health
Department:
Health
REPUBLIC OF SOUTH AFRICA

SAHPRA
South African
Health Products
Regulatory Authority

VACCINE SAFETY AND ADVERSE EVENTS FOLLOWING IMMUNISATION FREQUENTLY ASKED QUESTIONS AND ANSWERS

STATUS OF VACCINES

INTRODUCTION

In view of the Covid-19 disease, South African Health Regulatory Authority (SAHPRA) has authorized four vaccines so far to be used in the country. At the moment, only two vaccines have been rolled by National Department of Health (NDoH), and these are Covid-19 Vaccine Janssen called J&J and the Pfizer-BioNTech (Comirnaty) referred to as Pfizer vaccine. In light of the mass roll-out of these vaccines, there's increased public interest with concerns that need to be clarified.

FAQ 1:
What is adverse event following immunisation (AEFIs)?
Answer: An Adverse event following immunisation (AEFI) is an untoward medical event which follows immunisation and does not necessarily have a causal relationship with the administration of the vaccine. The adverse event may be an unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Serious adverse event following immunisation
An AEFI is considered serious if it:

- is a medically important event or reaction
- requires hospitalisation or prolongs an existing hospitalisation
- causes persistent or significant disability or incapacity
- is life threatening
- causes a congenital anomaly/birth defect
- results in death.

FAQ 2:
What is adverse event following of special interest (AESIs)?
An AESI is a pre-specified medically significant (important) event that has the potential to be causally associated with the vaccine product based on past experience, the technology used to make the vaccine or the infection the vaccine is used to protect against. AESIs need to be carefully monitored and any potential association to vaccination confirmed by further analysis and studies.

FAQ 3:
What is the difference between "emergency use" vaccines and the "normal" fully registered vaccines available in pharmacies and clinics?
Answer: The mandate of the South African Health Products Regulatory Authority (SAHPRA) is to ensure the health and safety of all South Africans. Therefore, it will only allow full market registration of medicines and vaccines once all required clinical trials have been completed and all data have been reviewed against required standards of safety, quality and efficacy.

In a public health emergency such as the COVID-19 pandemic, approval for the emergency use of vaccines that are not yet registered can be streamlined through a Section 21 emergency-use authorisation, which is normally valid for six months. For COVID-19 vaccines, many regulators around the globe, including the SAHPRA, have issued emergency-use authorisation, based on a review of data from completed Phase 3 clinical trials and others that are ongoing. All role-players have agreed to accept and evaluate data from companies on a rolling basis to enable a full market registration.

FAQ 4:
Are all the approved vaccines still under clinical trial or have these been concluded?
Answer: Based on completed clinical trials for the vaccines SAHPRA has registered the vaccine for use in South Africa, subject to certain conditions. These conditions include that the vaccine be supplied and administered in accordance with the National COVID-19 vaccination plan and guidelines. Furthermore, the companies must submit to SAHPRA longer term clinical data from ongoing studies to monitor the safety of the vaccine (pharmacovigilance) with agreed timelines, as outlined in their approved risk management plan.

FAQ 5
Why has it taken SAHPRA such a short time to approve vaccines when it usually takes so long?
Answer: In view of the Covid-19 pandemic, there has been an urgent need for vaccines to be made available to the public, as a result, SAHPRA used different mechanisms to avail the vaccines in the country. SAHPRA used the Section 21 authorisation system for emergency use, where the Authority reviews the submitted information to ensure that the vaccines meet all the safety, quality and efficacy requirements. Section 21 authorisations are usually for a short period to accommodate an urgent need. The Authority has therefore used the rolling review process to ensure full registration of the vaccines. With the rolling review, the pharmaceutical company submits the information to the Authority as and when it becomes available. Therefore, the review time lines depends on the data presented and how robust it is. SAHPRA have committed to a rapid review process for all Covid-19 vaccine application.

FAQ 6:
Which of the SAHPRA approved vaccines are the best and safest?
Answer: All vaccines rolled-out in South Africa were approved by SAHPRA and therefore fulfilled the safety, quality and efficacy requirements. Therefore, all of the available vaccines are safe and effective in protecting against severe disease, hospitalisation and death. The vaccines have similar mild side effects which ease within the first few days after vaccination.

VACCINE SAFETY

FAQ 7:
Why do I need to be vaccinated against COVID-19 if I have previously recovered from COVID-19 more than once? Surely this shows I can fight the virus on my own without being vaccinated.
Answer: Scientific evidence shows that the immune response after SARS-CoV-2 infection is much weaker and more short-lived than the immune response to the COVID-19 vaccines. This weaker, short-lived response is exactly why you have suffered more than one episode of COVID-19. Receiving the COVID-19 vaccine will provide you with a much stronger and more long-lasting immune response. The common mild and transient side effects usually last only a few days.

FAQ 8:
Why has the time between the two doses of Pfizer vaccine been extended instead of shortened, given that one dose is not very effective against the Delta variant?
Answer: Scientific evidence shows that one dose of the Pfizer vaccine is effective against severe COVID-19 disease and death, including from the Delta variant. The time was extended because of the evidence that the immune response is much stronger and lasts longer when the second dose is given 42 days after the first dose.

FAQ 9:
Can people with chronic conditions such as high blood pressure get the vaccine?
Answer: People with chronic conditions such as high blood pressure, heart disease and diabetes are at a higher risk of severe outcomes when contracting COVID-19. The vaccines will help them to prevent severe illness or death from COVID-19. In addition to getting the COVID-19 vaccine, they should also control their medical

conditions by taking their prescribed chronic medication and going for regular medical check-ups. If you are unsure about your health condition, consult your medical practitioner.

FAQ 10:
I have COVID-19 symptoms – is it safe to get vaccinated?
Answer: You should not get vaccinated when you have symptoms of COVID-19 and should rather be tested. If you have COVID-19, you should wait at least 30 days after you have recovered from COVID-19 before you get your vaccine.

ALLERGIES AND VACCINATION

FAQ 11:
How dangerous is an allergic reaction to a COVID-19 vaccine?
Answer: Anaphylaxis is the most dangerous allergic reaction to any vaccine BUT it is very rare and can be managed successfully. It usually occurs within seconds or minutes after vaccination, which is why ALL people are required to undergo a 15-minute observation period after receiving the vaccine to ensure there is no serious allergic reaction.

FAQ 12:
In the case of people with allergies, who should NOT receive a particular COVID-19 vaccine?
Answer: If you fall into one of the following categories, then you should NOT get a particular COVID-19 vaccine:

1. Anyone with a history of anaphylaxis or a severe hypersensitivity reaction to any component of the vaccine.
2. Anyone who experienced anaphylaxis after getting the first dose of a specific vaccine, should not get the second dose of that vaccine.
3. Anyone who is allergic to polyethylene glycol should not get the Pfizer vaccine because it is one of the components of the vaccine.
4. Please always discuss with your doctor

FAQ 13:
In the case of people with allergies, who should first consult with their doctor before getting the COVID-19 vaccine?
Answer: Anyone with a history of anaphylaxis or a non-severe immediate allergic reaction to other vaccines (not COVID-19 vaccines) should first consult with their doctor to ascertain what component caused the allergic reaction. If it is decided that you can receive the vaccine, and if your previous reaction to other vaccines was severe, you should be vaccinated in a hospital setting and be observed for 30 minutes after vaccination. If your previous reaction was a non-severe immediate allergic reaction, you can be vaccinated in a clinic setting and you must undergo a 30-minute observation period after receiving the vaccine to ensure there is no allergic reaction.

FAQ 14:
In the case of people with allergies, who should receive the COVID-19 vaccine?
Answer: Anyone with a history of food, insect venom, oral medication, environmental or latex allergies or a family history of anaphylaxis to other vaccines, should receive the COVID-19 vaccines. All people with any allergy that is unrelated to vaccines or injectable medicines must be observed for 30 minutes after vaccination.

FAQ 15:
Is it safe to get the COVID-19 vaccine if you have an egg allergy?
Answer: None of the COVID-19 vaccines contain any egg proteins. It is therefore safe to get the COVID-19 vaccines. If you have a history of allergies, you will undergo the required 30-minute observation period after receiving the vaccine instead of 15 minutes.

ILLNESS OR DEATH POST VACCINATION

FAQ 16:
I have heard of elderly people dying shortly after receiving the COVID-19 vaccine. Is the vaccine safe for the elderly?
Answer: Yes, it is very safe. Unfortunately, old age is in itself a major risk factor for death. For example, if we had a very safe vaccine that was totally ineffective, we would expect that the death rate in the vaccinated elderly would be exactly the same as the death rate in the unvaccinated elderly. Since the vaccine is both safe and highly effective in preventing severe COVID-19 disease and death from COVID-19 in the elderly, almost all of the deaths from COVID-19 in the elderly have been occurring in unvaccinated elderly people.

FAQ 17:
Why do some people still get COVID-19 within two weeks after being vaccinated?
Answer: It takes at least two weeks for the body to develop immunity after being vaccinated. A person is only considered fully vaccinated 30 days after receiving the J&J vaccine or five days after the second dose of the Pfizer vaccine. If you are infected during this time, you are less protected and may develop COVID-19. Also, if a person develops COVID-19 within a few days after being vaccinated, it means that the person had already been infected before receiving the vaccine and that they were in the incubation period at the time of vaccination.

FAQ 18:
Can the COVID-19 vaccine cause COVID-19?
None of the COVID-19 vaccines used in South Africa contains the live virus that causes COVID-19. The COVID-19 vaccine can therefore not make you sick with COVID-19.

FAQ 19
Can the Pfizer vaccine cause heart inflammation (myocarditis and pericarditis)? Is it safe to give the vaccine to elderly people?
Answer: It is not yet clear if the very rare risk of heart inflammation seen mostly in young men who received the Pfizer vaccine is coincidental or caused by the vaccine. These effects were usually seen within two weeks after the second dose of the vaccine. These events are mostly mild and can be treated successfully, followed by a recovery shortly thereafter. People should therefore be aware of the symptoms and seek medical help immediately.

KEY MESSAGES

Deaths after vaccination
"Reports of deaths following immunization are taken very seriously by both SAHPRA and the NDoH. They are however not automatically assumed to be caused by vaccination. A thorough investigation of causal association is currently underway to determine whether these deaths are as a result of vaccination or not.

If these deaths are found to be related to the vaccines, then the benefit-risk profile of the vaccines will need to be re-evaluated.

Assuming causality/relationship between the reported deaths and these vaccines without facts, may result in denying the public safe and effective vaccines based on wrong interpretations and conclusions about the data reported."

Breakthrough infections after covid-19 vaccines
Current data on Covid-19 vaccine efficacy suggests that the emergence of viral variants of concern has shifted the vaccine efficacy end-point from primary prevention of disease to secondary prevention of Covid-19 complications of severe disease requiring hospitalization or death. The NDoH and SAHPRA are closely monitoring these breakthrough infections in order to ensure that, while vaccinees may still get infected as expected, they only experience mild Covid-19 symptoms, and that the benefit-risk ratio of Covid-19 vaccines remains favourable towards the prevention of disease complications of severe disease requiring hospitalization, or death.