What are THC and CBD?

SAHPRA
South African Health Products Regulatory Authority

Cannabis contains a large number of active components, called **cannabinoids**.
The two cannabinoids of interest for **medicinal purposes** are:

- **tetrahydrocannabinol (THC)**,
  which is **psychoactive**
  and **causes a "high"**; and

- **cannabidiol (CBD)**,
  which is **not psychoactive**

The effects and safety of these two cannabinoids affect how strictly they are regulated. Substances are listed in the Schedules to the Medicines and Related Substances Act, 1965, (Act 101 of 1965), as amended (The Act), and are then controlled in terms of the Act. The controls relate to who may possess the substances, where and under what conditions they can be sold, and whether they require a prescription or not.

CBD SCHEDULING STATUS OF CANNABINOIDS

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- **Amended schedules** relating to cannabis, **THC** and **CBD** were issued on **22 May 2020.**
- These amendments specify that **SAHPRA regulates substances** for medical purpose for quality, safety and efficacy.
- Products made from cannabis containing less than **≤ 0,001% THC** with no medical claims, are **excluded** from schedules of the Medicines Act.

CBD is a Schedule 4 substance except in:

1. Complementary medicines with 600mg of CBD per sales pack, with a maximum daily dose of 20mg.
2. Processed products made from cannabis raw plant material intended for ingestion with <_0.00075% of CBD in naturally occurring quantity.

SCHEDULE DEFINITIONS

- **SCHEDULE 0** — Available through general sales outlets
- **SCHEDULE 1** — Pharmacy Over The-Counter (OTC) products
- **SCHEDULE 2** — Pharmacist-prescription products
- **SCHEDULE 3-6** — Prescription-only medicines; authorised prescribers
- **SCHEDULE 7** — Banned substances
- **SCHEDULE 8** — Limited use of banned substances; special permits

THC & CBD CONTROL FRAMEWORK

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The **cultivation, manufacture** or **distribution** of cannabis for medical purposes is regulated in terms of Section 22C (1)(b) and Section 22A.

CULTIVATION

MANUFACTURE

DISTRIBUTION

Currently, there are **no THC/CBD registered products.**
Authorisation of THC /CBD medical products would be in terms of Section 21.

A licence and authorisation is issued following **evidence of a valid market** and **compliance of the manufacturing facility** to Good Manufacturing Practice (GMP) requirements.

LICENCE APPLICATION PROCESS

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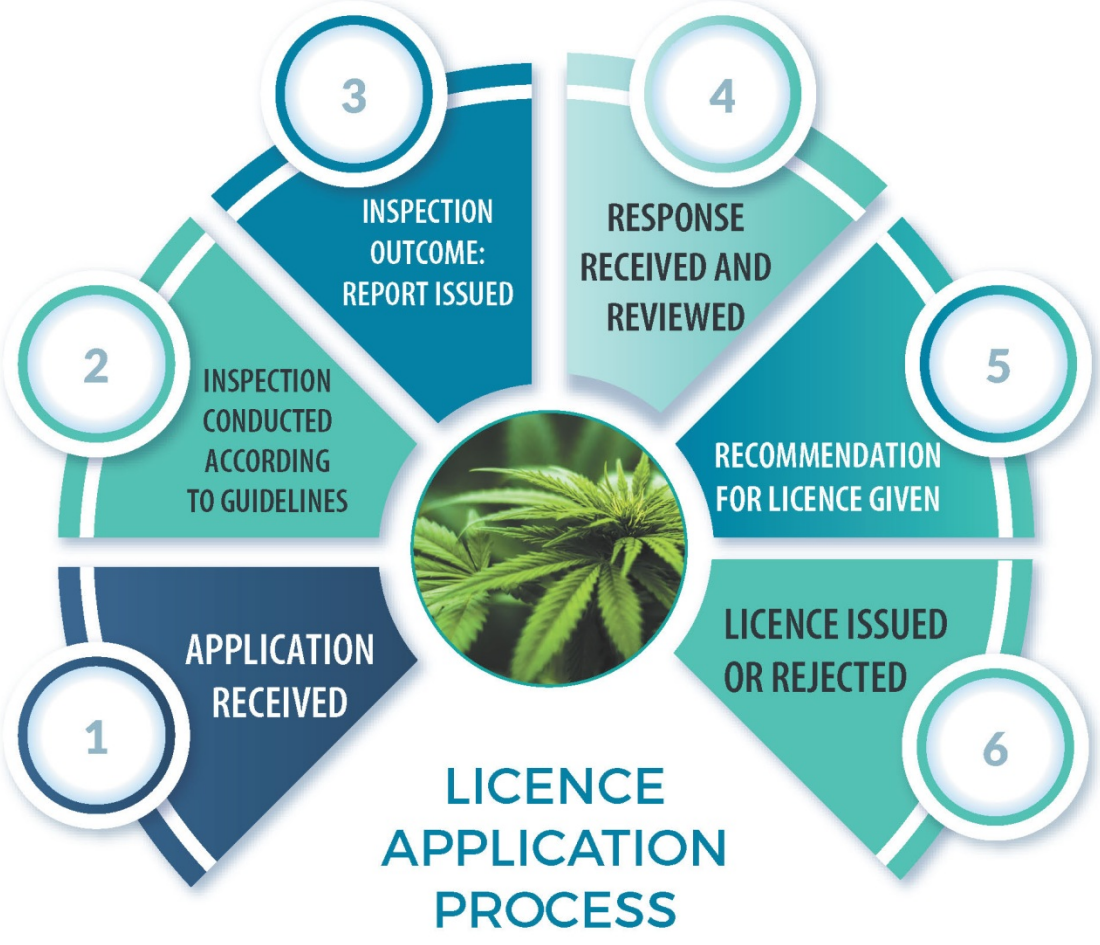

Licences are issued to establishments that meet the regulatory requirements for cultivation or manufacture of Cannabis for medicinal purposes for approved local, export or import markets.

Applicants may request an **application status letter**. This letter will indicate areas where the applicants have complied with regulatory requirements as well as missing or outstanding information that is required.

LICENCE, PERMITS & ELIGIBILITY

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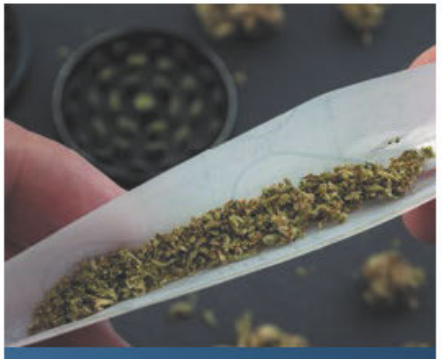
LICENCE

A **Licence holder** includes a **cultivator, manufacturer, wholesaler, importer, exporter or distributor** of a medicine or scheduled substance in terms of Section 22C (1(b) of the Act.



PERMIT

A Permit is required to **acquire, use, possess, manufacture, or supply THC containing substances** according to Section 22A(9)(i) &/ 22A(11) of the Act.

WHO ARE ELIGIBLE FOR PERMITS?

Licence holders and research institutions may apply for a permit. Research permits are **not intended for commercial purposes.**

Matters relating to **hemp** should be referred to the Department of Agriculture, Land Reform and Rural Development **(DLRRD).**