# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 531**

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

**Dr S S Thembekwayo (EFF) to ask the Minister of Health: [77] [Question submitted for oral reply now placed for written reply because it is in excess of quota (Rule 137(8))]:**

Whether his department conducted any internal assessment on the safety of any of the COVID‑19 vaccines administered to South Africans; if not, why not; if so, has he found evidence of any elements of the vaccine that may put the lives of persons at risk? **NW576E**

**REPLY:**

Adverse Events Following Immunisation (AEFI) and safety concerns in terms of contraindications, special precautions and warnings are reviewed and included in the product Information leaflet. All potential risk factors are outlined in the product information leaflet and the clinician/health care provider prescribing the vaccine is thereby informed. If there are critical concerns/risks, the product will not be registered and will not be made available to public.

The responsibility for pharmacovigilance and surveillance is ultimately with the regulator, SAHPRA. All clinicians and the public themselves have been encouraged to report both side effects and adverse events. There is ongoing assessment of safety of all medicines and vaccines. This information is shared globally so that all countries can combine their experiences and determine actions where appropriate.

In the case of the Covid-19 vaccines in use in the country there is a great deal of information available, it is included in the product information. There are known rare adverse events, just as rare side effects are known for all medicines. The evidence is that no elements of the two Covid-19 vaccines may put the lives of persons at risk any more that another medicine. There is however evidence that the vaccines improve immunity and protect the vaccinees from severe infection.

END.