# NATIONAL ASSEMBLY

**FOR WRITTEN REPLY**

**QUESTION NO. 2**

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**(INTERNAL QUESTION PAPER NO. 01)**

**Mr N Singh (IFP) to ask the Minister of Health:**

(1) Whether he is aware of a proposed 2 dose Glaxo Smith Klein (GSK) ChAd155-RSV Vaccine Trial, to be conducted in the Republic (details furnished); if not, what is the position in this regard; if so,

(2) why is the Government exposing infants to (a) untested and (b) potentially fatal drugs for profit and ongoing science experimentation contrary to the protection contained in the Bill of Rights in the Constitution of the Republic of South Africa, 1996?

###### NW946E

**REPLY:**

(1) Yes. I am aware that the MRC Respiratory and Meningeal Pathogens Research Unit (based at the University of the Witwatersrand) is taking part in a multi-centre, multi-country study that aims to provide critical information on the safety, reactogenicity and immunogenicity profile of the ChAd155-Respiratory Syncytial Virus (RSV) vaccine in infants likely to be unexposed to RSV. Sites in European, South American and North American countries are also participating.

 Although RSV infection is a leading cause of death in young children, interventions to protect children against RSV infection and to treat children who acquire RSV infection are not available. For this reason, the World Health Organisation ranked a vaccine against RSV as the most important vaccine that needs to be developed in order to protect children in low- and middle-income countries from preventable mortality.

(2) (a) The vaccine should not be regarded as untested. The immunogenicity, safety and reactogenicity of the ChAd155-RSV vaccine in healthy adults has been evaluated and determined to be satisfactory by an Independent Data Monitoring Committee (IDMC). A clinical study is currently being conducted in RSV-sero positive infants aged 12 to 23 months (study 204838 [RSV PED-002]) in Europe. The proposed study will only proceed if the safety profile of the current study is evaluated as being satisfactory by an IDMC. The study will be monitored by an IDMC at each step for safety, and any reports communicated to the regulatory authorities in real-time.

 (b) There is no merit in the concern that children are being exposed to a dangerous vaccine, since this is a non-replicating vaccine and the vaccine itself cannot biologically cause any illness. As noted above, the trial will be conducted in line with clinical trial guidelines and will be strictly monitored to ensure the safety and well-being of all participants.

END.