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Department:
Health
REPUBLIC OF SOUTH AFRICA

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INTERNAL MEMO

Date:	2nd March 2021		
To:	**Minister ZL Mkhize,** **Honourable Minister of Health**	From:	**Ministerial Advisory Committee (MAC) on COVID-19 Vaccines**

ADVISORY ON CONCERN FOLLOWING RELEASE OF DATA ON REDUCED NEUTRALISING ANTIBODY ACTIVITY IN SERA FROM PFIZER VACCINEES
- 3RD UPDATE -

Problem Statement

Background

- There is currently no clinical data on how well the Pfizer [BNT162b2] vaccine protects against infection or illness caused by the 501Y.V2 [B.1.351] variant, the dominant strain in South Africa.
- Several in-vitro studies of neutralising antibodies from Pfizer vaccinees have been published, one in a peer-reviewed journal [NEJM Feb 18,2021], and five in non-peer-reviewed scientific publications - MedRxiv and BioRxiv [see annexure].
- All studies using pseudovirus constructs containing the three critical mutations of the receptor binding domain have revealed reductions in neutralising antibody activity against the 501Y.V2 variant.
- . These studies have revealed reductions in neutralisation from 2.7-fold to 8.6-fold.
- A recent study, however, also using a pseudo-virus neutralisation assay has shown a reduction of neutralising activity with Pfizer vaccinee sera of up to 94-fold.
- However, it has been shown that the mean concentration of antibodies produced by vaccination with the Pfizer vaccine is several-fold higher than the mean antibody concentrations following infection.

Points considered

- The Pfizer vaccine has demonstrated extremely high protection in the phase 3 clinical trial of 95% and has demonstrated similar protective efficacy, from 90 to 100% (for different endpoints), in the nationwide mass vaccination in Israel, and an 85% decrease in the risk of hospitalisation after one dose in a recently published Scottish study.
- The latest publication from the laboratory study using a pseudovirus neutralisation assay on vaccinee sera showing a neutralization reduction of up to 94-fold is of concern and needs to be further interrogated.

- Since it is not known to what extent reductions in neutralisation translate into reductions in efficacy, the neutralisation assay results should not be over-interpreted as equating to reductions in clinical efficacy.
- Urgent talks will be held with the VMAC's Technical Working Group on Vaccines and Variants and the principals of Pfizer (as well as Johnson & Johnson) on 3 March 2021, to further interrogate the interpretation of these laboratory findings well as further investigations including animal challenge investigations.
- Adjustments to mRNA vaccines to address the variant can be rapidly done and Pfizer is at an advanced stage of development of a new vaccine designed to address the 501Y.V2 variant. At the TWG meeting of 3 March 2021 the company will be asked about progress in development of this vaccine and plans for clinical evaluation.

Recommendations

1. Negotiations to secure the Pfizer vaccine should proceed as before as there is no clinical evidence to suggest that the efficacy of the vaccine is lower against the 501Y.V2 variant for mild, moderate, or severe Covid-19.This is supported by scientific data demonstrating the robustness of antibody production following vaccination which leads to the high levels of antibody associated with severe disease more consistently, with mean antibody titres greatly exceeding mean convalescent antibody concentrations.
2. An assurance should be incorporated in the negotiations with the Pfizer manufacturers that the new vaccine or booster doses with the adjustment for the variant, should be preferentially supplied to South Africa as soon as the new vaccine becomes available, pending authorization by SAHPRA.
3. The NDoH negotiators responsible for the terms of the contract with Pfizer, should propose a clinical study to be carried out in South Africa in collaboration with Pfizer, to assess the new 501Y.V2-adjusted Pfizer vaccine when used either as a prime or as a booster, given that South Africa would be well suited to conducting trials assessing the efficacy of the vaccine against the 501Y.V2 variant.
4. There have been media reports that Pfizer may be placing unfair terms in its agreements with some countries. The MAC's assessment in this Advisory is based only on the scientific merits of the Pfizer vaccine, as the MAC is, appropriately, not involved in any procurement agreements. The MAC has therefore not provided comment on Pfizer's requirements for selling their vaccine to South Africa. However, the MAC notes with concern that one-sided unfair terms in procurement agreements will place an undue burden on our country.

Thank you for consideration of this request.

Kind regards,

PROFESSOR BARRY SCHOUB
CHAIRPERSON: MINISTERIAL ADVISORY COMMITTEE ON COVID-19 VACCINES
DATE: 2 March 2021

CC:

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