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Investing in Cannabis in South Africa

March 2021

an inspiring place to do business

To what extent has cannabis been legalised in South Africa?

Various separate events have influenced the legality of cannabis in South Africa since 2017.

- In 2017, the Department of Health introduced a licencing framework for the domestic cultivation and manufacture of medicinal cannabis.
- In 2018, the Constitutional Court of South Africa decriminalised private use and cultivation of cannabis based on the right to privacy.
- In 2019, the Minister of Health rescheduled cannabidiol (CBD), and temporarily (for up to one year) excluded certain preparations containing CBD from the operation of the Schedules to the Medicines and Related Substances Act.
- In 2020,
 - The Minister of Health confirmed the exclusion of certain CBD-containing products permanently from Schedule 4, however with certain differences from the 2019 exclusion. CBD is thus listed as Schedule 4, while exempt CBD products are regulated as Schedule 0.
 - Cannabis, dronabinol and tetrahydrocannabinol (THC) are no longer listed as Schedule 7.
 - THC is rescheduled and is now listed as Schedule 6, with certain exceptions.
- In 2020, the Department of Justice and Correctional Services introduced the Draft Cannabis for Private Purposes Bill for comment. The purpose of this bill is to give effect to the Constitutional Court judgement of 2018.

1. Cannabis

1.1. What is cannabis?

Cannabis is made from the dried flowering heads and leaves of a plant called *Cannabis sativa*. Cannabis contains a complex mix of approximately 60 unique 'cannabinoids' along with many other chemical compounds. The main active ingredient responsible for the 'high' produced by cannabis is delta-9-tetrahydrocannabinol (THC).

Other related substances in cannabis include cannabidiol (CBD) and cannabinol (CBN), both of which have quite different pharmacological effects. These are collectively known as 'cannabinoids'. Different strains of cannabis produce different amounts of these chemical substances.

1.2 What is medicinal cannabis?

'Medicinal cannabis' is a term that refers to legal, high quality and standardised products made from crude or raw cannabis. Crude cannabis is a difficult drug for doctors to prescribe because the dose and potency of the drug in each case is not tested or known. Pharmaceutical preparations of cannabis use modified active components of cannabis in medical formulations, which maximise the therapeutic benefit and minimise side effects.

Pharmaceutical preparations, such as a tablet, capsule or spray, mean the concentration can be standardised and the dose controlled. Many medicinal cannabis products contain a combination of THC and CBD. Some products contain CBD only and others contain predominantly THC.

1.3. Differences between medicinal and recreational cannabis

Medicinal cannabis is legally produced under strict pharmaceutical conditions. Doctors and pharmacists know exactly what the medicine contains. The ingredients, potency and quality of illicit recreational cannabis are untested. Contamination with microbes, pesticides and heavy metals can occur. Medicinal cannabis products are generally available as oils, sprays, tinctures and capsules. By contrast, illicit cannabis is usually smoked. These differences mean cannabis sourced through illicit channels cannot be described as 'medicinal cannabis'.¹

2. Legal Framework

2.1 How is medicinal cannabis currently regulated in South Africa?

The South African Health Products Regulatory Authority (SAHPRA) controls the sale, possession and manufacture of any medicine or Scheduled substance in South Africa. This is regulated by the Medicines and Related Substances Act, 1965 (the Medicines Act). SAHPRA is the new name for the old Medicines Control Council (MCC).

2.2 Patient access

2.2.1. Application for access to unregistered pharmaceutical products

There are currently no registered cannabis-containing medicines in South Africa, therefore patients wanting to use such medication need to follow the procedure for obtaining permission to use an unregistered medicine.

Currently patients are able to obtain cannabis products for medicinal use in terms of section 21 and 22 of the Medicines Act, which allows medical practitioners to apply to SAHPRA for permission to access and prescribe unregistered medicines. Under this process medicinal cannabis products may be made available, under medical supervision and in exceptional circumstances, to specific patients. Until now, patient access to unregistered pharmaceutical products containing cannabinoids had been enabled by SAHPRA through the importation of these products only.

The new licencing framework carves out the possibility for cannabis-containing medicines to be registered in South Africa by SAHPRA. Until such time as registered cannabis-containing medicines are available, access to such products will continue to rely on the section 21 approval process.¹

2.2.2. Scheduling of CBD and THC

From May 2019 –May 2020 certain preparations of CBD were excluded temporarily from scheduling, which meant that CBD products could be sold over the counter under restricted conditions.²

On 22 May 2020³, the Minister of Health issued a new notice in which he confirmed the exclusion of CBD (but with different conditions) and further amended the Schedules as follows:

1. Cannabis, dronabinol, and tetrahydrocannabinol are no longer listed as Schedule 7.
2. **Cannabidiol (CBD)** is listed in Schedule 4, except:
 - in complementary medicines containing no more than 600 mg cannabidiol per sales pack, providing a maximum daily dose of 20 mg of cannabidiol, and making a general health enhancement, health maintenance or relief of minor symptoms (low-risk) claim; or
 - processed products made from cannabis raw plant material intended for ingestion containing 0,0075 percent or less of cannabidiol where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product.
 - Products that meet those listed conditions will instead be regulated as Schedule 0.
3. (-)-transdelta-9-tetrahydrocannabinol (THC) is listed in Schedule 6, except –
 - in raw plant material and processed products manufactured from such material, intended for industrial purposes and not for human or animal ingestion, containing 0,2 % percent or less of tetrahydrocannabinol;
 - processed products made from cannabis containing 0,001 percent or less of tetrahydrocannabinol; or
 - when raw plant material is cultivated, possessed, and consumed by an adult, in private for personal consumption.

What does this mean?

Cannabidiol (CBD)

Medicines containing CBD and claiming to treat, prevent or cure a disease are **Schedule 4**

- will have to be registered by SAHPRA;
- can only be brought at a pharmacy, on the basis of a prescription from an authorised prescriber (or dispensed by a licensed dispensing practitioner); and
- are controlled as Schedule 4 substances.

Complementary medicines containing CBD are **Schedule 0**

- May be sold in any retail outlet (as Schedule 0 substances);
- May be advertised to the public;
- May only make a general health claim (e.g. aids in the management of sleep);
- May contain not more than 600 mg of CBD per sales pack;
- May provide not more than 20 mg of CBD as a daily dose; and
- May only be manufactured, imported or distributed by a complementary medicine establishment licensed by SAHPRA.

¹ SAHPRA Media Release: SAHPRA To Issue Cultivation Licences For Medicinal Cannabis. 16 April 2019. SAHPRA website 2021.

² Government Gazette No. 42477. 23 May 2019.

³ Government Notice No. 586, Government Gazette No. 43347.

Processed products containing CBD **are excluded** from the requirements of a medicine and the control of SAHPRA if:

- It is made from the raw plant material; and
- Contains not more than 0,0075% of naturally-occurring CBD; and
- Does not make any general health claim or therapeutic claim.

Tetrahydrocannabinol (THC)

Medicines containing THC and claiming to treat, prevent or cure a disease are **Schedule 6**

- Will have to be registered by SAHPRA
- Can only be bought at a pharmacy, on the basis of a prescription from an authorised prescriber (or dispensed by a licensed dispensing practitioner); and
- Are controlled as Schedule 6 substances (this is the most stringent category, with significant restrictions).

THC is excluded from Schedule 6 if:

- In **raw plant material and processed products** manufactured from such material, intended for industrial purposes and not for human or animal ingestion, containing 0,2% or less THC;
- **Processed products** made from cannabis containing 0,001% or less of THC; or
- When raw plant material is cultivated, possessed, and consumed by an adult, in private for **personal consumption**.

A product containing 0,001% or less of THC that makes a general health claim will be regulated as Schedule 0/ complementary medicine.

Imported or locally produced

Excluded products are therefore allowed to be obtained without a doctor's prescription. As companies obtain licences to produce cannabis containing products (see below), these CBD preparations would be able to be produced locally by licenced cultivators and manufacturers. Alternatively such products would be imported.

2.3. Is it legal to cultivate and manufacture medicinal cannabis products in South Africa?

A licencing framework for domestic cultivation of cannabis and manufacture of cannabis-related pharmaceutical products for medicinal and research purposes was introduced at the end of 2017 by SAHPRA and the Department of Health.⁴

It was introduced in order to ensure availability of standardised quality-assured medicinal cannabis grown locally for the manufacture of suitable pharmaceutical products.

Application can be made to SAHPRA for a licence in terms of the provisions of Section 22C(1)(b) of the Medicines Act to –

- 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 scope of requirements as set out in the licencing framework includes:

- Personnel requirements
- Security requirements
- Buildings and facilities
- Equipment
- Production and manufacturing
- Storage and distribution
- Documentation
- Good manufacturing practices
- Compliance and enforcement

⁴ Available at <https://www.sahpra.org.za/wp-content/uploads/2020/10/General-guide-to-Medicinal-Cannabis-Cultivation-or-Manufacturing.pdf>.

Note that cultivation for any purpose other than allowed for within the licencing framework, for research purposes as permitted, or for private use as permitted (see below), is still a criminal offence.

3. What is the legal situation regarding private use and cultivation?

A 2018 Constitutional Court Case⁵ decriminalised private use and cultivation of cannabis. The following findings were made:

- Certain sections of the Drugs and Drug Trafficking Act and of the Medicines and Related Substances Control Act are found to be inconsistent with section 14 of the Constitution to the extent that they criminalise the use or possession in private, or cultivation in a private place, of cannabis by an adult for his or her own personal consumption in private.
- Parliament was given 24 months to rectify the constitutional defects by amending the relevant legislation. This process is ongoing.

In August 2020, the Department of Justice and Correctional Services published the draft *Cannabis for Private Purposes Bill* for comment.⁶ No further drafts have yet been published. This bill gives effect to the Constitutional Court judgment.

4. Investment in Medicinal Cannabis

4.1. Is there potential for investment in the medicinal cannabis industry in South Africa?

The introduction of the licencing framework for cultivation and manufacture of medicinal cannabis opens new investment opportunities in South Africa. The Western Cape region in particular has already attracted significant investor interest based not only upon its strength in agriculture, but also because Cape Town is fast becoming Africa's leader in pharmaceutical research and development, as well as health- and biotech. The Western Cape is home to four world-class universities, making it a hub in Africa for skills and innovation.

4.2. The Western Cape as an agricultural investment destination

The Western Cape is the powerhouse of South Africa's agricultural exports. In 2020, the Western Cape accounted for 41.05% of South Africa's agricultural exports, with six of the Western Cape's top 10 export products being agricultural products. More than a million bottles of wine from the Western Cape are sold globally per day. The African continent is also an increasingly important destination for the province's exports, consuming an estimated R2,69 billion worth of the Western Cape's agricultural exports in 2020.⁷

In light of recent climatic challenges and the probability of lesser rainfall going forward, the local agricultural sector recognizes the need to embrace new technology in order to overcome changing climatic and hence, agricultural conditions. Examples hereof include controlled environment agriculture as well as precision agriculture amongst others, with intense greenhouse agriculture increasing by 43% between 2013 and 2017. Approximately 6,464 hectares of land is currently under shade netting and tunnel infrastructure. The Western Cape's Department of Agriculture (DoA) does a provincial aerial survey to track actual cultivation. This data, which is freely available to the public ([here](#) and [here](#)), is reflective of cultivation methods over time and enables agriculture planners to identify suitable land for their produce.

4.3. Medical cannabis market

Why is the medical market (as opposed to recreational) more attractive from a grower's perspective in the Western Cape? The answer is twofold. In the first place, global cannabis demand is met by current supply, even if it has been illegal. There is therefore a large and established recreational supply market and the growers in this segment will most likely be able to meet legal recreational demand over the medium term. The second reason is that in the future (and already in the present), medical cannabis will have to be cultivated in laboratory-like conditions and hence, will require extensive greenhouse environments and make use of pesticide free soil.

In recent years, there has been a large-scale expansion of green houses in the Western Cape to cater for the demand for crops such as blue berries and tomatoes. The long hours of sunshine are a massive boost to natural growth conditions with artificial lighting only used periodically during winter months. Further, the province has a strong historical performance in terms of production and expertise in agriculture, and finding skilled workers will not be a problem. Since water will be used in a controlled environment it will also mean that crops will use less water than in open growth areas.

Based on various expectations the legal cannabis market is expected to grow at approximately 20% per annum for the next 10 years. For this reason, there has been a global explosion in cannabis related investment. In the short term there will more than likely be an oversupply of both recreational and medical material, but as high-cost suppliers are eliminated, the low-cost destinations will flourish, thereby creating many thousands of new jobs and propelling economic growth.

By 2023, the value of Africa's legal cannabis market could be worth over USD 7.1bn. The medicinal cannabis market in South Africa is projected to reach USD 667 million by 2023.⁸

⁵ Minister of Justice and Constitutional Development and Others v Prince; National Director of Public Prosecutions and Others v Rubin; National Director of Public Prosecutions and Others v Acton and Others [2018] ZACC 30 of 18 September 2018

⁶ Available here <https://www.parliament.gov.za/bill/2292553>.

⁷ Quantec, 2021.

⁸ Prohibition Partners. African Cannabis Report. 2019.

4.4. Argument for the Western Cape as a health industry investment destination

The health technology sector in the Western Cape currently contributes an estimated R1.7bn to the Western Cape economy and creates approximately 2 500 fulltime jobs. The Province hosts one of the highest concentrations of medical device and healthcare companies, research institutes and research groups in South Africa.

South Africa is the only country in the Southern African Development Community (SADC) that meets the World Health Organisation's Good Manufacturing Practice standards. This positions South Africa as a gateway to the Southern African market for manufacturers of pharmaceutical products.

South African-based companies have also been steadily investing in the African continent with manufacturers like Aspen and Adcock Ingram operating in several African countries.

Some of the top companies in the healthtech sector include Biovac Institute, H3D, Roche Diagnostics, Cipla, CapeRay, Aspen Pharmaceuticals, Sinapi Biomedical, TASK and Afriplex. Foreign companies operating in South Africa include Pfizer (United States), GlaxoSmithKline (United Kingdom), Sanofi (France), Bristol Myers Squibb (United States) and Johnson & Johnson (United States).

The Western Cape benefits from four world-class universities, two academic hospitals, the South African Medical Research Council as well as the Centre for Proteomic and Genomic Research (CPGR), providing state-of-the-art services to the life science and biotech communities in SA.

The Western Cape is home to one of the three highest international standards laboratories: the International Centre for Genetics Engineering and Biotechnology (ICGEB). This is an intergovernmental organisation within the United Nations Common System, where innovative research in life sciences is carried out. Currently more than 60 researchers are investigating infectious (HIV/AIDS and malaria) and non-communicable (cancer) diseases.

The Western Cape is perfectly situated for doing business in Africa. The African region represents about 40% of the top 10 Western Cape export markets of medical technology, whereas Europe, the United States and the United Kingdom were the top export markets for pharmaceuticals.

5. Is it legal to cultivate hemp?

A framework for the legalisation of hemp in South Africa is under development. Currently raw hemp materials and products can be imported under specific conditions, but hemp cultivation is still forbidden.

6. What is the City of Cape Town's role?

The City of Cape Town's Enterprise and Investment Department is focussed on positioning Cape Town as a forward looking globally competitive City.

The City of Cape Town is the local sphere of government responsible for:

- Administering and regulating land use planning and building plan approval
- Providing for a range of engineering and social services across the City
- In certain circumstances making City owned land available for sale and lease to investors
- Administering an incentive scheme for job creating investment

The City also provides a free investment facilitation service that assists investors land their investment in the City, as well as a Business Support Hotline +27 21 417 4043 or email business.support@capetown.gov.za.

For more information please contact the Enterprise and Investment Department by email on info@investcapetown.com, or via their website www.investcapetown.com/contact-us, LinkedIn page www.linkedin.com/company/investcapetown or Twitter account [@InvestCapeTown](https://twitter.com/InvestCapeTown).

7. What is Wesgro's role?

Wesgro is the tourism, trade, and investment promotion agency for Cape Town and the Western Cape. Wesgro supports trade and investment in medicinal cannabis in accordance with its mandate to support economic growth and job creation in the local economy. Such support is strictly in accordance with the laws of South Africa, including the licencing framework under the Medicines and Related Substances Act, 1965, as published by the South African Health Products Regulatory Authority and the Department of Health.

Wesgro's Investment Promotion unit offers a free and confidential service to companies and organisations looking to establish and grow in a world-class African business destination. Our team of portfolio managers has more than 40 years of experience in supporting businesses, covering the following sectors:

- Agribusiness
- Hotel and Real Estate
- Tech
- Manufacturing
- Oil and Gas
- Business Services
- Green Economy

Key services provided include:

- Guidance regarding accessing governmental incentives and grants
- Site location
- Facilitation of access to finance
- Professional referral service
- Policy advocacy leveraging strategic support of the InvestSA One Stop Shop Western Cape
- Strategic match making
- Sector specific research via the Wesgro Research unit
- Intergovernmental linkages

Wesgro's Trade Promotion unit focusses on increasing the rand value of exports into global markets and the number of jobs resulting from export orders, as well as the facilitation of outward investment by Western Cape companies into the rest of Africa.

The trade unit's business facilitation and trade promotion activities include:

- Accessing finance
- B2B meetings and forging strategic collaboration and facilitation
- Inward buying and outward selling missions
- Advocacy and specialised advisory services
- Access to strategic networks
- Marketing of value-added goods and services

Contact us

If you are interested in finding out more about investing in Cape Town and the Western Cape, or would like more information on the medicinal cannabis industry in South Africa, please contact the Wesgro Investment Promotion Team at: +27 (0) 21 487 8600 or invest@wesgro.co.za.

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