# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 625**

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**(INTERNAL QUESTION PAPER NO. 06)**

**Mr B S Madlingozi (EFF) to ask the Minister of Health:**

Whether the Johnson & Johnson vaccine that is being used to vaccinate persons is still part of a study; if not, is it a roll-out of an approved vaccine; if so, what are the relevant details?

###### NW741E

**REPLY:**

Yes, the Johnson & Johnson vaccine that is currently being used to vaccinate healthcare workers is still part of a study.

The vaccine was used in a large international Phase 3 study which enrolled nearly 40,000 participants. The study showed that, in South Africa where we have the 501Y.V2 variant, the vaccine reduced severe disease by 81.7% and moderate disease by 64%. The Phase 3a study provided evidence of efficacy and safety of the vaccine. Because there is often a time lapse between a Phase 3 study being successfully completed, and the registration of a product for use outside of a clinical trial, an open label study is often used to bridge this gap. Phase 3b studies, the context in which this vaccine is being used, allows for early access to the vaccine and also enables the collection of additional data on safety, efficacy and how to introduce a new product. In a phase 3b study, although evidence of safety and efficacy is confirmed, informed consent must be obtained. In a phase 3b study, placebo is not used in the study and does not involve experimentation with any unproven vaccines.

A medicine is registered based on the evidence of safety and efficacy obtained from Phase 3 studies. The use of a registered medicine does not require informed consent, although as with any medicine, patients must understand what the vaccine is for, whether there are any specific side effects, and they must be willing to take it.

A phase 3b study and a vaccine roll-out both involve wide-scale implementation of Covid-19 vaccines, they differ only insofar as the type of regulatory approval required as well as the informed consent and information collected from those being vaccinated

END.