SOUTH AFRICA

I. Introduction

1. Identify the geographic scope and limits of your answers to the questions below.

South Africa.

II. Legislation

2. Please provide links to applicable statutes and regulations.

Medicines and Related Substances Act 101 of 1965 ("Medicines Act")

Pharmacy Act 53 of 1974 ("Pharmacy Act")

A. Is there any pending legislation that could materially alter applicable statutes or regulations?

No.

B. Is there any proposed legislation that could materially alter applicable statutes or regulations?

Proposed legislation with regard to medicinal use:

Certain CBD preparations have been excluded from the operation of the Schedules of the Medicines Act by the Minister of Health for a time-limited period, as per the Exclusion Notice. The time-limit expired on May 15, 2020, thus it is expected that further regulation will be published after this date.

Proposed legislation with regard to recreational use:

In the Constitutional Court case, Minister of Justice v Prince, the court gave parliament 24 months from the date of the judgment to bring the ruling in line with South African laws, with a new bill expected to be released soon.

For further background, in September 2018, the Constitutional Court ruled that it is not a criminal offence for an adult citizen to use, possess or grow cannabis in private for personal consumption. However, the Constitutional Court did not define the scope of private, rather they left this to the discretion of those who enforce the law – the police, prosecutors and the courts. The Constitutional Court did not prescribe the quantity of cannabis that would qualify for personal use. Until these provisions are made, South Africa's law enforcement officials have the discretion to decide whether the amount of cannabis in a person's possession could reasonably be believed to be more than what is necessary for private use. If so, the individual could be considered to be "dealing" in cannabis in contravention of the Drugs and Drug Trafficking Act 140 of 1992.

3. Are cannabis laws in your jurisdiction pretty well settled or are they constantly changing in material ways?

Constantly changing in material ways.

III. General information (e.g., governing bodies, licenses, import/export)

4. What governing body regulates/licenses or enforces activities that are allowed in your jurisdiction?

SAHPRA (South African Health Products Authority), previously known as the MCC (Medicines Control Council) for the medicinal use of cannabis and the South African Police Service for recreational use.

5. What cannabis functions are allowed in your jurisdiction? E.g., growing, processing, retailing.

Cultivation, production, manufacturing and the use thereof for medicinal and research purposes. The cultivation, production, manufacture and use of medicinal Cannabis products may only occur through a licence issued by the SAHPRA (under the Guideline on the Cultivation of Cannabis and Manufacture of Cannabis-Related Pharmaceutical Products for Medicinal and Research Purposes) and a permit issued by the Department of Health (under the Medicines Act). Additionally, a manufacturer would need to be licensed to manufacture medicines in terms of section 22C(1)(b) of the Medicines Act. This process takes around a year (including obtaining a premises license under the Pharmacy Act and being recorded as a manufacturing pharmacy with the South African Pharmacy Council ("SAPC"). A manufacturer also needs to engage a full time responsible pharmacist, recorded as such with the SAPC.

The use, possession and growing of cannabis in private for personal consumption.

6. What sales or use is allowed in your jurisdiction? E.g., edibles, vaping, tinctures, food additives, etc.

Certain processed hemp and cannabis seeds products may be sold. CBD containing medicinal products that have been excluded from the Schedules to the Medicines Act in terms of the Exclusion Notice may also be sold in general outlets, including health shops and from pharmacies. CBD as an additive or ingredient is not permissible in foodstuffs. Only the naturally occurring trace amounts are allowed in foodstuffs.

All cannabis cultivated in a private place for a person's own use may only be used by the grower/ cultivator and may not be sold/supplied to others.

A. Are the rules different for medical vs. adult recreational use?

See above.

B. Are retail sales of any cannabis products restricted to specific retail channels? E.g., medical dispensaries, government-owned stores, etc.

See above.

C. Are there zoning restrictions on where medical, wellness, or adult-use (recreational) outlets can be located? Applicable to all cannabis products?

No recreational outlet is permitted. No zoning restrictions as far as we are aware in terms of building regulations, of course the Medicine Act restrictions would apply.

7. What import and export is allowed in your jurisdiction?

In general no person, other than a pharmacist, pharmacist intern or pharmacist's assistant acting under the personal supervision of a pharmacist, shall sell (which includes importing) or export a Schedule 1, Schedule 2, Schedule 3, Schedule 4, Schedule 5 or Schedule 6 substance for analytical purposes, manufacture of foods, cosmetics, educational or scientific purposes, unless a permit, issued in accordance with the prescribed conditions has, subject to paragraph (b), been obtained from the Director-General for such purpose. This provision will apply relevant to the schedule the product one is trying to import/export is locating in.

Thus, CBD, as an active pharmaceutical ingredient (API) intended for the production of a medicine, is currently listed as a Schedule 4 substance in the Schedules to the Medicines Act and has not been excluded except as outlined in the Exclusion Notice. An importer of CBD, as an API or raw material, must be in possession of a section 22C(1)(b) licence issued by SAHPRA.

Manufacturers and importers of CBD-containing processed products which fall within the parameters of paragraph (b) of the Exclusion Notice, and which are not intended for medicinal purposes, do not require a licence to manufacture or import in terms of section 22C of the Medicines Act, but must be able to provide verifiable proof of the CBD and/or THC content of the product and comply with the provisions of other applicable legislation (for example, the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 "Foodstuffs Act").

A. Are there restrictions in relation to the countries of origin, i.e. which countries of origin are permitted?

None.

B. Please describe restrictions on the import of cannabis seeds.

See above, read with the fact that processed cannabis seed products (e.g. hemp seed oil, cosmetics containing hemp seed oil) are specifically excluded from Schedule 7 of the Medicines Act when: (a) the THC concentration is ≤ 0,001 % and (b) the product does not contain whole cannabis seeds. Therefore, inferring that cannabis seeds may not be imported.

8. Does your region distinguish between different types of cannabis products? (E.g., high or low concentrations of THC.)

Yes.

A. If so, what distinctions exist?

Cannabis (the whole plant or parts or products thereof) and THC are currently listed as Schedule 7 substances in terms of the Medicines Act, 1965, except when present in processed hemp fibre and products thereof, in a form not suitable for ingestion, smoking or inhaling purposes, and containing not more than 0,1 % THC; or when present in processed products from cannabis seed containing not more than 0.001 % THC; or when separately specified in Schedule 6 for therapeutic use.

Synthetic cannabinoid substances are also listed separately in Schedule 7.

THC (also known as the synthetic variant, dronabinol) is listed in Schedule 6, when intended for therapeutic purposes.

CBD is listed as a Schedule 4 substance. Certain CBD preparations have been excluded from the operation of the Schedules by the Minister of Health for a time-limited period, as mentioned above.

B. If so, briefly describe the differences.

Schedule 7 substances are deemed to have no legitimate medicinal use and can only be accessed by means of a permit issued by the Director- General of the National Department of Health (NDoH). Medicines and substances categorised as Schedule 4 or Schedule 6 are only available on the prescription of an authorised prescriber and can only be obtained from a pharmacy or the holder of a dispensing licence issued in terms of the Medicines Act.

C. Identify any related laws that should be considered when answering this question.

Drugs and Drug Trafficking Act 140 of 1992 and Prevention of and Treatment for Substance Abuse Act No. 70 of 2008.

9. Are there legal requirements on Cannabidiol (CBD) products (without THC)?

Cannabidiol, when intended for therapeutic purposes is a schedule 4 medicine in terms of the Medicines Act.

IV. Patients and prescriptions

10. What specific medical conditions, if any, are recognized for treatment with cannabis?

None.

11. Is there a licensed practitioner requirement in order to prescribe cannabis for medical purposes?

Yes, one must be a medical practitioner and comply with the Medicines Act.

12. Are there patient registration or cardholder requirements?

Yes, in terms of the Medicines Act, a medical practitioner must get a permit for a particular patient.

V. Special requirements

13. Does your jurisdiction require any recordkeeping from seed planting to the time of end user sale? For all cannabis products?

Not for recreational products, but for medicinal products, yes.

14. Are special taxes imposed? On what and when?

Not as far as we are aware.

15. Are there any special rules or limitations that apply to the industry? E.g., banking, patent or trademark protection, labeling requirements.

Normal rules would apply, for example, the labelling requirements for medicines in terms of the Medicines Act and for foodstuffs in terms of the Foodstuffs Act.

16. What is the legal status of access to financial services, including banking, merchant services, and cash handling?

There is access.

17. Is data collected to determine the social or health impact of the rules in your jurisdictions? E.g.,

A. Impact on use by under age/minors.
B. Impact on beer, wine and spirit sales.
C. Tax revenue.
D. Impact on crime, including drug and alcohol addiction.

Not as far as we are aware.

VI. Risks and enforcement

18. What are the most critical issues currently facing the industry in your jurisdiction?

The need for legal certainty.

19. What is the current enforcement landscape with respect to cannabis? E.g., strict enforcement, low-enforcement, decriminalization, legalization.

As mentioned above, until more detailed provisions are made regarding the personal use of cannabis, South Africa's law enforcement officials have the discretion to decide whether the amount of cannabis in a person's possession could reasonably be believed to be more than what is necessary for private use. If so, the individual could be considered to be "dealing" in cannabis in contravention of the Drugs and Drug Trafficking Act 140 of 1992. This will of course be effected by what product type the cannabis is in.

For the medical use of cannabis in South Africa, enforcement with the law is strict.

A. Does enforcement differ based on quantity?

Yes, see above.

B. Does enforcement differ based on product type?

Yes, see above.

VII. Your practice and useful links

20. Tell us a little about your cannabis practice and how it interacts with other practices at your firm. Remember to include any recognition awards your firm has received in this practice area. How much experience does your firm have providing services to cannabis companies and how much interest does your firm have to grow its cannabis practice?

Since regulation in South Africa is new, no one has immense experience. We have a very keen interest of growing our cannabis practice as the industry grows in South Africa.

21. Please provide links to any firm website, blogs, reputable trade publications, or attorneys that would help others understand the state of the law in your jurisdictions.

A. Are there any relevant trade organizations?

No.

B. Are there any relevant lobbying organizations?

No.

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