# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 1277**

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**(INTERNAL QUESTION PAPER NO. 13)**

**Ms H Ismail (DA) to ask the Minister of Health:**

(1) What are the relevant details of the Johnson and Johnson vaccine trials in the Republic with regard to the (i) number of Johnson and Johnson trials that have been conducted in the Republic, (ii) relevant details and results of such trials, (iii)(aa) number of participants in each ensemble and (bb) their relevant details, outcomes and results and (iv) breakdown of the results for each trial test;

(2) (a) where were the specified trials conducted and (b) what are the details of the administering bodies, hospitals and/or clinics?

###### NW1470E

**REPLY:**

1. (i) There were three Johnson&Johnson trials conducted in South Africa, the ENSEMBLE 1 trial which was a Phase 3 single dose study, ENSEMBLE 2 which is a phase 3 two dose study (which is still ongoing), and the SISONKE study which was an open label phase 3b trial.

(ii) The SISONKE trial ended recently (on 17 May 2021) and the analysis is only just starting.

The ENSEMBLE trial was published in the New England Journal of Medicine, main author GJ Sadoff: Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. A summary of the results: “A single dose of vaccine protected against symptomatic Covid-19 and asymptomatic COVID-19 infection and was effective against severe-critical disease, including hospitalisation and death. Safety appeared to be similar to that in other phase 3 trials of Covid-19 vaccines.

(iii)-(iv) (aa) SISONKE: the trial ended on 17 May and the analysis on the data is starting now.

ENSEMBLE: a total of 44 325 participants underwent randomisation of which 43 783 received either placebo or vaccine. The per-protocol population included 39 321 participants, 19630 of which received vaccine and 19630 received placebo.

(bb) SISONKE: the trial ended on 17 May and the analysis on the data is starting now.

ENSEMBLE participants

Median age: 52 years

Gender: female 45% male 54.9% other <0.1%

Ethnicity: American Indian/Alaskan native <1%; South American 9%; Asian 3%; Black 19%; Pacific Islander <1%; White 58%; Multiracial 6%; unknown 3%.

Country: Latin America 40.9%; South Africa 15%; USA 44.1%

> coexisting condition: 40.8%

Outcomes & Results: Vaccine efficacy after 28 days administration

Moderate to severe-critical COVID-19: 66.1% (95% confidence interval 55.0 – 74.8%)

Symptomatic COVID-19 of any severity: 66.5% (55.5-75.1)

No differences in vaccine efficacy were observed among subgroups (sex, race or ethnic group). Only a marginal decrease in vaccine efficacy noted in participants > 60 with comorbidities after 28 days after administration. Vaccine efficacy against hospitalisation was 100% 28 days after administration. Of the South Africa population, 95% of participants had the 501Y.V2 variant, but the vaccine efficacy remained high.

(2) (a) ENSEMBLE was conducted in South Africa, Latin America (Argentina, Brazil, Chile, Colombia, Mexico, Peru) and the USA.

SISONKE was conducted in the following 17 institutions, from all 9 provinces:

EC: Frere, Livingstone, Nelson Mandela Academic, Netcare Greenacres hospitals

FS: Bongani, Fezi Ngumbentombi, Life Rosepark, Pelonomi, Universitas hospitals

GP: Ahmed Kathrada, Charlotte Maxeke, Chris Hani Baragwanath, Dr George Mukhari, Netcare Milpark, Steve Biko Academic hospitals

KZN: General Justice Gizenga Mpanza, Edendale, Madadeni, Netcare St Augustines, Prince Mshiyeni Memorial hospitals

LP: Tshilidzini, Donald Fraser, Malamulele, Mediclinic Polokwane, Netcare Pholoso, St Ritas hospitals

MP: Ermelo, Life Cosmos, Mediclinic Nelspruit, Mapulaneng, Rob Ferreira hospitals

NC: Mediclinic Upington, Robert Mangaliso Sobukwe hospitals

NW: Job Shimankana Tabane, Klerksdorp-Tshephong Tertiary, Life Peglarae, Mahikeng Provincial, Moses Kotane hospitals

WC: Groote Schuur, Tygerberg, Gatesville, George, Karl Bremer, Khayelitsha District, Paarl, Worcester hospitals.

(b) ENSEMBLE was a multi-national study funded by Janssen Research and Development and others.

Vaccines for SISONKE were secured by the Department of Health and were administered by teams of researchers and vaccinators. Research staff from the South African Medical Research Council where responsible for ensuring the cold chain and drawing up the correct amount of vaccine. Vaccinators where responsible for complete assessment checks, administering the vaccine and monitoring the participants for a few minutes after administration. END.