

Statement by the Minister of Health, Dr Zwelini Mkhize, on the FDA's Temporary Suspension of Johnson and Johnson vaccine rollout in the United States.

13 April 2021

We have noted the decision taken by the Food and Drug Administration in the United States of America to advise the temporary suspension of the Johnson and Johnson vaccine rollout in the US.

This has occurred to due reports of 6 females who developed unusual blood clots with low platelets. These incidents occurred between 6 and 13 days after vaccination in women between the ages of 18 and 48 years old. It must be noted that over over 6,6 million citizens have been inoculated with Johnson and Johnson vaccine in the U.S.

In South Africa, we have not had any reports of clots that have formed after vaccination, and this is after having inoculated **289 787** health care workers under the Sisonke Protocol.

Having said that, after this advisory came to my attention I held urgent consultations with our scientists, who have advised that we cannot take the decision made by the FDA lightly. Based on their advise, we have determined to voluntarily suspend our rollout until the causal relationship between the development of clots and the Johnson and Johnson vaccine is sufficiently interrogated. SAHPRA will collate information from Johnson and Johnson, the FDA and other regulatory bodies to make a thorough assessment of the situation and advise us as a regulatory body that has exercised its authoritative powers on the approval of the vaccine in their own right.

I humbly call for calm and patience as we ensure that we continue to be properly guided by science in ensuring the safety of our people as we rollout the vaccine campaign.

We hope that the deliberations will only take a few days. Given the preliminary literature on hand, our scientists are confident that the FDA's decision is on a precautionary basis and we expect that this will not result in the complete withdrawal of the Johnson and Johnson vaccine from the vaccination armament.

We also wish to assure citizens that these kinds of reports are expected to emerge as part of a robust post market surveillance system- this should provide comfort that medical authorities keep a vigilant watch on all new products that are deployed into the market to ensure they remain safe and effective for human consumption. It is for this reason that we implemented the Sisonke Protocol and will also implement a similar post market surveillance study for Pfizer when we roll out the first batch of doses to health care workers.

I am glad to say, however, that there are good news in the midst of this development.

I am happy to announce that we have successfully negotiated for another 10 million doses from Pfizer and, of these, we expect just under 2 million to be delivered in May. This therefore means we have secured 30 million doses of Pfizer vaccine for this financial year.

This also reassures us that, in the extremely unlikely event that Johnson and Johnson rollout is completely halted, we will not have any impediment to proceed with phase two of the rollout with Pfizer.

We are confident that the rollout of Johnson and Johnson will resume and so, with 30 million doses of Johnson and Johnson and 30 million doses of Pfizer secured we now have enough doses to exceed the 40 million we were targeting this year. This is in line with our commitment to vaccinate as many people as possible in this financial year- in the ideal scenario we would vaccinate every single adult found in South Africa.

This development is an example of how we, as government, make commitments and work to the best of our ability to honour those commitments, however science must be respected at all times, and this sometimes means a disruption in our plans. Although we are operating in a dynamic and ever changing environment, the government is constantly seeking to secure vaccines that will protect us from the 501Y.V2 variant.

We therefore urge South Africans to be supportive of our experts and scientists as they work under enormous pressure to give us answers on this worrying development so that we may proceed safely with the global vaccination programme. We commit to keeping the public informed of all developments

I Thank You

Issued By the Ministry of Health

(Original Text: any additions by the Minister have not been added)