



31 October 2018

**UPDATE ABOUT THE ONGOING WORK OF THE
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
DURING INTERIM CLOSURE OF THE CIVITAS BUILDING, PRETORIA**

To all Stakeholders

Further to the media release of 14 August 2018 regarding the protest action at the Civitas Building, we hereby inform all stakeholders that the Department of Labour issued a directional notice in terms of Section 30 of the Occupational Health and Safety Act (OHSA), 1993 (Act no. 85 of 1993), as amended, to the Department of Health, that occupation of the Civitas Building should be prohibited due to health and safety issues.

The Director-General of Health issued a communication to all employees that the prohibition notice must be adhered to and employees have to vacate the building with immediate effect.

We are urgently exploring options for interim office space to allow for the continuation of essential services while the process to procure new premises for SAHPRA is in progress.

Please note the following regarding deliveries to SAHPRA:

- The delivery of paper documents to SAHPRA this week, initially arranged for 01 November 13h00 – 14h00, will not be possible.
- The new submission date for clinical trial applications, initially scheduled for 02 November 2018, will be communicated in due course.
- Applicants will be contacted regarding the collection of registration certificates, and individual arrangements will be made at the time.
- Please refer to the communication 9.113 for the submission procedure for Section 21 authorisations (orthodox medicines for human use only), and communication 9.114 regarding the submission of post marketing pharmacovigilance correspondence.
- With regard to the submission of Type B pharmaceutical amendments (communication 9.115), the alternative arrangements for submission will also be communicated shortly.

The emergency contact numbers are the following:

Ms Portia Nkambule (Acting CEO): 078 802 0781

Mrs Estelle Taute – Submissions (other than Section 21): 079 528 7755

Mrs Santhani Chetty – Registration certificates: 071 386 0867

Dr Dorah Diale – Clinical Trials: 060 548 4332

Dr Shyamli Munbodh – Section 21 Orthodox medicines for human use only: 072 134 4546

Ms Adelaide Molatoli – Section 21 Orthodox medicines for human use only: 063 771 8906

Mr Tohlang Sehloho – Safety notifications: 082 302 0222

Ms Florah Matlala – Pharmacovigilance: 083 387 3358

NADEMC – 021 447 1618

Mr Khamusi Mutoti – Biological Medicines - Vaccines: 071 302 2135

Dr Alice Sigobodhla – Section 21 Veterinary medicines: 074 379 1178

Mr Griffith Molewa – Permits, Section 36 exemptions: 071 604 7751

Mr Jerry Molokwane – GMP, WHO CPP certificates and any other Inspectorate related activities: 076 422 4934

Mr Mlungisi Wondo – Product Quality Related Complaints and Possible Recalls: 082 256 2626

Ms Daphney Mokgadi Fafudi – Section 36 Exemptions: 066 301 1878
Dr Kaizer Thembo – Section 21 Complementary medicines: 071 134 3709
Ms Andrea Julsing Keyter – Medical devices & IVDs: 082 062 2594

SAHPRA will offer continued guidance to stakeholders while attempts to resolve the situation regarding office space continue.

Ms P Nkambule
Acting Chief Executive Officer