, you should wait until you have recovered from the initial COVID-19 illness and have completed your isolation period before getting vaccinated.