SAHPRA
SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY

STATUS OF CANNABIS-CONTAINING PRODUCTS (INCLUDING OILS) AND THE CULTIVATION OF CANNABIS FOR MEDICINAL USE

1 INTRODUCTION

On the 18th September 2018 the Constitutional Court handed down a judgment[1], which declared existing legislation, criminalising the use, possession, and cultivation of cannabis, unconstitutional. It would, therefore, now not be an offence for an adult person to:

a. use or be in possession of cannabis in private for his or her personal consumption in private; and

b. to cultivate cannabis in a private place for his or her personal consumption in private.

The Court also found section 22A(9)(a)(i) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) to be unconstitutional, to the extent that it prohibits the actions listed above, and suggested amended wording to that section, which will be in effect until reviewed by Parliament.

2 STATUS OF CANNABIS-CONTAINING PRODUCTS (INCLUDING OILS)

The Constitutional Court judgment should not be misconstrued to mean that persons may be allowed to prepare cannabis-containing products, including extract cannabis oils from cannabis cultivated in a private place, and then to sell such products to the public.

Currently, there are a number of outlets and individuals that are selling cannabis-containing products (including oils) for medicinal use. In terms of the provisions of section 14(1) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965), *"no person shall sell any medicine, medical device or IVD which is subject to registration by virtue of a declaration published in terms of subsection (2) unless it is registered.*" The cannabis-containing products and oils that are currently available in South Africa and which have not been registered or approved by SAHPRA are, therefore, illegal. Suppliers and users of such illegal products are exposing themselves and others to legal and health risks as the safety, efficacy and quality of these products cannot be assured.

An applicant wishing to apply for registration of a cannabis-containing product must lodge an application with the SAHPRA. At the same time, an application to licence the manufacturer, importer, distributor of the product has to be submitted *(see section 3)*. The safety, efficacy and quality of the product will be evaluated as well as the compliance with GMP requirements.

[1]Minister of Justice and Constitutional Development and Others v Prince (Clarke, Stobbs and Thorpe Intervening) (Doctors of Life International Inc as Amicus Curiae); National Director of Public Prosecutions and Others v Rubin; National Director of Public Prosecutions and Others v Acton and Others. Case Number: CCT108/17. https://collections.concourt.org.za/handle/20.500.12144/34547

If, after review, SAHPRA finds that the product is safe, effective and of good quality, and the manufacturer is GMP compliant, it will be registered, allowing it to be available on the market.

In certain specific instances, however, it is possible to apply for individual patient access to unregistered medicines containing cannabis, or specific cannabinoids (tetrahydrocannabinol and/or cannabidiol), in terms of section 21 of the Medicines and Related Substances Act, 1965 (Act 101 of 1965). As no quality-assured sources for such products are as yet available in South Africa, approval will need to be sought for the importation thereof from other countries (e.g. Canada and The Netherlands).

To date, 56 such applications have been approved by SAHPRA, based on motivation for use in specific patients by an authorized prescriber.

3 CULTIVATION OF CANNABIS FOR MEDICINAL USE

In order to ensure the availability of standardised, quality-assured, locally grown cannabis for the manufacture of suitable pharmaceutical products, the SAHPRA and the Department of Health may permit the cultivation of cannabis solely for medicinal and research purposes. This framework, developed in consultation with the Department of Agriculture, Forestry and Fisheries (DAFF), is intended to control the cultivation, production and manufacturing of cannabis-containing products intended for medicinal use in South Africa. Licensed domestic cultivation of cannabis for medicinal use is aimed at ensuring sufficient local supply for medical, scientific and clinical research purposes and the implementation of control measures necessary to prevent diversion and misuse, as well as to ensure patient safety.

In November 2017, SAHPRA published a guideline on the "Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes" (Doc No: 2.44; accessible at *https://www.sahpra.org.za/Publications/DownloadDoc/5576*). This guideline provides information relating to the standards and controls required for the cultivation and processing of cannabis as a herbal starting material and identifies the critical production steps that are needed to ensure a product of reliable and reproducible quality.

An applicant may apply to SAHPRA for a licence in terms of the provisions of Section 22C(1)(b) of the Medicines and Related Substance Act, 1965 (Act 101 of 1965) for any or all of the following activities:

- Cultivate/grow and produce cannabis and cannabis resin;
- Extract and test cannabis, cannabis resin and/or cannabinoids;
- Manufacture a cannabis-containing or cannabinoid-containing medicine;
- Import a cannabis-containing medicine;
- Export a cannabis-containing medicine;
- Distribute a cannabis-containing medicine.

The cultivation of cannabis for medicinal use and the manufacturing of cannabis-containing pharmaceutical products shall be subject to strict monitoring to avoid any diversion for unapproved purposes. SAHPRA inspectors will conduct compliance investigations and inspection of sites applying for a licence to conduct regulated activities as well as licensed sites.

4 STATUS OF LICENCE APPLICATIONS FOR THE CULTIVATION OF CANNABIS FOR MEDICINAL USE

To date, SAHPRA has received 21 licence applications for the cultivation of cannabis for medicinal use. Of these, one application has subsequently been withdrawn. Of the remaining applicants, 16 applicants have been inspected and four (4) applicants are scheduled for inspection. No licences have yet been issued, but a developmental approach to the approval of suitable licencees is being pursued.

However, as pointed out above, in the interim, section 21 approval has been given for the importation of unregistered cannabis-containing products, in order to meet local needs.