



SOUTH AFRICAN CANNABIS COMMUNITY & REGULATORY ASSOCIATION

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PROPOSAL FOR THE REGULATION OF COMMERCIAL CANNABIS

Because Cannabis has so many diverse and easily accessible benefits, a legal Cannabis industry has the capacity to radically benefit all South Africans in many ways if implemented with equality of opportunity.

Raw Cannabis is self-regulating and so needs very little interference from the law. However, Cannabis extracts, although extremely safe and effective when properly made, need more regulation as the integrity of the natural plant can easily be compromised through the use of inferior solvents and extraction methods. It is essential therefore that any extraction intended for therapeutic purposes by ingestion be regulated for the protection of both the public and the integrity of the medicine itself.

Due to Cannabis Sativa L. the whole plant and all components of the plant being on Schedule 7, no-one other than the Director-General of the Dept of Health for a specific medical practitioner (doctor) for a particular patient or for research or educational purposes, can access Cannabis. The only exception is for personal use by an adult in a private setting.

It is therefore clear that the only way to responsibly implement an equitable Cannabis industry in this country is to re-schedule the plant immediately to **Schedule 0** and to regulate the sale and production of Cannabis and Cannabis products through licensing growers, manufacturers and sellers within an appropriate system. This system can be simple, affordable and equitable.

“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.

The sale of Cannabis flowers to children under the age of 18 can be specifically excluded and Cannabis extracts for treatment purposes can be specifically restricted to under the care of a registered medical practitioner, traditional healer or natural medicine practitioner.

Once an evidence based, responsible industry has been established, it is then viable to remove the plant from the schedules of the Medicines Act and therefore the Drugs Act altogether.



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REGULATION OF SALES

TIER ZERO LICENSE – CULTIVATION LICENSE

This license is for growing Cannabis for commercial purposes to supply licensed retailers only and does not include the sale of Cannabis to the public unless coupled with a Tier One license as well.

We recommend the cost of the license be R1 000/acre under cultivation annually.

The applicant can submit GPS co-ordinates of the land for verification. A general license like this can cover growing for medicinal and/or industrial purposes. The growing methods will simply vary accordingly. Until evidence is supplied that Cannabis does not store any toxins or harmful substances accumulated from the soil/environment, soil testing and testing of the flowers for medicinal purposes can be a condition of the license. This will make it possible for many small growers to be included in the industry in cities, townships and sovereign lands as sole proprietors or independent micro-industries.

TIER ONE – RETAIL LICENSE

This license is for the sale of raw Cannabis to members of the public identified to be over 18 years of age, in any form when its use is not intended for therapeutic purposes. This includes dried, cured flowers for smoking or eating, and any food, drink or any other product containing Cannabis or components of Cannabis not intended for therapeutic purposes. This license will be regulated under the Foodstuffs, Cosmetics and Disinfectants Act, 1972 (Act 54 of 1972).

We recommend the cost of the license be R2 500 per annum per outlet.

An outlet is any singular entity i.e. individual of legal age or shop selling raw Cannabis. This will make it possible for many small sellers and tertiary producers to be included in the industry and will allow adults of all social and economic status to generate income from their homes in cities, townships and sovereign lands as sole proprietors or independent micro-industries, without the necessity for capital outlay.

TIER ONE - PRODUCTION LICENSE

This license includes the sale of natural Cannabis extracts by trained and accredited producers, to Tier 2 and above license holders only (not the public) and full extract Cannabis oil for sale to Tier 3 license practitioners only. Batch testing will be obligatory. This will ensure the production of the highest quality oils.

We recommend the cost of the license be R2 500 per annum per producer.



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TIER TWO LICENSE – FOR THE SALE OF CANNABIS AND NATURAL CANNABIS EXTRACTS FOR THERAPEUTIC PURPOSES (GREEN PROTOCOL) See www.saccra.org.za

This license is for the sale of raw Cannabis, Cannabis edibles and natural Cannabis extracts such as tinctures, topical balms, and direct extract oils (reduced concentration) for therapeutic purposes where no prescription pharmaceutical drugs are engaged and when treatment is effected for listed green protocol ailments as described by the S.A.C.C.R.A. Medical Council.

This is the equivalent of “over the counter” medicines and includes everything under Tier 1 licenses as well.

We recommend the cost for this license be R5 000 per annum per accredited practitioner.

An accredited practitioner is someone who has successfully completed appropriate training and/or an apprenticeship in Cannabis treatment, such as that developed to date and to be further developed by the S.A.C.C.R.A. Medical Council.

This will make it possible for many small sellers such as Nyanga (herbalists) and accredited secondary producers to be included in the industry and create many small to medium and micro-industries across all tiers of society.

TEIR THREE LICENSE – HEALTH PRACTITIONERS LICENSE (AMBER AND RED PROTOCOL)

This license is for the sale of all Cannabis and Cannabis extracts which are intended for therapeutic purposes in the case of listed amber and red protocols i.e. where pharmaceutical drugs are being used and/or in the case of life-threatening and/or chronic diseases, by registered health practitioners i.e. medical doctors, researchers, homeopaths, nurses, pharmacists, traditional healers, and natural health practitioners, who have been further trained and certified in cannabinoid treatment. This is the only license that includes the sale of full extract Cannabis oil to the public. This license includes everything under Tier 1 and Tier 2 licenses as well.

It is recommended that funding be allocated for the development of appropriate curricula and the roll out of training that covers both the extracts and the other natural treatment protocols which have shown to contribute to healing when engaged together for all sectors.

It is also recommended that curricula be developed for a new type of layman health practitioner i.e. specialised Cannabis Health Practitioners which will be accountable to the Allied Health Practitioners Council and/or the Traditional Health Practitioners Council.

We recommend that the cost of this license be R25 000 per annum.



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This will allow for the most effective results being obtained by people who will also have access to medical industry diagnostics and therapeutic tools and will protect the public from uninformed or unscrupulous oil makers who do not understand the principles of healing or how to extract the medicine correctly.

PHARMACEUTICAL/EXPORT LICENSE (FOR THE SALE OF CANNABIS TO COUNTRIES WHERE IT IS LEGALISED)

This license is for S.A.H.P.R.A. registered, quality controlled natural extracts for export and pharmaceutical products as prescribed by current S.A.H.P.R.A. regulations.

We recommend that the cost for this license be **R 250 000** per annum for registered natural extracts and **R 1 250 000**, or to be determined by S.A.H.P.R.A. in the case of pharmaceutical products. We also recommend that the quantity of product able to be exported be subject to reasonable restrictions to preserve quality of product and equality of opportunity.

Below please see the regulatory agreements developed by the S.A.C.C.R.A. Executive Council with regards to the essential regulatory requirements to ensure a safe, beneficial, equitable Cannabis industry at local levels.

APPENDIX 1: S.A.C.C.R.A. REGULATORY AGREEMENTS

AGRI/ECO COUNCIL: GROWING

DOMESTIC, MEDICAL, ECOLOGICAL, COMMERCIAL:

1. Regulate males where appropriate.

DOMESTIC, MEDICAL, ECOLOGICAL, INDUSTRIAL, COMMERCIAL:

2. Soil testing for contaminants.
3. Cannabis used as a bio-accumulator to be destroyed or used for appropriate industrial purposes only.

MEDICAL, COMMERCIAL:

4. Use effective natural methods such as vermicomposting, Effective Micro-organisms and companion planting, and natural pesticides such as Khakibos, Marigold, stinging nettle etc. as opposed to chemical pesticides, fungicides and herbicides.
5. Absolutely, no synthetic fertilisers, fungicides or pesticides after two weeks into shutdown as any contaminants applied externally will be absorbed into the plant.



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ACCEPTED CRITERIA FOR MEDICINAL GRADE CANNABIS IN A LEGAL INDUSTRY

1. Verified, authentic genetics or seed.
2. Cloned plants to ensure genetic purity.
3. Repeatability of growing conditions as far as possible.
4. Natural fertilisers, pesticides, fungicides and nothing but water in the last two weeks of flowering.
5. Seedless, or at least minimal seeds for sale in commercial medical grade production.
6. Quality control before harvest.
 - Flowers are fully mature – more than 70% pistils browning off.
 - No bud rot, fungus or mildew.
 - High resin content, preferably high THC content (20%).
7. Harvesting, curing and packaging methods which ensure no contamination and longevity of the plant.
8. Batch numbers with date harvested and true name of genetics.
9. Specific recorded curing methods: Dried in well ventilated area out of direct sunlight; cured correctly; bottled and stored correctly.

MEDICAL COUNCIL: TESTING

Licensees agree to testing of raw plant and extracts for contaminants and cannabinoid content and ratios on a regular basis at their own cost via a S.A.C.C.R.A. accredited facility.

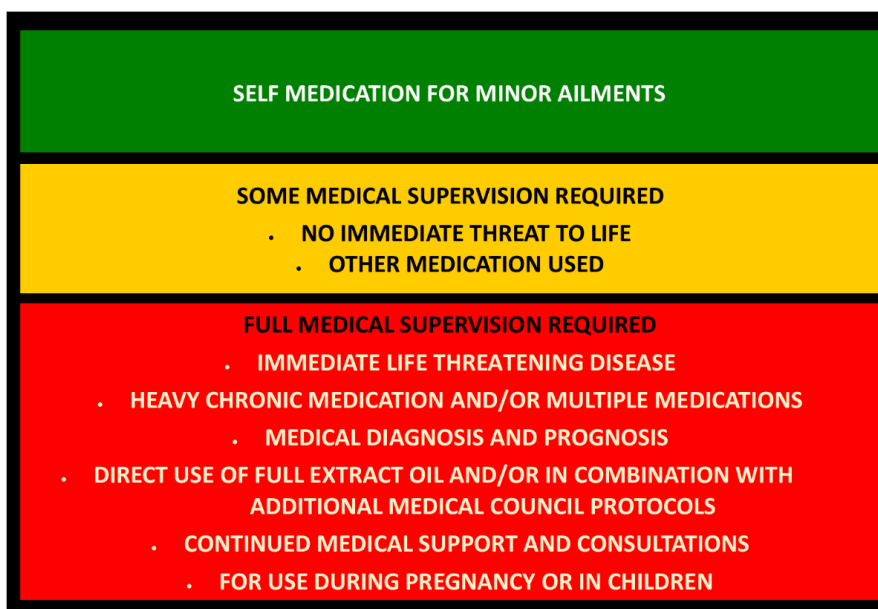
MEDICAL COUNCIL: SUPPLIER AGREEMENT

TREATMENT/REFERRAL

1. Engage directly with clients and inform them fully of the recommended supplementary protocols and treatments, as well as dosage and medical support protocols.
2. Abide by the following treatment guidelines and label products accordingly:
 - a) Suppliers agree to consult with a S.A.C.C.R.A. verified Cannabis Health Practitioner, in conjunction with the client's doctors, in the case of clients who fall in the **amber** category to ensure proper treatment protocols are followed, especially if the client is on pharmaceutical medication.
 - b) Suppliers agree to refer clients who fall in the **red** category directly to a S.A.C.C.R.A. verified Cannabis Medicine Practitioner, all of whom are well versed in Cannabis medicine, have medical knowledge, and/or use other medical protocols such as diet, ozone therapy, Vitamin C therapy, hyperbaric oxygen therapy, and who work with doctors to monitor results.



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GREEN LABEL

- This classification includes **domestic use of Cannabis and simple remedies for a range of minor to chronic ailments** and is the standard equivalent of over the counter pharmaceutical medication.
- **Full dosage instructions and protocols** to be outlined and included in all supply.
- Applications include any reduced extract e.g. tincture, topical, coconut or olive oil infusion, edibles, vape oils and tisanes.

AMBER LABEL

- This classification applies where a **medical diagnosis** has been made in the case of a serious illness such as epilepsy or asthma, and **pharmaceutical medications** are being used, especially where the intention is to wean clients off pharmaceutical medicine.
- Consultation with a S.A.C.C.R.A. verified Cannabis Medicine practitioner and the client’s doctor to ensure the best results for clients.
- Some medical support may be required to assess results.
- Full dosage instructions and protocols to be outlined and included in all supply.
- Applications include any reduced extract e.g. tincture, topical, coconut or other safe carrier oil infusion, edibles, vape oils.



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RED LABEL

This classification applies in all cases where:

- **Full extract Cannabis Oil** is used;
- **Cancer** is being treated;
- Any other **serious chronic or life-threatening illness** is being treated;
- **Prescription medication** is being used;
- **Vulnerable people** e.g. children or the aged, are being treated.

This is because full extract Cannabis Oil can have serious side effects and implications for ailing organs where the body is already under stress from disease. Most of the time, successful treatment requires other protocols to be included in treatment. Treatment at this level requires **specialised medical knowledge and support**, and failure of treatment can occur if supplementary natural treatment protocols such as an alkalinising diet and maintenance doses are not adhered to.

In certain cases, people treating cancer who are not under specialised treatment are having great success in reducing or even eliminating tumours in the short term but stop taking the medicine too early and the cancer comes back very aggressively leading to perceived product failure and even unnecessary death.

THE RULE OF THUMB FOR SUPPLIERS IS “WHEN IN DOUBT, CONSULT A S.A.C.C.R.A. ACCREDITED CANNABIS MEDICINE PRACTITIONER”. NOTE: MOST HEALTH PRACTITIONERS INCLUDING DOCTORS, TRADITIONAL AND NATURAL HEALERS ARE NOT YET FAMILIAR WITH CANNABIS NOR WELL VERSED IN THE APPLICATIONS OF CANNABIS MEDICINE AND HOW TO ACTUALLY PRESCRIBE TREATMENT SUCCESSFULLY, SO SOME FORM OF EXTRA TRAINING IS REQUIRED AT ALL LEVELS.

MEDICAL COUNCIL: LABELLING

- Label according to Red/Amber/Green protocol colour code
- in accordance with the relevant laws.
- Include “Keep out of reach of children and animals”
- Include “Keep refrigerated” when appropriate
- Detailed package inserts including generic dosage instructions



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MEDICAL COUNCIL: PRODUCER AGREEMENTS

PRIMARY PRODUCERS

Only an accredited primary producer may produce accredited i.e. tested, full extract Cannabis Oil from verified genetics for supply to Tier 3 licence holders. They may also produce tinctures and/or reduced concentration extracts and supply specialised reduced concentration products and supplements to licensed Tier 2 and Tier 3 licence holders as appropriate.

Primary producers agree to:

- Use only the highest certified quality solvent – 93 to 96.4% potable alcohol;
- Use all accepted laboratory hygiene etiquette according to approved SOP;
- Use only medicinal grade, organically grown Cannabis flowers of verified genetics;
- Have each batch tested at their own expense;
- Maintain batch records;
- Contribute dosage, method and result data to the S.A.C.C.R.A. Medical Council for research and refinement of protocols;
- Follow the supply and treatment protocols as outlined above.

SECONDARY PRODUCERS

Secondary producers make reduced concentration and/or direct extracts i.e. any product where Cannabis is infused into a carrier like tinctures and topical balms.

They will either use full extract oil from a primary producer to infuse into carrier oils e.g. hempseed oil, coconut oil, olive oil, almond oil, grapeseed oil, etc. or make reduced extracts by infusing directly into certain carriers.

Secondary producers agree to:

- Purchase full extract Cannabis oil only from licensed primary producers;
- Use only medicinal grade, organically grown Cannabis flowers of the best genetics possible for direct extracts;
- Have their oil tested regularly at their own expense;
- Maintain batch records;
- Follow the supply, labelling and treatment protocols as outlined;
- Always refer clients to a S.A.C.C.R.A. verified Cannabis Medicine Practitioner in the case of serious illness.



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TERTIARY PRODUCERS

Tertiary producers make products containing Cannabis or Cannabis extracts for human consumption which have **no specific claim as medicinal treatment and which are not intended for therapeutic purposes, but which may still have beneficial effects** e.g. raw Cannabis flowers, cosmetics, bath oils, vape oils, edibles, and drinks.

Topical applications are considered consumption due to absorption of the active ingredients through the skin into the bloodstream.

Although all Cannabis consumed will have some medicinal value and can be included in any treatment regime as supplementary consumption, in the case of tertiary products the dosage is not sufficient to treat illness and the products are not geared to treat illness on their own.

Tertiary producers agree to:

- Where extracts are bought in, use an accredited primary or secondary producer;
- Use the highest quality natural ingredients in their products;
- Use clear labelling protocols particularly relating using clear and accurate terminology;
- Clearly state on packaging "Although all Cannabis products will have some medicinal value, the dosages in these products are not specifically geared to treat illness. Please consult a S.A.C.C.R.A. accredited Cannabis Medicine Practitioner for medicinal treatments."
- Test products for strength and purity at own cost.

MEDICAL COUNCIL: PRODUCTION PROTOCOLS

Full extract and tinctures:

- Only 190 proof / 95% **potable alcohol** such as Royal vodka to be used as a solvent. No chemical solvents such as benzene, isopropyl alcohol, butane, ethyl acetate or absolute alcohol i.e. 99.9% ethanol which contains small quantities of any of the abovenamed chemicals;
- Use all generally accepted hygiene and laboratory protocols to preserve purity of the product and prevent any form of contamination.

Reduced Extracts:

- Only top-quality cold press, organic, virgin coconut oil and other appropriate carrier oils to be used for ingestible and topical products – no denatured products which do not contain the carrier molecule chains.
- Products extracted into hempseed oil to be clearly demarcated to prevent confusion.



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Other:

- Industry laboratory hygiene and safety standards apply.

TO MAINTAIN THE INTEGRITY OF CANNABIS MEDICINE S.A.C.C.R.A. MEMBERS AND COMMERCIAL PRODUCERS AGREE TO ABIDE BY THE ABOVE PROTOCOLS WHEN SUPPLYING ANY PRODUCT TO A THIRD PARTY.