Classified

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LEGAL SERVICES

WWW.LAWYER.CO.ZA

DEATHS

DR NEIL PATON
Passed away on
1st May 2020 in Howick.
He was much loved and will be sadly missed by his family and friends. MHDSRIP

LEGAL NOTICES

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VPD Vaccine Preventable Diseases
RMPRU Respiratory & Meningeal Pathogens Research Unit

PUBLIC NOTICE (IN TERMS OF REGULATION 9 OF THE REGULATIONS TO THE GENETICALLY MODIFIED ORGANISMS ACT 15 OF 1997) TO IMPORT A GENETICALLY MODIFIED ORGANISM

The Respiratory and Meningeal Pathogens Research Unit (RMPRU) is seeking to obtain approval from the South African Health Products Regulatory Authority (SAHPRA), the Department of Agriculture Forestries and Fisheries (DAFF) and the Witwatersrand Human Research Ethics Committee (WHREC), to conduct "An adaptive phase Ib/IIa randomised placebo-controlled study to determine safety, immunogenicity and efficacy of non-replicating ChAdOx1 SARS-CoV-2 vaccine in South African adults living without HIV; and safety and immunogenicity in adults living with HIV" trial in South Africa.

The COVID-19 epidemic has caused major disruption to healthcare systems with significant socioeconomic impacts. Containment measures have failed to stop the global spread of virus, which is now at pandemic levels. There are currently no specific treatments available against COVID-19 and accelerated vaccine development is urgently needed. South Africa is still at an early stage of its COVID-19 epidemic, which is expected to start peaking toward the end of July 2020 but has already documented 7220 cases and 138 deaths as of 05 May 2020 (Worldometer.info). Recent modelling data indicates that globally there are likely to be 3-4 waves of COVID-19 outbreaks, possibly extending through to 2021.

The ChAdOx1 nCoV-19 vaccine manufactured by Advent on behalf of the University of Oxford is a recombinant replication-defective chimpanzee adenovirus expressing the SARS-CoV-2 spike (S) surface glycoprotein with a leading tissue plasminogen activator (TPA) signal sequence.

The study will assess safety, immunogenicity and efficacy of one and/or two doses of ChAdOx1 nCoV-19 study in adults aged 18-55 years living with and without HIV in South Africa. There are 3 trial groups with an overall initial sample size of 650. Once group 1 is fully recruited, safety data will be reviewed by a data and safety monitoring board, and once approval to continue enrolment is issued, participants will be enrolled in parallel into Groups 2 and 3. Participants will be followed for a period of 12 months in the study.

The clinical trial will be conducted at the following sites:

1.	**Respiratory and Meningococcal Pathogens Research Unit (RMPRU)** First Floor, Central Wing, Nurses Residence, Chris Hani Baragwanath Academic Hospital, Chris Hani Road, Soweto, Johannesburg, Gauteng, South Africa, 2013
2.	**Setshaba Research Centre (SRC)** 2088 Block H, Soshanguve, 0152, Gauteng, South Africa
3.	**Wits RHI Shandukani Research Centre** 2nd Floor, Hillbrow Health Precinct, Corner Esselen Street and Klein Street, Hillbrow, Johannesburg, South Africa, 2001

The clinical trial protocol includes the following stringent precautions to ensure that no vaccine will be released into the environment:

- The vaccine is supplied in sealed single-dose vials.
- There is restricted access to storage facilities as per local and international guidelines.
- Administration of the injection will be performed within a medical clinic environment and only to adult participants who have consented to their participation in the trial.
- There are stringent procedures regarding the disposal of used syringes as bio-hazardous waste.

Upon the completion of the Clinical Trial any unused doses of the vaccine will be returned to the University of Oxford or will be destroyed in accordance with local guidelines for disposal of bio-hazardous materials.

A copy of the application is available on the DAFF website at **www.daff.gov.za**

Interested parties may submit comments or objections in writing to:
The Registrar of Genetically Modified Organisms (GMO's)
Private Bag X973, Pretoria, 0001 • **Fax:** 012 319 6298
E-Mail: GMOAppComments@daff.gov.za

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