



health

Department  
Health  
REPUBLIC OF SOUTH AFRICA



**Ministerial Advisory Committee on Covid-19 Vaccines**

**Date: 14 July 2021**

**Time: 18:00 – 19:30**

**Venue: Zoom Link**

**Meeting Minutes**

Attendees:

Prof Barry Schoub (BS - Chairperson); Prof Clive Gray (CG); Prof Gregory Hussey (GH); Prof Jeffrey Mphahlele (JM); Ms Glaudina Loots (GL); Prof Wolfgang Preiser (WP); Dr Morena Makhoana (MM); Prof Penny Moore (PM); Dr Tumi Semete (TS); Dr Anban Pillay (AP); Dr Nicholas Crisp (NC); Dr Owen Kaluwa (OK).

Apologies:

Bishop Malusi Mpumlwana; Prof Richard Lessells (RLs); Prof Ames Dhali (AD); Dr Angelique Coetzee (AC); Prof Koleka Mlisana (KM); Dr Mark Bletcher (MB).

Secretariat:

Mrs Nasreen Seedat (NS); Dr Ruth Lancaster (RL); Ms Khadija Jamaloodien (KJ); Marione Schonfeldt (MS); Dr Lesley Bamford (LB).

Recused:

Prof Helen Rees (HR)

Visitors:

AstraZeneca: Barbara Nel, Ruth Field, Jennifer Jackson, Tina Guina, Qutaiba Al Manaseer, Beth Kelly, Tonya Villafana, Viraj, Shabir Madhi, Sylvia, Priti Shah.

WHO: Dr Nono Simelela

## 1. Welcome & Apologies

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- The Chairperson welcomed all the members to the meeting.

## 2. Conflict of Interest Declarations

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- HR recused herself from the meeting citing potential bias due to SAHPRA association.

## 3. Presentation by AstraZeneca

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See presentation.

### Discussion:

- BS: Regarding the pre-print study that was presented which showed 92% efficacy of hospitalisation, did this include elderly patients? The AZD2016 that is being planned, will that also include elderly subjects?
- AZ Team: In the pre-print paper there are older adult subjects included. The AZD2016 study will also include older adult patients - in the UK and other places there is very good representation of the 65+ age group.
- BS: Is there a plan to have a study around the AZ boost to the J&J vaccine?
- AZ Team: There is currently no plan to do a study with boosting J&J. The current design of the study is to look at a booster regimen to the AZ vaccine or to mRNA vaccines. This is because in a lot of countries, most people are getting mRNA vaccines. A boost for J&J can be looked at in the future.
- PM: Are there any concerns that the second-generation vaccine was based on the beta variant, given that the emerging data suggests that responses triggered by beta may not very effective against delta? How is the AZ team planning to move forward with that?
- AZ Team: Data is also being generated of the booster vaccine regimen against variants of concern. So far, the results are showing that the booster strategy that is being looked at will be effective against these VoC. The study will be evaluated and some pre-clinical data that is not yet in the public domain has shown these results.

Important to note is that there is a baseline of pre-existing immunity and boosting with something antigenically distinct helps increase the breadth of response.

- TS: In the efficacy studies did you look at whether the participants had previous infection or not? After the efficacy was seen in terms of reduction of hospitalisation, were there breakthrough infections? Would participants who were enrolled in the South African study receive the second-generation vaccine?
- AZ Team: It is unlikely that South Africa will enrol in the booster strategies as the way it is being done in the UK and other places is that people must be three months out from their last vaccination, and priority is given to those who were enrolled in the previous studies. Regarding the efficacy studies, the US phase 2 studies did have people who were seropositive, and a boosting response was seen. The seropositive subjects were excluded from the efficacy analysis. It is important to note that a very small number of breakthrough infections in baseline seropositive study participants was seen.

#### **4. VMAC Discussion**

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- PM: The data looks good. From a virological perspective, it was always assumed that this vaccine would provide protection against severe disease however there was no data to support that and now there is effectiveness data.
- GH: The only issue in terms of introducing a third vaccine into the system is that if this vaccine can be used for all age groups or only targeted to specific groups given the concern around the adverse events associated with the vaccine.
- BS: What would extension of the original registration entail?
- TS: The first authorisation is ending on the 20<sup>th</sup> July and can be extended. NDoH can apply and extend the timeframes by another 6 months or AZ can choose to apply themselves (as the original registration was for SII). The one concern lies with supply chain issues especially if India continues to limit exports.
- BS: If the vaccine does not come from SII, how would that impede the registration process?

- TS: If it comes from a different manufacturing site, a GMP inspection will need to be done. If an FDA inspection was done, reliance can be applied, and the process will be quicker.
- WP: An issue with the EU is that it does not recognise this vaccination for incoming travellers unless it is manufactured in India and the reason for this is unknown. In many other countries they have adopted the mix and match scenario in the younger age groups who had the first dose of AZ because of the clotting issue. Also, the issues around clotting have destroyed the public confidence in the AZ vaccine which have made surplus doses available via the COVAX scheme.
- GL: There was also an issue previously regarding the HIV component and this has not been addressed anywhere. Can we also assume that the delta variant has completely displaced beta?
- PM: Beta is essentially eliminated for now. There is no guarantee that there will not be another variant but at the moment the immune evasion properties of beta are outweighed by the transmissibility of delta. Regarding the HIV issue, the concern was rather with Novavax as the HIV immunogenicity looks good for those living with HIV and the AZ vaccine.
- BS: This discussion will continue tomorrow on the issues related to the supply side.

## **5. Closure**

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- Members were thanked for their attendance.
- Meeting closed at 19:24.