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Wesgro Webinar - Cannabis

Scheduling of Cannabis and Specific Cannabinoids
Momeena Omarjee
22 April 2021

Licensing Process for Cultivation of Cannabis for Medicinal Purposes
Daphney Fafudi
22 April 2021

Presentation Outline

- SAHPRA's legal remit
- Regulatory framework for scheduling and control
- International legal status of cannabis
- Legal status of cannabis in SA
- Current cannabis inscription
- Low-THC cannabis (hemp)
- Cannabidiol
- Cultivation of cannabis for medicinal use
- Scenarios
- Licence application, review and inspection
- Updates on licence applications

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South African Health Products Regulatory Authority (SAHPRA)

- Responsible for the regulation of all medicines, including complementary medicines, medical devices and radiation control
- Mandated and governed by the Medicines and Related Substances Act, 1965 (Act 101 of 1965), as amended, and the schedules and regulations thereto, together with the guidelines made in terms of this Act.

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Scheduling and Control of Medicines: General Principles

- Allows for different *levels of regulatory control* over substances, whether in the form of naturally-occurring substances, APIs, or finished pharmaceutical products (medicines).
- Primary consideration is *safety* in relation to therapeutic use.
- Substances may 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 to which South Africa is signatory (1961/1971/1988).

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International Legal Status of Cannabis

- South Africa is a signatory to the UN *1961 Single Convention on Narcotic Drugs*, the *1971 Convention on Psychotropic Substances*, and the *1988 Convention against Illicit Traffic in Narcotic and Psychotropic Drugs*.
- Under the *1961 Single Convention*, cannabis is classified under Schedules I and IV making it subject to special restrictions.
- The *International Narcotics Control Board* (INCB) monitors member states compliance with:
  - regulatory frameworks for enabling medical and research access
  - regulatory procedures for licensing and registration of suitable products
  - control systems for commercial cultivation of cannabis
  - specification of cannabis varieties which may be authorised for cultivation

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Status of Cannabis Schedules in South Africa

- Amendment to Schedules published in Government Notice No. 586, Government Gazette No. 43347, issued on 22 May 2020

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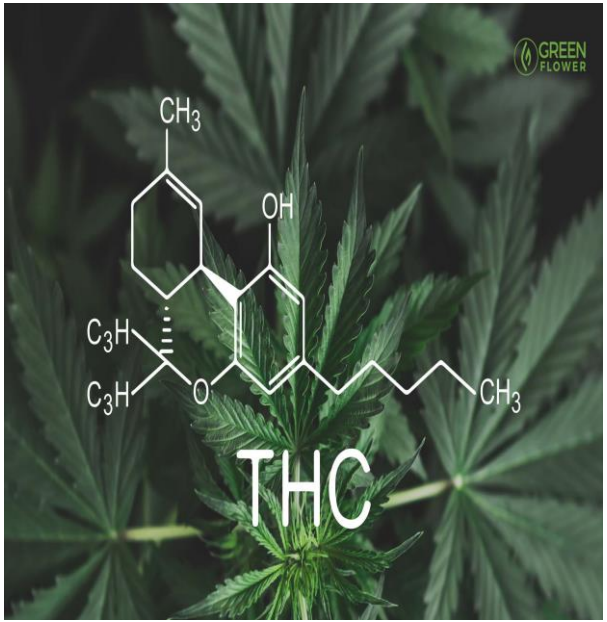
Amendment to Schedules
THC

- Previous entries for **cannabis, dronabinol,** and **tetrahydrocannabinol** in Schedule 7 have been deleted
- **(-)-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.



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Clarification of the Amendment
THC

Cannabis plant is removed from Schedule 7 (reserved for illicit substances)

- the psycho-active ingredient THC is listed in Schedule 6 , with specific exemptions made for industrial application of low-THC cannabis.
- personal use of the cannabis plant by an adult, in private, is enabled in accordance with the 2018 Constitutional Court judgment.

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Implications of the Amendment
THC

- Cannabis is still a prohibited drug in terms of the Drugs and Drug Trafficking Act until commercialisation/ industrialisation is permitted by law

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Implications of the Amendment
Low-THC Cannabis (Hemp)

- Low-THC cannabis (raw material) and the processed product from the raw material is now **excluded** from the schedules **provided** that the raw material and the processed products:
  - do not contain more than **0,2 percent of THC**;
  - Are intended for industrial processes and not suitable for ingestion.
- **Processed products** made from low-THC cannabis are ***excluded*** from the Schedules provided that the processed products :
  - do not contain more than **0,001 percent of THC;**

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Implications of the Amendment Low-THC Cannabis (Hemp)

- The requirement to obtain a Section 22A(9)(*a)*(i) permit issued by the Director-General of Health to acquire, use, possess, manufacture or supply low-THC cannabis falls away.;
- the cultivation of low-THC cannabis falls outside the remit of the Medicines Act, to be regulated and controlled by the **Department of Agriculture, Land Reform and Rural Development**;

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Implications of the Amendment
THC for Medicinal Use

- The commercial cultivation of cannabis for medicinal use and the manufacturing thereof still requires:
  - Section 22C(1)(b) licence issued by SAHPRA and is outlined in the guideline "Cultivation of cannabis and manufacture of cannabis-related pharmaceutical products for medicinal and research purposes"
  - Section 22(9)(*a*)(i) permit from the DG of Health for schedule 6 manufacturing.

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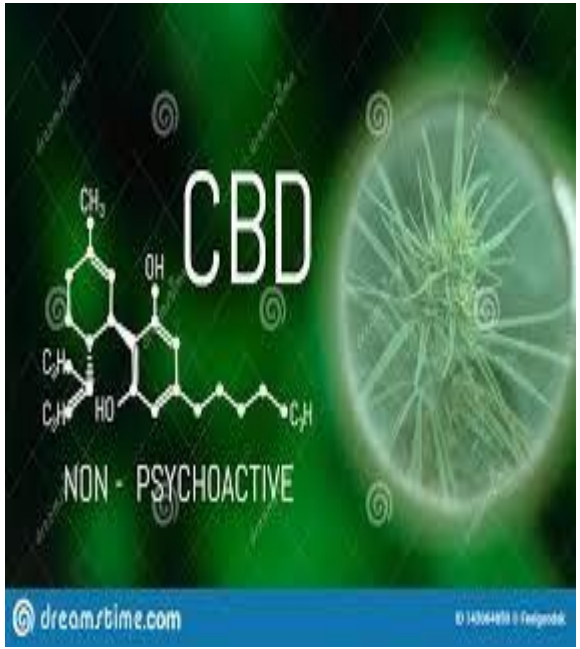
Amendment to Schedules
CBD

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 (S0); **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 (S0)



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Clarification of Amendment to Schedules

- Variations from exclusion notice (published in May 2019):
  - Complementary Medicine (Category D) is specified in in (a)
  - Maximum concentration and pack size of 600 mg stipulated

- Daily dose limit of 20 mg remains the same
- The exclusions for CBD-containing processed products (b) remain the same
- CBD-containing products that meet the listed conditions will be regulated as **Schedule 0**
  - This allows for their free sale without any need for prescription or control over the circumstances of sale.
  - However, they will remain subject to the Medicines Act if they meet the definition of a medicine (in this case, a complementary medicine).

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Clarification of Amendment to Schedules

Products that have substances listed in Schedule 0 are not necessarily registrable as medicines

Preamble to Schedule 0

All substances referred to in this Schedule are excluded when specifically packed, labelled, sold and used for –

(i) industrial purposes including the manufacture or compounding of consumer items or products which have no pharmacological action or medicinal purpose, and which are intended to be ingested by man or animals as a food or applied to the body as a cosmetic, and which are approved for such use in terms of the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972) or that are registered in terms of the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act, 1947 (Act 36 of 1947); and

(ii) analytical laboratory purposes.

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Clarification of Amendment to Schedules

A. **Allows for the listing and eventual registration of CBD containing complementary medicines as Schedule 0 with conditions;**

Paragraph (*a*)

- Complementary medicines must satisfy the conditions prescribed in either paragraph (*a*) or (*b*).
- **Does not** exclude any CBD-containing products which contain any other APIs, including THC
- Manufacturers and importers of a CBD containing complementary medicine must be in possession of a licence issued in terms of **section 22C(1)*(b)*** of the Medicines Act and comply with the relevant standards
- Such persons must be able to present verified assessment by an accredited laboratory, licenced in terms of section 22C(1)*(b)* of the Medicines Act of the CBD and/or THC content of any medicinal product, when requested to do so by the Authority.

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Clarification of Amendment to Schedules

B. Allows exceptions to a Schedule 4 listing of processed products made from cannabis raw plant material, where only the naturally occurring quantity of cannabinoids found in the source material are contained in the product, and which contain not more than 0,0075 % total cannabidiol (CBD)

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Clarification of Amendment to Schedules

Paragraph (*b*)

- A processed product containing only the naturally occurring trace amounts of **CBD (≤ 0,0075 %) in the source material,** is regarded as Schedule 0, when the product does not make any medicinal claim;
- **Extracted CBD as an added ingredient to a processed product is not permissible**
- Manufacturers and importers of CBD-containing processed products, which fall within the parameters of paragraph (*b)*, and which are not intended for medicinal purposes, do not require a licence to manufacture or import in terms of section 22C of the Act.
- **However**, they 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

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Implications of the Amendment

- Sale of unregistered CBD-containing complementary medicines is allowed **provided** that the products comply to the criteria set out in the schedules and the licensing, labelling and GMP requirements for complementary medicines
- Call-up notice for registration of CBD-containing complementary medicines will trigger registration of products

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Implications of the Amendment

Proliferation of CBD-containing products on the market

- purported medicinal products
  - claiming treatment for a variety of diseases and symptoms
- CBD-containing foodstuffs and cosmetics
  - claiming treatment for a variety of diseases and symptoms
- Intentionally mislabelled products
  - claiming low THC, low CBD
- Aggressive marketing and false advertising
  - Using logos, cartoons, pictorials

These are all illegally manufactured and distributed without regulatory oversight and often with unverified contents

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Cannabis Legislation in South Africa

- Provisions of the Convention are enacted within domestic legislation
- SA has implemented pathways permitting licensed activities and use of narcotic drugs and psychotropic substances for medical and scientific use.
- This is to ensure that accurate data on licensed activities (e.g. cultivation) and the production of controlled drugs accurately reflect the national estimates and assessments reported to the INCB by Competent National Authorities
- DOH and SAHPRA are under obligation to establish efficient, accountable and transparent systems for regulatory oversight of the supply chain, prioritising public health and safety and minimising the risk of diversion of all controlled substances, including cannabis.

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Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes

Key elements:

- Licensing of growers to enable ***controlled cultivation*** of high-THC or high-CBD cannabis
- Licensing of manufacturers to enable **controlled manufacture of cannabis-containing products**
- Availability of *standardised, quality-assured* herbal material and products for medical, scientific and research purposes.
- Clinical decision-making support for approval of medicinal use.
- Review and approval of clinical trials and related scientific research.

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Cultivation of Cannabis and Manufacture of Cannabis-related Pharmaceutical Products for Medicinal and Research Purposes

- Provides guidance on *minimum standards* required, in terms of:
  - Quality
  - Security
  - Quality systems
  - Personnel
  - Buildings and facilities
  - Compliance and enforcement
  - Documentation
- Identifies the *critical* production steps that are needed to ensure a product of reliable and reproducible quality.
- Subject to *strict monitoring* to avoid any unintended use.
- SAHPRA inspectors conduct *compliance* investigations and inspections of applicants for licensed cultivation sites.

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Cannabis for Medicinal Use Licence

- Currently, the commercial cultivation of cannabis for medicinal purposes requires:
  - a licence in terms of section 22C(1)(*b*) from SAHPRA; and
  - a Section 22A(11) and a section 22(9)(*a*)(i) permit from the DG of Health for manufacturing, acquisition, use, possession, import/export of schedule 6
- A licence may be issued for any or all of the following activities:
  - *Cultivate cannabis and produce 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 product.*

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Licence Scenarios

Cultivate cannabis for medicinal use and export bulk cannabis)
(sell or export to other licence holders or authorised overseas vendors)

Cultivate cannabis for medicinal use, process, package the herbal raw material and export
(export to authorised overseas vendors)

Cultivate cannabis for medicinal use, extract CBD/ THC, and manufacture a registered cannabis-containing medicine

Extract CBD/ THC/ other cannabinoids from cannabis plant
(sell to other licence holders or authorised overseas vendors)

Extract CBD/ THC/ other cannabinoids from cannabis plant and manufacture a registered cannabis-containing medicine

Extract CBD/ THC/ other cannabinoids from cannabis plant and to manufacture a CBD-containing processed product

Import a THC-containing medicine (Also require a Section 11 import permit for schedule 6 substances)

Import a CBD-containing medicine

Manufacture a registered cannabis-containing medicine (using localy procured or imported API)

Import CBD as a raw material (API)

Analytical Testing of cannabis starting materials, intermediates, bulk (cannabis herbal material) and/or finished product (cannabinoid-containing medicine)

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Section 22A(9)(*a*)(i) permit + Section 22C licence

Possess and cultivate cannabis for medicinal use and export bulk cannabis)

(sell or export to other licence holders or authorised overseas vendors)

Possess and Cultivate cannabis for medicinal use, process, package the herbal raw material and export

(export to authorised overseas vendors)

Possess and Cultivate cannabis for medicinal use, extract CBD/ THC, and manufacture a registered cannabis-containing medicine

Possess and Extract CBD/ THC/ other cannabinoids from cannabis plant

(sell to other licence holders or authorised overseas vendors)

Possess and Extract CBD/ THC/ other cannabinoids from cannabis plant and to manufacture a registered cannabis-containing medicine

Possess THC extract and manufacture a registered cannabis-containing medicine

Analytical Testing of cannabis starting materials, intermediates, bulk (cannabis herbal material)

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Section 22C licence

Import a THC-containing medicine (Also require a Section 11 import permit for schedule 6 substances)

Manufacture a registered CBD-containing medicine

Import a registered CBD-containing medicine

Import CBD as a raw material (API)

Analytical Testing of finished product and cannabinoid-containing medicine

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Section 22A(9)(*a*)(i) permit

Acquisition, use, possession of cannabis and cultivation of low-THC cannabis (hemp)

Acquisition, use, possession for research , scientific or educational purposes

Acquisition, use, possession, supply by a medical practitioner for the treatment or prevention of a medical condition in a particular patient

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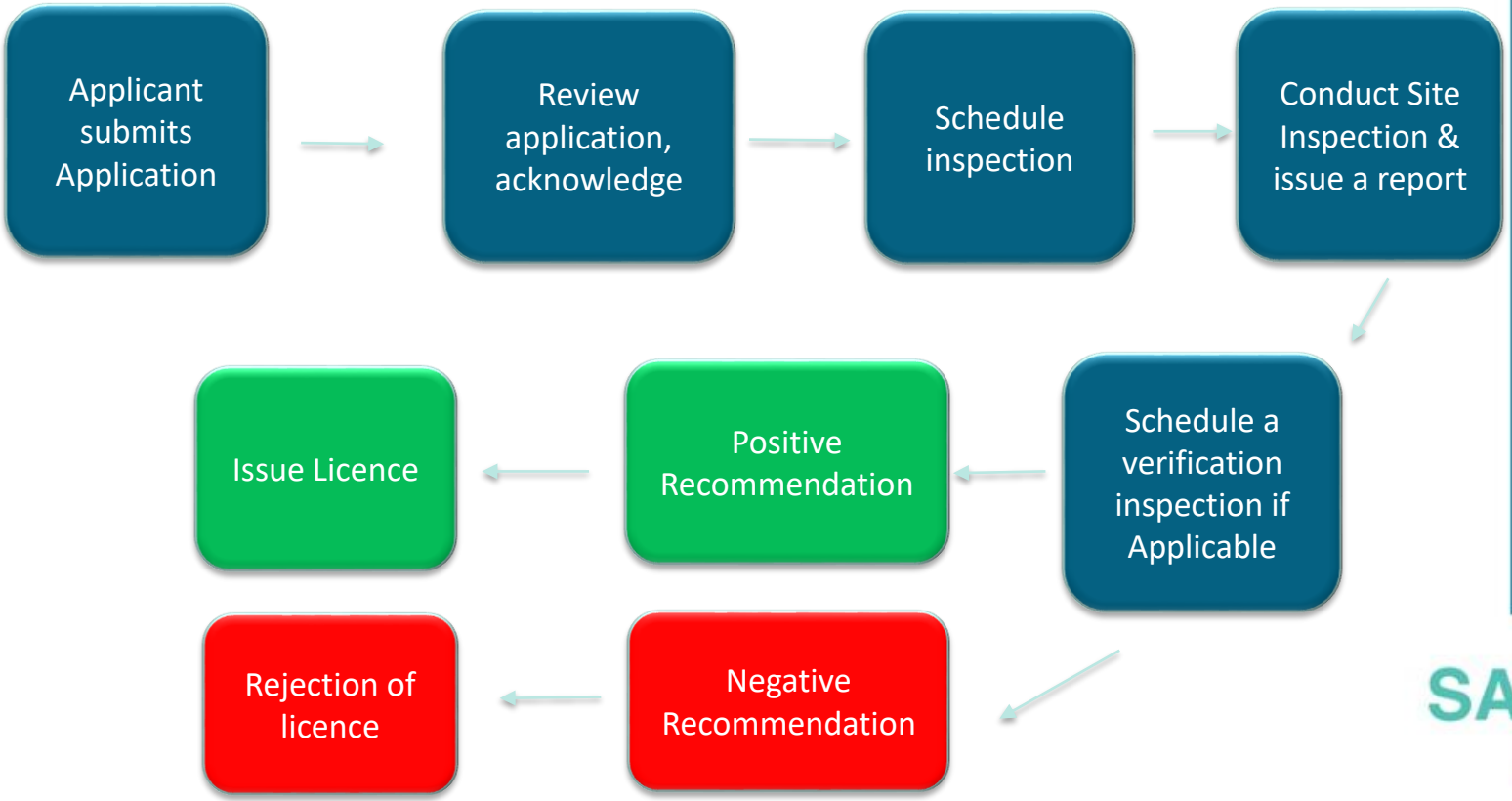
Cannabis Licensing Process



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Costs of Cannabis Licence Application

- R25 200
- SAHPRA does not dictate cost of compliance to the guidelines
- The applicant's readiness is demonstrated by the QMS systems in place/ ability to produce a quality & safe product for the specific market as per off-take agreements.

N.B If there is no valid market: no licence will be issued (INCB reporting on consumption)

- SAHPRA is engaging with relevant stakeholders to ensure SAHPRA complies with its mandate whilst still being enabling to the industry

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Applications to Date

206 (22 received between December & April)

Province	Numbers	Resolutions for Licence	Licenses issued
Gauteng	58	15	11
Limpopo	11	3	3
KwaZulu-Natal	42	3	2
Eastern Cape	16	4	3
Western Cape	49	6	4
Mpumalanga	10	1	1
North West	11	1	1
Northern Cape	4	1	1
Free State	4	0	0
TOTAL	**206**	**34**	**26**

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Licences Issued

No.	NAME OF COMPANY	ADDRESS	Licence issue date
1	Leaf Botanicals (Pty) Ltd	Northern Cape	2020/10/21
2	Felbridge (Pty) Ltd	Western Cape	2020/10/09
3	Thusanang Enabling Support Services (Pty) Ltd	KwaZulu-Natal	2020/10/16
4	Southern Right Naturals (Pty) Ltd	Gauteng	2020/10/21
5	Afriplex (Pty) Ltd	Western Cape	2020/08/17
6	House of Hemp (Pty) Ltd	KwaZulu-Natal	2020/10/09
7	Africannabis Holdings (Pty) Ltd	Eastern Cape	2020/10/16
8	El Passo Farm/ Big Cedar	Gauteng	2020/10/16
9	Medcan (Pty) Ltd	Gauteng	2020/10/23
10	Cannsun (Pty) Ltd	Western Cape	2020/10/16
11	Zandrivier Boerdery CC	Limpopo	2021/02/18
12	Cilo Cybin Pharmaceutical	Gauteng	2020/10/16
13	CBD Full Spectrum Manufacturers International (Pty) Ltd	Gauteng	2020/10/21
14	Hydro Crop (Pty) Ltd	Gauteng	2020/10/16

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Licences Issued

No.	NAME OF COMPANY	ADDRESS	Licence issue date
15	HEMPCO (Pty) Ltd	Gauteng	2020/10/26
16	Sweet Water Aquaponics	Eastern Cape	2020/10/22
17	Titi Medical (Pty) Ltd	Limpopo	2020/10/27
18	Healthcann Grow (Pty) Ltd	Eastern Cape	27/10/2020
19	Farmer Growers	North West	2020/12/04
20	Silverleaf	Gauteng	2021/04/14
21	First Growth	Western Cape	2021/02/23
22	Biogest Laboratories Pty Ltd	Western Cape	Not yet issued
23	SafriCanna	Gauteng	2020/12/11
24	Medi Extract (Pty) Ltd	Gauteng	2020/12/02
25	Origo International Holding	Gauteng	2021/02/01
26	CannaPharm SA (Pty) Ltd	Limpopo	2021/04/14
27	Mercurial	Mpumalanga	2021/03/23
28	Aurora (Pty) Ltd	Western Cape	Not yet issued

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Progress on Licences Issued

- 34 resolutions issued and of those 26 licences are Issued
  - Applicants can start relevant activities for cultivation e.g. seeds acquisition processes etc.
- Less than 10 companies have started cultivation activities
- 3 companies are ready to export their product
- Most facilities that have been Inspected did not meet the minimum requirements
- A number of applicants postponed inspection dates due to a lack of readiness

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Contact Details

Names and Scheduling

- Ms Momeena Omarjee momeena.omarjee@sahpra.org.za

Regulatory Compliance (Cannabis Licencing and Permit Queries)

- Ms Daphney Fafudi mokgadi.fafudi@sahpra.org.za
- Mr Mlungisi Wondo mlungisi.wondo@sahpra.org.za
- Mr Ramarumo Chepape ramarumo.chepape@sahpra.org.za

Executive

- Dr B Semete boitumelo.semete@sahpra.org.za
- Ms P Nkambule portia.nkambule@sahpra.org.za

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THANK YOU