SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
402 Kirkness Street
Arcadia
0083

MRS THOSAGO DH
SAHPRA Reference: 20200495

Ms Mary-Anne Bopape
The Wits Reproductive Health and HIV Institute
A Division of Wits Health Consortium (Pty) Ltd
31 Princess of Wales,
Parktown, Johannesburg

Dear Ms Bopape

AUTHORISATION FOR THE IMPORTATION OF UNREGISTERED MEDICINE IN TERMS OF SECTION 21 OF THE MEDICINES AND RELATED SUBSTANCES CONTROL ACT, 1965 (ACT 101 OF 1965)

PRODUCT: Dexamethasone (High-Dose) 30/21.5.1/0382

Your application letter dated 11 June 2021 refers.

1. RESOLUTION AND APPROVAL

It was recently resolved by the South African Health Products Regulatory Authority (SAHPRA) that; the clinical trial application according to the following:
Protocol be approved :-
RECOVERY Version 15.0 dated 12 April 2021
RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY) - High-dose dexamethasone in hospitalised patients with COVID-19

1.1 **BEFORE COMMENCEMENT OF TRIAL**

Please Note: Copies of written Ethics Committee approval/(s) to be submitted to SAHPRA before the study commences.

2. AUTHORISATION

Authorisation is hereby granted for the importation and administration of a sufficient quantity, for the duration of the trial, of the unregistered medicine:
Dexamethasone (High-Dose) 30/21.5.1/0382
solely for the purpose of a clinical trial to be conducted by:

Prof C Menezes	Chris Hani Baragwanath Hospital	Co-Principal Investigator
Dr M Tsitsi	Chris Hani Baragwanath Hospital	Co-Principal Investigator
Dr M Venter	Chris Hani Baragwanath Hospital	
Dr SA van Blydenstein	Chris Hani Baragwanath Hospital	
Dr J Nel	Chris Hani Baragwanath Hospital	
Prof Mendelson	Groote Schuur Hospital	Principal Investigator
Prof Meintjes	Groote Schuur Hospital	
Dr. I Kalla	Charlotte Maxeke Johannesburg Academic Hospital	Principal Investigator
Dr. L Murray	Charlotte Maxeke Johannesburg Academic Hospital	
Dr. JJ van Vuuren	Pelonomi Hospital, Bloemfontein	Principal Investigator
Dr. D Steyn	Pelonomi Hospital, Bloemfontein	
Dr. S Maasdorp	Pelonomi Hospital, Bloemfontein	
Dr. N Magula	Clairwood Hospital	Principal Investigator
Dr. S Kubheka	Clairwood Hospital	
Prof S Pillay	Clairwood Hospital	

3. PLEASE FORWARD

It is a requirement that a copy of this letter be forwarded to all the relevant Investigator/(s), including the approving Ethics Committee(s).

4. THIS AUTHORISATION IS SUBJECT TO THE FOLLOWING PROVISOS:

(a) SAHPRA shall be informed immediately of any toxic effects or death, which may occur during the Clinical Trial and of any data received which, might cast doubt on the validity of the continuation of the Clinical Trial.

(b) SAHPRA shall be notified of any decision to discontinue the Clinical Trial. The reason for such cancellation shall be stated.

(c) The Clinical Trial shall be conducted in accordance with the Protocol submitted to SAHPRA. Any Amendment/(s) to the Protocol shall first be submitted to SAHPRA for approval. All Clinical Trials be conducted in accordance with ICH GCP Guidelines, and the South African Clinical Trials Guidelines.

(d) The medicine shall be administered by or under the direction of the authorised Investigator/(s). In the case where the Investigator permits another Medical Practitioner to administer a medicine, which is exempted from the registration for the purpose of the Trial, the Investigator shall remain responsible for any eventuality arising from such usage.

(e) Where a Investigator who is not authorised in the initial Authorisation, is requested to participate in the Clinical Trial, SAHPRA requests that the relevant SAHPRA Curriculum Vitae Format be completed detailing their Full Names, Address and Qualifications of the proposed Investigator (Practitioner) concerned and be submitted to SAHPRA for Approval.

(f) In the event of the authorised Investigator ceasing to participate in the Clinical Trial, SAHPRA shall be informed and the reason for such cessation shall be given.

5. PROGRESS REPORTS

SAHPRA must be furnished with signed six-monthly Progress Report from each Investigator including a report of the Final Results.

6. INFORMED CONSENT

It is a SAHPRA requirement that in all Clinical Trials the 'Principles of Informed Consent' should be adhered to. This applies to Trial Volunteers, as well as Participants (Patients). (Reference: ICH GCP Guidelines and SACT Guidelines).

7. THE STUDY IS APPROVED ON CONDITION THAT THE APPLICANT MUST AGREE TO FOLLOWING

a) Submission of 2 weekly safety monitoring and futility reports to SAHPRA.

b) Immediate submission of all Data and Safety Monitoring Committee reports to SAHPRA.

Yours faithfully

B Semete-Makokotlela
B Semete-Makokotlela (Sep 10, 2021 12:26 GMT+2)

DR BOITUMELO SEMETE-MAKOKOTLELA
CHIEF EXECUTIVE OFFICER

DATE APPROVED: 10/09/2021
SAHPRA REFERENCE: 20200495