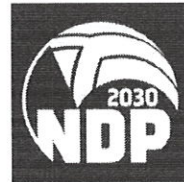




health

Department:
Health
REPUBLIC OF SOUTH AFRICA



Enquiries: Prof B Schoub
E-mail: barry.schoub@gmail.com

Date:	30 April 2021		
To:	Minister ZL Mkhize, Honourable Minister of Health	From:	Ministerial Advisory Committee (MAC) on COVID-19 Vaccines

ADVISORY
FEEDBACK FROM THE VMAC ON SPUTNIK V, GAMALEYA INSTITUTE

Problem Statement

Background

- A meeting was held on 30th March 2021 via Zoom, to discuss and examine the potential of the Sputnik V vaccine produced by the Gamaleya Institute, Russia, for vaccine rollout in South Africa.
- Prior to the meeting the following was circulated to the delegates from the Gamaleya Institute:

The VMAC is requesting that all vaccine manufacturers who are invited to present to the VMAC as part of enquiries for being considered as providers of vaccines to South Africa, should provide the following information before the meeting with the VMAC. This information will also be independently required by the South African Health Products Regulatory Authority:

- *A summary of all supporting laboratory, animal and clinical data on vaccine safety and efficacy including studies on vaccine efficacy in the context of the 501Y.V2 variant. If studies are in progress or being planned can the information on these studies also be provided.*
- *As South Africa has highly competent local laboratories who have been doing studies using convalescent and vaccinee sera, the VMAC further requests that you provide vaccinee sera from study participants involved in Phase 3 trials, so that this can be evaluated in South African laboratories against all variants identified in South Africa to date.*
- *Please provide the VMAC with data on proposed post-marketing surveillance that will monitor safety and effectiveness in the context of the 501Y.V2 variant.*

This question was specific for the Gamaleya Institute:

- i. There is particular concern regarding the use of the Ad5 vector for the boosting dose, given published findings from the Step and Phambili trial several years ago, of increased susceptibility to HIV infection. Please provide:
- ii. Existing data or proposed studies that provide assurance that this increased risk in HIV acquisition does not occur with your Ad5 construct. This can include either existing data or proposed studies.
- iii. Proposals for substituting a booster vaccine to replace the Ad5 vaccine.
- iv. Evidence for the supplementary boosting immune response from a heterologous vaccine regimen.

- **Follow-up.**

Following on the meeting the way forward was agreed to and proposed to the delegation from Gamaleya:

1. Data is required on the in-vitro effectiveness of the Sputnik V vaccine against the 501Y.V2 variant. For this purpose, it was proposed that 501Y.V2 coronavirus samples will be sent from the KZN laboratories to Gamaleya, for their laboratories to generate the required data. (Gamaleya indicated that they had recently received these samples and had yet to start their investigations.) In addition, the request was made for panels of vaccinee sera to be sent to South African laboratories for the requisite neutralisation antibody tests to be carried out in South Africa. (The delegates from Gamaleya made the point that regulatory problems may prevent these samples from being sent out of the country. In which case these vaccinee sera may need to be sourced from countries which have already rolled out the Sputnik V vaccine.)
2. The issue of the Ad5 vector for the booster dose of Sputnik needs to be addressed. The proposal of Sputnik Light, i.e., single dose of Ad26 Sputnik V, needs to be evaluated as regards efficacy against the 501Y.V2 variant.
3. Data on the efficacy and safety of the vaccine in elderly people.
4. Data on the definitions of mild, moderate and severe disease.

Points considered

- The utility of proposed coronavirus vaccines in South Africa needs to be measured by their efficacy against the 501Y.V2 variant predominating in the country.
- While the precise *in-vitro* correlates of protection are still undergoing investigation, it is widely believed that a very significant determinant of vaccine efficacy would be obtained by pseudo-virus and live-virus neutralisation assays.
- It is also to be noted that there are no data on the efficacy, immunogenicity and safety in people living with HIV.

Recommendations

1. The VMAC recommends that for a vaccine which does not have clinical trial data of protective efficacy against the 501Y.V2 variant, *in-vitro* laboratory testing of panels of vaccinee sera need to be provided in order to be tested in South African laboratories.

Thank you for consideration of this request.

Kind regards,



PROFESSOR BARRY SCHOUB

CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES

DATE: 30 April 2021

CC:

- » **Dr S Buthelezi (Director-General)**
- » **Dr T Pillay (Deputy Director-General: Health Regulations and Compliance Management)**