SAHPRA
SOUTH AFRICAN
HEALTH PRODUCTS
REGULATORY AUTHORITY

The Status of Cannabis for Medicinal and Research Purposes

Presentation to Portfolio Committee on Health

04 SEPTEMBER 2019

Presentation Outline

- Legal framework for scheduling and regulatory control
- International and local status of cannabis
- Access to cannabis for medical and research purposes
- Cultivation of medicinal cannabis
- Industrial hemp cultivation
- Intergovernmental and external stakeholder engagement

SAHPRA's Public Health and Regulatory Mandate

Two distinct objectives:

- Protect patients against harmful or ineffective medicines
  - Gatekeeper function with obligation to apply stringent standards of assessment and to restrict availability where deemed necessary.
- Protect patients against the consequences of untreated disease
  - Enabling availability to ensure that patients have timely access to safe and effective medicines.

Legal Framework for Scheduling and Regulatory Control:

- The sale, supply and use of a medicine or scheduled substance in South Africa is governed by section 22A of the Medicines and Related Substances Act (Act 101 of 1965) ("Medicines Act"), relevant Schedules and supporting Regulations.
- All medicines are subject to a scheduling process on the basis of their active pharmaceutical ingredients (APIs).
- Section 22A(2) – Schedules are approved by the Minister, on the recommendation of SAHPRA.
- Section 37A – provides for amendments to the Schedules.
- Schedules are published in the Gazette or amended by subsequent notice in the Gazette.

Principles of Scheduling

- Allows for different levels of regulatory control over substances, whether in the form of naturally-occurring products, APIs, or finished pharmaceutical products (medicines).
- Primary consideration is safety in relation to therapeutic use. Substances may be listed in one of eight Schedules.
- Substances may also be listed in more than one Schedule, based on the indication, dosage form, route of administration, strength, dose, duration, or a combination of these factors.
- Framework ensures compliance with international drug control Conventions and Treaties which South Africa is signatory to.

Scheduling and Control of Medicines

With regard to substances which may be abused or misused:

- Ensure medical needs are met with appropriate levels of control, consistent with international drug control conventions.
- Ensure timely implementation of policies and resolutions of the International Narcotics Control Board (INCB).
- Ensure that scheduling in terms of the Drugs and Drug Trafficking Act (Act No. 140 of 1992), the Prevention and Treatment of Drug Dependency Act (Act No. 20 of 1992) and the Criminal Procedure Act (Act 51 of 1977) are based on the Schedules to the Medicines and Related Substances Act (Act 101 of 1965).

Framework for Scheduling

- Schedule 0: Available through general sales outlets
- Schedule 1: Pharmacy OTC products
- Schedule 2: Pharmacist-prescription products
- Schedules 3-6: Prescription-only medicines; authorised prescribers
- Schedule 7: Prohibited substances; special permits
- Schedule 8: Limited use; special permits

The Legal Status of Cannabis Internationally

- RSA is a signatory to the United Nations (UN) Single Convention on Narcotic Drugs, 1961
- Under this Convention, cannabis is classified under Schedules I and IV making it subject to special restrictions.
- The International Narcotics Control Board (INCB) requires member countries to establish:
  - regulatory frameworks for enabling medical and research access
  - regulatory procedures for licensing and registration for suitable products
  - define control systems for cultivation of medicinal cannabis
  - define which cannabis varieties may be authorised for cultivation
- Global efforts currently aimed at easing restrictions on cannabis use under international treaties.

The Legal Status of Cannabis in South Africa

- In SA, cannabis is currently controlled in line with the 1961 Single Convention and is listed in the Schedules as follows:
  - Schedule 7
  - Schedule 6 (tetrahydrocannabinol, THC) for therapeutic use
  - Schedule 4 (cannabidiol, CBD) for therapeutic use
  - Schedule 0 (cannabidiol, CBD) as a supplement in a limited dose
- Section 22A (9)(a)(i) of the Medicines Act provides that no person may acquire, use, possess, manufacture or supply a Schedule 7 or Schedule 8 substance.
- This section also provides for the Director-General to issue a permit authorising a medical practitioner, analyst, researcher or veterinarian to use cannabis, on the prescribed conditions, for the treatment of a patient, or for the purposes of education, analysis or research.

Cannabis Inscription in Schedule 7

”Cannabis (dagga), the whole plant or any portion or product thereof, except:

- *when separately specified in the Schedules; (S6) (S4); or*
- *processed hemp fibre containing 0.1 percent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and is in a form not suitable for ingestion, smoking or inhaling purposes; or*
- *processed product made from cannabis seeds containing not more than 10 milligram per kilogram (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds.”*

“Synthetic cannabis substances (synthetic cannabinoids) including but not limited to:

- *cannabicyclohexanol;*
- *JWH-018; JWH-073; JWH-200; CP-47497; CP 47497-C6; CP 47497-C7; CP 47497-C8; CP 47497-C9; HU-210”*

Access to Cannabis for Medicinal Use

- Framework enables patients who are in possession of a valid prescription for medicinal use to access the product in the following ways:
    1. Pharmaceutical cannabis products registered by SAHPRA.
    2. Cannabis pharmaceutical products that are not yet registered by SAHPRA may be obtained under Section 21 of the Medicines Act by authorised medical practitioners for their patients.
    3. Controlled and quality-assured herbal cannabis products obtained from licensed producers, which have standardised levels of cannabinoids and tested to be free of harmful contaminants.
- Note: SAHPRA's regulatory mandate focuses on cannabis for medical and research purposes and ensuring the safety, quality and efficacy of cannabis-containing products. This mandate does not extend to policing private or recreational use which remains the function of law enforcement agencies.

Cannabis for Medicinal Use: Section 21 Access

Access in terms of Section 21 of the Medicines Act with specified conditions:

- Clinical need exists for a medicine available in other countries, but yet not registered in South Africa.
- Patients with serious illnesses where a clinical need can be demonstrated and where evidence exists to support the request.
- SAHPRA has published a guideline on the procedure for Section 21 applications to enable patient access to unregistered medicines. (https://www.sahpra.org.za/documents/06b69aa69.113_Section_21_Authorisation_Oct18_v2.pdf).
- Applications for Section 21 approval of cannabis-containing medicines can be made on SAHPRA's electronic web portal (https://goo.gl/forms/RcM1Kbh6Q9tEUy5Z2).

Medicinal Cannabis: Section 21 Access (cont.)

- Objective evidence to support the proposed use must be provided.
- The dosage, route of administration and duration of treatment must be specified.
- Appropriate monitoring of the patient during and after treatment must be in place in order to assess efficacy and adverse events.
- Regular reporting on treatment outcomes is required.
- Informed consent by the patient or legal representative is required.

Patient eligibility for medicinal cannabis

- Includes the following conditions:
  - Severe muscle spasms or severe pain in patients with multiple sclerosis
  - Severe nausea, vomiting or wasting arising from cancer, HIV/AIDS
  - Severe epileptic seizures where other treatment options have failed or have intolerable side effects
  - Severe chronic pain conditions

Registered Products in RSA and other Countries

- Dronabinol is registered in some jurisdictions, including RSA, for nausea and loss of appetite in cancer and AIDS patients respectively.
- Nabilone is registered for chemotherapy associated nausea and vomiting in other countries.
- Sativex is registered for multiple sclerosis and pain management in other countries.
- Epidiolex (cannabidiol, CBD) has recently been approved in the US and EU for treatment of seizures in patients with Lennox-Gastaut syndrome and Dravet syndrome.

Framework for Medical Use and Research

Key elements of the framework:

- Licensing of growers to enable controlled cultivation of medicinal cannabis for medical, scientific and research purposes.
- Availability of a standardised, quality-assured product for medicinal use.
- Clinical decision-making support for approval of medicinal use.
- Review and approval of clinical trials and related scientific research.

Cultivation of Medicinal Cannabis

- SAHPRA and the Department of Health have developed a framework to regulate proposed growers of medicinal cannabis by licensing and issuing of permits to allow for controlled cultivation.
  - Enable cultivation, manufacture and supply of standardised, high quality medicinal cannabis products
- The Department of Agriculture, Land Reform and Rural Development:
  - Support development of good agricultural practices for cultivation of medicinal cannabis and hemp through lessons learned from cultivation trials jointly overseen.
- The Medical Research Council and academic institutions
  - Support for ongoing clinical and pharmaceutical research on medicinal cannabis

Guidelines for Cultivation and Manufacture

- Guidelines published on “Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes” (https://www.sahpra.org.za/Publications/DownloadDoc/5576).
- Provides guidance on minimum standards required for the cultivation and processing of cannabis and the manufacture of cannabis-related products.
- Identifies the critical production steps that are needed to ensure a product of reliable and reproducible quality.
- Cultivation of cannabis and manufacturing of cannabis-containing products are subject to strict monitoring to avoid any unintended use.
- SAHPRA inspectors conduct compliance investigations and inspection of licensed sites.

Applications for Cultivation of Medicinal Cannabis

- An applicant may apply to SAHPRA for a licence in terms of the provisions of Section 22C(1)(b) of the Medicines Act, for any or all of the following activities:
  - Cultivate and produce cannabis and cannabis resin;
  - Extract and test cannabis, cannabis resin and/or cannabinoids;
  - Manufacture a cannabis-containing or cannabinoid-containing medicine;
  - Import, export or distribute a cannabis-containing medicine.
- SAHPRA has received 80 applications for cultivation licences. The majority of these applications were found to be non-compliant and did not meet the minimum requirements needed.
- Five sites have been approved and consideration of the remaining applications, including site inspections, is ongoing.

Industrial Hemp Cultivation

- Hemp is excluded from the provisions of the Medicines Act when cultivated and used for industrial purposes provided the hemp fibre does not contain more than 0.1 percent THC or in the case of a processed product, not more than 0.001 percent THC.
- Hemp cultivation trials (initiated in 1999):
  - Collaboration between Departments of Agriculture and Health
  - Intended to explore suitability of hemp as an agricultural crop
  - Agricultural Research Council developed RSA genetically modified seeds for industrial hemp cultivation.
- Hemp cultivation will be controlled under the Department of Agriculture and will ensure adherence to good agricultural practices

Intergovernmental and External Stakeholder Engagement

- SAHPRA has established a Medicinal Cannabis Working Group to develop an enabling regulatory framework for access to medicinal cannabis.
- Consultation with intergovernmental departments and external stakeholders to ensure an integrated approach to the policy framework.
- Engagement and support to provincial government, rural farmers and traditional healers to develop enabling mechanisms for cultivation and access to cannabis for medicinal use.
- The growing number of unlicensed outlets and individuals selling unregistered cannabis products for medicinal use remains a concern and requires an integrated approach by all law enforcement agencies.
- A Ministerial Advisory Committee is also proposed to address the wider cannabis policy issues, including legislative and regulatory amendments required.

Thank you