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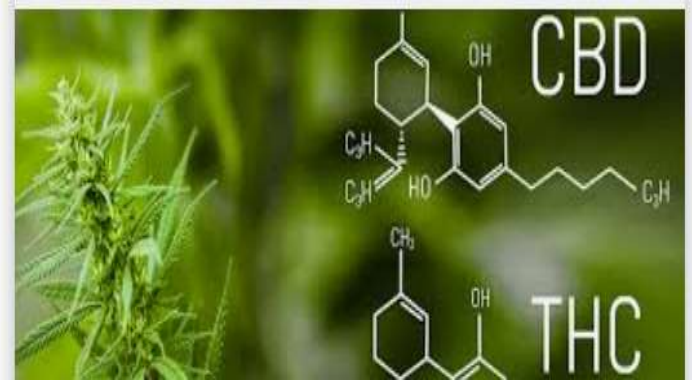
Status of Cannabis in RSA

30 June 2022

International Expert Hearing on Cannabis Legislation on 30 June 2022

Outline

- Background
- Legislative Frameworks and status of cannabis & cannabinoids
  - Licenses, permits & products



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RSA Context

- What is the current legal situation on medical and recreational cannabis in South Africa?
- How does RSA ensure the participation of traditional actors (e.g. formerly illegal cannabis farmers, members of indigenous communities, those convicted of possession of small amounts) in the regulated cannabis market?

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Background on control framework

The increased global interest in cannabis together with the 2018, Constitutional Court judgement on cannabis led to review of relevant legislation

- The sale, supply and use of a medicine or scheduled substance are regulated by the Medicines and Related Substances Act, 1965 (Act 101 of 1965 as amended), and supporting Regulations
- There is a cannabis Bill for private purpose intending to address private and non-medical use (in process)
- Industrial use of low THC cannabis/Hemp is regulated via Agriculture under the Plant Improvement Act

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Legislative Amendments and Government Depts

Department	Relevant Legislation	Amendments which may be required
Health	Medicines and Related Substances Act ,1965 (Act 101 of 1965)	Schedules
Department of Justice and Constitutional Development	Drugs and Drugs Trafficking Act, 1992 (Act 140 of 1992)	• Section 4(b) • Part III of Schedule 2
	Cannabis for Private Purposes Bill	• New Bill proposed, currently in Parliament
Department of Agriculture, Land Reform and Rural Development	Plant Improvement Act, 1976 (Act 53 of 1976)	• Designate hemp as being subject to this legislation • Allow for the regulation of hemp for industrial (non-medicinal) purposes.
Department of Health	Traditional Health Practitioners Act, 2007 (Act 22 of 2007)	• Enable cultivation and extemporaneous preparation of cannabis as a category I medicine
	Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972)	• Promulgate regulations defining allowable cannabinoids and quantities in foodstuffs and cosmetics
	Mental Health Care Act, 2002 (Act 17 of 2002)	• Address relevant mental health management issues

Public Health 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 development to ensure that patients have access as early as possible to safe and effective medicines.

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Summary of amendments to Schedules in terms of the Medicines Act (1/2)

- Published in Government Notice No. 586, Government Gazette No. 43347, on 22 May 2020 relating to:
  - Removal of **Cannabis Plant** from Schedule 7
  - Listing of the psycho-active substance tetrahydrocannabinol (THC) in Schedule 6
  - Cannabidiol (CBD) is listed in either Schedule 4 or 0 depending on medical claims and concentration in the finished product
  - Cultivation of cannabis for medicinal use would only require a section 22C(1)(b) licence to cultivate
- Specific exemptions made for industrial application of low-THC cannabis/hemp which contains 0,2 % or less of THC as a raw plant material
- Products made from cannabis containing ≤ 0,001% THC with no medical claims are excluded from schedules of the Medicines Act.
- The cultivation of low-THC cannabis (commonly referred to as Hemp) falls outside the remit of the Medicines Act, to be regulated and controlled by the **Department of Agriculture, Land Reform and Rural Development**
- SAHPRA handed over ~160 permits DALRRD

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Summary of amendments to Schedules in terms of the Medicines Act (2/2)

CBD is a Schedule 4 substance

- Medical claims proven by scientific studies are made

- CBD at low doses with general health claims is Schedule 0
  - In complementary medicines with ≤ 600mg of CBD per sales pack, providing a maximum daily dose of 20 mg of CBD. i.e. health products with **low doses** of CBD and **only general health enhancement or maintenance claims**, are **schedule 0**.
  - processed products made from cannabis raw plant material intended for ingestion containing ≤ 0,0075% of CBD in naturally occurring quantity of cannabinoids found in the source material are contained in the product
  - CBD as an added ingredient is not permissible under complementary medicines

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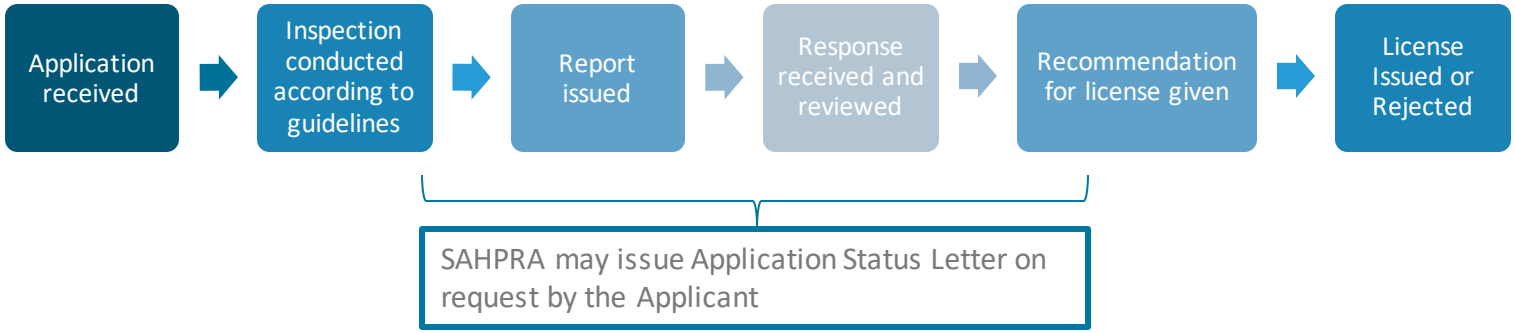
Licensing process



- Over 65 facilities are licenced for cultivation, manufacture and for export market with
- SAHPRA has given applicants time and guidance to comply with the medicines regulatory framework as the framework is relatively new for all.
- Applicants may request a SAHPRA application status letter, which states areas that applicants has complied with the regulatory requirements and areas where there are still gaps to be addressed prior to issuance of a regulatory decision.
- Currently there are no registered THC/CBD products and authorization of medical products is either in terms of Section 21 or as complimentary medicine as published in Gov Notice of May 2020

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Hemp / Low THC Cannabis

- Health & SAHPRA has handed over the control of the cultivation of low-THC cannabis for industrial purpose to Dept of Agriculture (DALRRD)
- All matters related to the cultivation of to low-THC cannabis will fall under the mandate of DALRRD, except when the cultivation of low-THC cannabis is intended for medicinal use.
- SAHPRA and Health continues to support DALRRD until it can fully implement the function.
- DALRRD also coordinates the National Cannabis Master Plan following the Cabinet decision of 2019.

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In 2018, Constitutional Court declared

- sections 4(b) (possession) and 5(b) read with Part III of Schedule 2 of the Drugs and Drug Trafficking Act, 1992 (the Drugs Act); and
- section 22A(9)(a)(i) of the Medicines and Related Substances Act, 1965, read with Schedule 7 of Government Notice No. R. 509 of 2003,
- unconstitutional on the premises that they amount to an impermissible limitation of the right to privacy.

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Some points of Court order

- The cultivation of cannabis by an adult in a private place for his or her personal consumption in private is no longer a criminal offence.
- In determining whether or not a person is in possession of cannabis for a purpose other than for personal consumption, an important factor to be taken into account will be the quantity of cannabis found in his or her possession.
- Where a person is charged with possession of cannabis, the State will bear the burden to prove beyond reasonable doubt that the purpose of the possession was not for personal consumption.

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Stakeholder engagements

- Between 2019 to date several meetings to discuss the implications and way forward were held on ongoing basis consisting of: SAHPRA,DOH,DALRRD,DOJCD, DSI,DSBD, DTIC,IDC, SAPS, Non-govt, interest groups, civil society etc. Forums such as MAC and IMC on cannabis were established; and the Cannabis Master Plan to enable a policy decision. Discussions are still ongoing
- Several Webinars and conferences between 2019-2022 educating and creating awareness on the amendments and implications have been held Hosts ranging from cannabis interest groups, business, government departments, science organizations, religious organizations, traditional leaders, civil society to media organisations.
- RSA continues to actively engage with INCB regarding:
  - status of medical cannabis research, cultivation and production
  - RSA participates in INCB lead development of global guidelines for cannabis to help countries understand requirements
  - RSA also engages with other regulatory organization on sharing ideas and experiences

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NATIONAL CANNABIS MASTER PLAN

- In 2019, the South African Cabinet endorsed the Re-imagined Industrial Strategy (RIS).
- The RIS re-emphasizes the role of the state in changing the growth trajectory of the South African economy through supporting improved industrial performance, competitiveness and job creation.
- Industrialization through Master Plans is one of the five growth engines which underpins the RIS.
- The Cannabis Master Plan (CMP) therefore responds to the RIS with the objective of increasing inclusive economic growth, creating jobs and alleviating poverty through the industrialisation and commercialization of Cannabis.

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NATIONAL CANNABIS MASTER PLAN

- The following priority areas have been identified in order to develop a framework in support of the industrialization and commercialization of Cannabis:
  - Sustainable seed supply systems & producer support systems;
  - Product development and Processing (including Research Development and innovation);
  - Market and supplier development;
  - Regulatory systems;
  - Education and training; and
  - Communication and awareness
- Consultation continues towards finalizing the CMP with private sector, labour and community constituencies.
- One of the major milestones achieved to date is the declaration of hemp (THC content of no more tan 0.2%) as an agricultural crop

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Permits

- Licence holders need permits for **possession, manufacture, export and import for** THC containing substances in terms of Section 22A(9)(a)(i) or Section 22A(11) of the Medicines Act
- Permits are also issued to **enable R&D on Cannabis for medicinal research**
  - These are largely issued to the local research / academic institutions
- **RSA licence holders exports** to countries such as Canada, USA, Portugal, Israel, Switzerland, Macedonia, Lesotho, Zimbabwe, Germany and the United Kingdom

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Thank you