SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

Media Release

SAHPRA TO ISSUE CULTIVATION LICENCES FOR MEDICINAL CANNABIS

From: The Acting CEO of SAHPRA
Date: 16 April 2019

In November 2017, the South African Health Products Regulatory Authority (SAHPRA) published a guideline on the cultivation of cannabis for medicinal use (accessible at *https://www.sahpra.org.za/Publications/DownloadDoc/5576*).

This document provides the legal framework for the cultivation and processing of cannabis as a herbal starting material for the production of registered medicines.

Between March and December 2018, SAHPRA received 21 applications for the cultivation of cannabis for medicinal use. One (1) site withdrew their application. Of the 20 applications, 16 sites were inspected in terms of their compliance with the requirements for cultivation as published in the guidelines. The remaining four (4) sites were scheduled for inspection in the first quarter of 2019. Of the 16 inspected sites, 12 sites were found to be non-compliant, as they did not meet minimum requirements needed (e.g. security measures were non-existent). Four (4) sites were found to have minimal deficiencies and were re-inspected. One (1) of these four (4) sites had minor deficiencies which were noted during the second round of inspection. The applicant has agreed to address these concerns.

The remaining three (3) sites have been issued with letters advising them that they are compliant with the required standards for the cultivation of cannabis for medicinal use and will be issued with the cultivation licences, to which cultivation conditions will be attached. The licences for the cultivation of medicinal cannabis will be valid for five years. All three of the sites to be licensed have applied only for the **cultivation** of the herbal material. None has applied for (and hence are not approved for) the manufacture of medicinal products containing cannabis such as oil extracts. Nonetheless, all of the sites will need to comply with the standards as laid down in "Guide to Good Manufacturing Practices for Medicines in South Africa" (accessible at *https://www.sahpra.org.za/Publications/DownloadDoc/5608*).

No cannabis-containing medicines have yet been registered by SAHPRA. Access to such products, therefore, still relies on the section 21 approval process.
The application process is outlined in the section 21 guidance document, accessible at *https://www.sahpra.org.za/documents/06b69aa69.113_Section_21_Authorisation_Oct18_v2.pdf*.
Electronic submissions need to be made via the web portal: *https://goo.gl/forms/RcM1Kbh6Q9tEUy5Z2*

The control over cannabis-containing products is also subjected to the Schedules to the Medicines and Related Substances Act, 1965 as amended. When intended for therapeutic purposes, tetrahydrocannabinol is listed in Schedule 6. Cannabidiol is listed in Schedule 4. Medicines containing either or both of these cannabinoids, therefore, require a prescription from an authorised prescriber.

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