



14 August 2018

**STATEMENT ABOUT THE ONGOING WORK OF THE
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
DURING PROTEST ACTION IN THE CIVITAS BUILDING, PRETORIA**

To all Stakeholders

An essential pillar of a successful health service is ensuring that health products available to the public are safe, effective and of good quality. The South African Health Products Regulatory Authority (SAHPRA) was established in February 2018 to replace the Medicines Control Council (MCC) as South Africa's regulatory authority. As the authority transitions from the MCC to SAHPRA it continues to be housed with the National Department of Health in the Civitas building in Pretoria. Since April 2018, Department of Health employees working in the Civitas building have been undertaking protest action because of concerns about working conditions in the building. This has affected the activities of SAHPRA staff and the overall functionality of the regulatory authority. The Board of SAHPRA shares the concerns of all parties about the Civitas building and supports the National Department of Health's efforts to address this problem.

However, as the health product regulator, SAHPRA has a mandate to ensure the safety, quality and efficacy of medicines available in South Africa. Part of this responsibility is to issue permits allowing individual, seriously ill patients suffering from life-threatening conditions to have access in emergencies to currently unregistered medicines. Special permits are also necessary to allow hospitals to maintain supplies of unregistered medicines required for emergency treatment of critically ill patients. Another aspect of SAHPRA's work, required at all times, is the ability to rapidly respond to safety signals relating to health products that are available either legally or illegally to the public. Ensuring ongoing provision of all these services may be lifesaving. For this reason, SAHPRA has developed contingency plans to ensure that these essential services are not disrupted during this period of protest action.

At present the delivery of paper documents to the SAHPRA offices is a challenge. In the event that there is an urgent submission required for a priority public health need, please phone the contact numbers below to discuss how this situation can be addressed. As attempts to resolve the situation at the Civitas offices continue, SAHPRA will evaluate the situation and offer continued guidance to stakeholders.

In the medium term, SAHPRA as a Section 3A public entity, will move into new premises appropriate for the efficient functioning of the Authority with state-of-the-art IT systems tailored to the needs of a regulator, and with user-friendly access for the public, industry and its stakeholders. For the present, we encourage the public and industry to contact us in an emergency and with legitimate concerns through the following contacts:

Ms Portia Nkambule (Acting CEO): 078 802 0781

Mrs Estelle Taute - Submissions: 012 395 8034 or 079 528 7755

Mr Tohlang Sehloho - Section 21 Orthodox Medicines: 082 302 0222

Dr Shyamli Munbodh - Section 21 Orthodox medicines: 072 134 4546

Ms Adelaide Molatoli - Section 21 Orthodox medicines: 063 771 8906

Ms Florah Matlala - Pharmacovigilance: 083 387 3358

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