M.C.C. LICENSE APPLICATION

TO CULTIVATE , MANUFACTURE OR IMPORT CANNABIS FOR MEDICAL PURPOSES

CURRENT LEGAL STATUS OF CANNABIS

- The plant remains in the Schedules of both the Medicines and Related Substances Act, and the Drugs and Drug Trafficking Act
- It is listed under Schedule 7, meaning it has no medical benefit
- Therefore, anyone being charged can be classified as a drug dealer or drug user, even though it is listed as a plant

CURRENT LEGAL STATUS OF CANNABIS

- Under the S.A.H.P.R.A. Act i.e. the Amended Medicines Act, all approved Cannabis-related medicines will be listed under Schedule 6 – highly controlled substances
- Cannabidiol (CBD) has already been listed under Schedule 4 of the Medicines Act, and requires prescription by a medical doctor

SCHEDULE 7

Schedule 0

GOVERNMENT NOTICE

DEPARTMENT OF HEALTH

NO. R 2008, 2010, 2012

MEDICINES AND RELATED SUBSTANCES ACT, 1965 (ACT 101 OF 1965)

SCHEDULES

SCHEDULE 7

SCHEDULE 7

All preparations or mixture of such substances containing or purporting to contain substances referred to in this Schedule include the following (unless expressly excluded or unless listed in another Schedule):

(i) the isomers of such substances, where the existence of such isomers is possible within the chemical designation;

(ii) the esters and ethers of such substances and of the isomers referred to in (i), as well as the isomers of such esters and ethers, where the existence of isomers of such esters, or ethers is possible;

(iii) the salts of such substances and of the isomers referred to in (i), as well as the salts of the esters, ethers and isomers referred to in (ii), where the existence of such salts is possible;

(iv) the isomers of any of the salts referred to in (iii), where the existence of such isomers is possible;

(v) all preparations and mixtures of any of the above.

(vi) all homologues of listed substances (being any chemically related substances that incorporate a structural fragment into their structures that is similar to the structure of a listed substance and/or exhibit pharmacodynamic properties similar to the listed substance in the schedules), unless listed separately in the Schedules.

SCHEDULE 7

Cannabis (dagga), the whole plant or any portion or product thereof, except:

a. when separately specified in the Schedules; (S6) or

b. processed hemp fibre containing 0.1 percent or less of tetrahydrocannabinol and products manufactured from such fibre, provided that the product does not contain whole cannabis seeds and is in a form not suitable for ingestion, smoking or inhaling purposes; or

c. processed product made from cannabis seeds containing not more than 10 milligram per kilogram (0,001 percent) of tetrahydrocannabinol and does not contain whole cannabis seeds.

["Processed" means treated by mechanical, chemical or other artificial means but does not include- (a) harvesting; or (b) the natural process of decay"].

SCHEDULE 7

Tetrahydrocannabinol and their alkyl homologues, except:

a. when separately specified in the Schedules;

b. dronabinol ((-)-transdelta-9-tetrahydrocannabinol), when intended for therapeutic purposes; (S6)

c. in hemp seed oil, containing 10 milligram per kilogram or less of tetrahydrocannabinols, when labelled "Not to be taken" or “Not for internal human use”; or

d. in products for purposes other than internal human use containing 10 milligram per kilogram or less of tetrahydrocannabinols.

["Hemp seed oil" means the oil obtained by cold expression from the ripened fruits (seeds) of *Cannabis sativa*.]

PART III OF SCHEDULE 2 OF THE DRUGS ACT lists Cannabis as an UNDESIRABLE DEPENDENCE PRODUCING SUBSTANCE…

PART III

Undesirable Dependence-Producing Substances

1. The following substances or plants, namely—

Amphetamine.

Brolamfetamine.

4-bromo-2,5-dimethoxyphenethylamine (2C-B), ("Nexus").

Bufotenine (N,N-dimethylserotonin).

Cannibis (dagga), the whole plant or any portion thereof, except dronabinol [(-)-transdelta-9 tetrahydrocannabinol].

Cathinone.

Dexamphetamine.

CURRENT CASES AROUND CANNABIS

a) The applicants seek a declaration that the legislative provision against the use of cannabis and the possession, purchase and cultivation of cannabis for personal or communal consumption is invalid.

- **The current court case being heard in the Constitutional Court (Prince and the DC) challenges the constitutionality of the criminalisation of the cultivation, possession and use of Cannabis by an adult in their private dwelling under the *right to privacy***

CURRENT CASES AROUND CANNABIS

Applicants also seek a declaration of invalidity of s 40(1)(h) of the Criminal Procedure Act 51 of (1977) ("the CPA") insofar as the latter refers to cannabis. Section 40 (1) (h) of the CPA empowers a peace officer without a warrant to arrest any person who is reasonably suspected of having committed an offence under any law and governing the making, supply, possession or conveyance of cannabis.

- **They challenge the Criminal Procedures Act as it relates to Cannabis for personal adult use in the home (Cannabis is only mentioned in the Schedules, not the Acts per se)**

CURRENT CASES AROUND CANNABIS

THE CURRENT CASES DO NOT SEEK TO REMOVE CANNABIS FROM ANY SCHEDULES AND THEREFORE DO NOT SEEK TO ACTUALLY MAKE IT LEGAL. RATHER, THEY WORK TO CONTROL IT.

CURRENT CASES AROUND CANNABIS

12.30 Improved state control of substances, as with alcohol and cigarettes, could provide taxes and significantly reduce the roles of drug dealers.

1.2. I have read the said affidavit deposed to by Mr. Stobbs and confirm that I associate myself with the contents of the affidavit and confirm the correctness thereof where it has bearing on me.

K CLARKE

Thus signed and sworn to before me at PRETORIA on this 14th. day of MAY 2011, the deponent having acknowledged that he knows and understands the contents of this affidavit, that it is both true and correct to the best of his knowledge and belief, that he has no objection to taking the prescribed oath and that the prescribed oath will be binding on his/her conscience.

SUID-AFRIKAANSE POLISIEDIENS
GEMEENSKAPSVERHOUDINGE SENTRUM
2011 -05- 14
SURREYSIDE
COMMUNITY SERVICES CENTRE
SOUTH AFRICAN POLICE SERVICE

COMMISSIONER OF OATHS

- The relief sought by **"Dagga Couple"** in their court case is for **"improved state control"**

CURRENT CASES AROUND CANNABIS

- Therefore, IF the relief they seek is granted, Cannabis will REMAIN IN BOTH SCHEDULES, and
- will REMAIN ILLEGAL TO CULTIVATE, POSSESS, USE, BENEFICIATE, AND/OR IMPORT/EXPORT,
- EXCEPT UNDER LICENCE AND/OR PRESCRIPTION AND/OR POSSIBLY IN THE PRIVATE DWELLING

IS THERE A LICENSE?

LICENSE APPLICATION

- In November 2017 the M.C.C. released their LICENCE APPLICATION to CULTIVATE, MANUFACTURE or IMPORT/EXPORT CANNABIS for MEDICINAL PURPOSES, and PRESCRIBED the STANDARD OPERATING PROCEDURES for these activities

LICENSE TO CULTIVATE

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

LICENCE APPLICATION TO CULTIVATE, MANUFACTURE OR IMPORT CANNABIS FOR MEDICINAL PURPOSES

- An application form for the purpose of **obtaining** a licence **or renewing** a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C and 22D to be read in conjunction with Regulation 23 and 24 of the Act.
- This form should be completed by or for each manufacturer of Cannabis who is not exempted from the requirement to hold a licence and who wishes to cultivate, manufacture or import or who wishes to renew their existing licence to cultivate, manufacture or import.
- Incomplete forms may be returned to the Applicant. Please type or print in black ink. Any alterations must be initialled and dated. Application forms with white out will be returned. All required copies of certificates should be certified.
- The prescribed application fee or proof of payment for a licence must accompany the licence application forms. For amount, refer to the fees payable as published in the Government Gazette and published on the MCC website, also available from the office of the Registrar.

  Note: Cheques should be made payable to **"Medicines Control Council'**

- An application form for the purpose of **obtaining** a licence **or renewing** a licence in terms of the provisions of the Medicines and Related Substance Act, 1965 Section 22C and 22D to be read in conjunction with Regulation 23 and 24 of the Act.

SECTION 22 C - LICENSING

(a) the Director-General may on application in the prescribed manner and on payment of the prescribed fee issue to a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, a licence to compound and dispense medicines, on the prescribed conditions;

(b) the council may, on application in the prescribed manner and on payment of the prescribed fee, issue to a manufacturer, wholesaler or distributor of a medicine or medical device a licence to manufacture, act as a wholesaler of or distribute, as the case may be, such medicine or medical device, upon such conditions as to the application of such acceptable quality assurance principles and good manufacturing and distribution practices as the council may determine.

SECTION 22 D – VALIDITY & RENEWAL

Section 22D - Period of validity and renewal of licence

A licence issued under section 22C shall be valid for the prescribed period but may be renewed on application in the prescribed manner and before the prescribed time or such later time as the Director-General or the council, as the case may be, may allow and on payment of the prescribed fee.

- **Successful applicants will require a license from the M.C.C. and a permit from the Director General of the Dept. of Health**
- **This permit will allow for limited amounts of specific plants/products for pharmaceutical use and research only**
- **License remains the property of the M.C.C.**

SECTION 22 C AND D - REGULATIONS

Section 35 - Regulations

(1) The Minister may, in consultation with the council, make regulations-

(i) prescribing the categories of persons by whom application may be made for the registration of any medicine or to whom a certificate of registration may be transferred;

(ii) prescribing the forms which shall be used for any application for the registration of any medicine and the particulars which shall be furnished with any such application (including particulars regarding the method by which the medicine in question or any component of such medicine is manufactured and the premises at which such medicine or any such component is manufactured);

"REGULATIONS" 23 AND 24

INFORMATION THAT MUST APPEAR IN THE REGISTER FOR MEDICINES

23. The medicines register shall, in respect of any registered medicine, contain the following information:

(a) the proprietary name of the medicine;

(b) the registration number allocated to the medicine;

(c) the approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(d) the dosage form of the medicine;

(e) the name of the holder of the certificate of registration;

(f) the name and address of the manufacturer(s) and the manufacturing facilities;

(g) the name of the final product release control;

(h) the name of the final product release responsibility;

(i) the date of registration of the medicine;

(j) the conditions of registration of the medicine as may have been determined in terms of section 15(6) of the Act;

(k) category of the medicine;

(l) pharmacological classification of the medicine; and

(m) if falling under Category D a statement identifying the-

(i) sub-category of the medicine; and

"REGULATIONS" 23 AND 24

APPLICATION FOR AN AMENDMENT TO THE REGISTER FOR MEDICINES

24. (1) An application for the amendment of an entry in the register in terms of section 15A of the Act shall be accompanied by a the relevant fee and must contain the following particulars-

(a) the registration number of the medicine;

(b) the name of the holder of the certificate of registration;

(c) business address of the holder of the certificate of registration;

(d) declaration by the holder of the certificate of registration that the information furnished is complete and accurate;

(e) the details of the amendment applied for; and

(f) any other information as may be required by the Authority;

STANDARD OPERATING PROCEDURES

MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

CULTIVATION OF CANNABIS AND MANUFACTURE OF CANNABIS-RELATED PHARMACEUTICAL PRODUCTS FOR MEDICINAL AND RESEARCH PURPOSES

This document highlights the quality, security and standard operating procedures relating to the cultivation, manufacture and use of Cannabis and related pharmaceutical products for medicinal and research purposes and also includes the minimum requirements to be in place should an application be submitted to the Medicines Control Council and the Department of Health for consideration. This guideline represents the Medicines Control Council's current thinking on the measures required to be in place to ensure that quality products are cultivated and harvested and made available to patients when prescribed by an authorized prescriber / physician. Council and the Department reserve the right to request any additional information and may make amendments in keeping with current knowledge.

STANDARD OPERATING PROCEDURES

This document highlights the quality, security and standard operating procedures relating to the cultivation, manufacture and use of Cannabis and related pharmaceutical products for medicinal and research purposes and also includes the minimum requirements to be in place should an application be submitted to the Medicines Control Council and the Department of Health for consideration. This guideline represents the Medicines Control Council's current thinking on the measures required to be in place to ensure that quality products are cultivated and harvested and made available to patients when prescribed by an authorized prescriber / physician. Council and the Department reserve the right to request any additional information and may make amendments in keeping with current knowledge.

- Quality, security, standard operating procedures for
- Cultivation, "manufacture" and use of Cannabis and related pharmaceutical products
- Minimum requirements in place for submitting an application for consideration

M.C.C. – S.A. HEALTH PRODUCTS REGULATORY AUTHORITY

(*g*) by the substitution for the definition of "medicine" of the following definition:

" '**medicine**'—

(*a*) means any substance or mixture of substances used or purporting to be suitable for use or manufactured or sold for use in—

(i) the diagnosis, treatment, mitigation, modification or prevention of disease, abnormal physical or mental state or the symptoms thereof in humans; or

(ii) restoring, correcting or modifying any somatic or psychic or organic function in humans; and

(*b*) includes any veterinary medicine;";

S.A.H.P.R.A.

In addition, the Medicines Act allows the MCC to issue a licence to manufacture either a medicine or a Scheduled substance (Active Pharmaceutical Ingredient/API). Section 22C(1)(b) of the Medicines Act enables the cultivation and manufacture of Scheduled substances and ensures the required oversight of the MCC in regulating these activities. This allows the MCC to license growers of Cannabis when intended for medicinal use and enables regulatory oversight in a way that is compliant with South Africa's international obligations.

The legislative framework addresses three regulatory aspects:

- Authorise Cannabis production domestically, for medicinal and research purposes.
- Satisfy the requirements of South Africa's international obligations, under the Single Convention.
- Align the access of Cannabis for medicinal purposes with that of other controlled medicines.

Cannabis is a prohibited narcotic substance in South Africa, and cultivation for any purpose other than that explicitly allowed for through the licence and permit system under the Medicines Act, is a criminal offence. Likewise, cultivation by non-licensees remains a criminal offense under this legislation.

S.A.H.P.R.A.

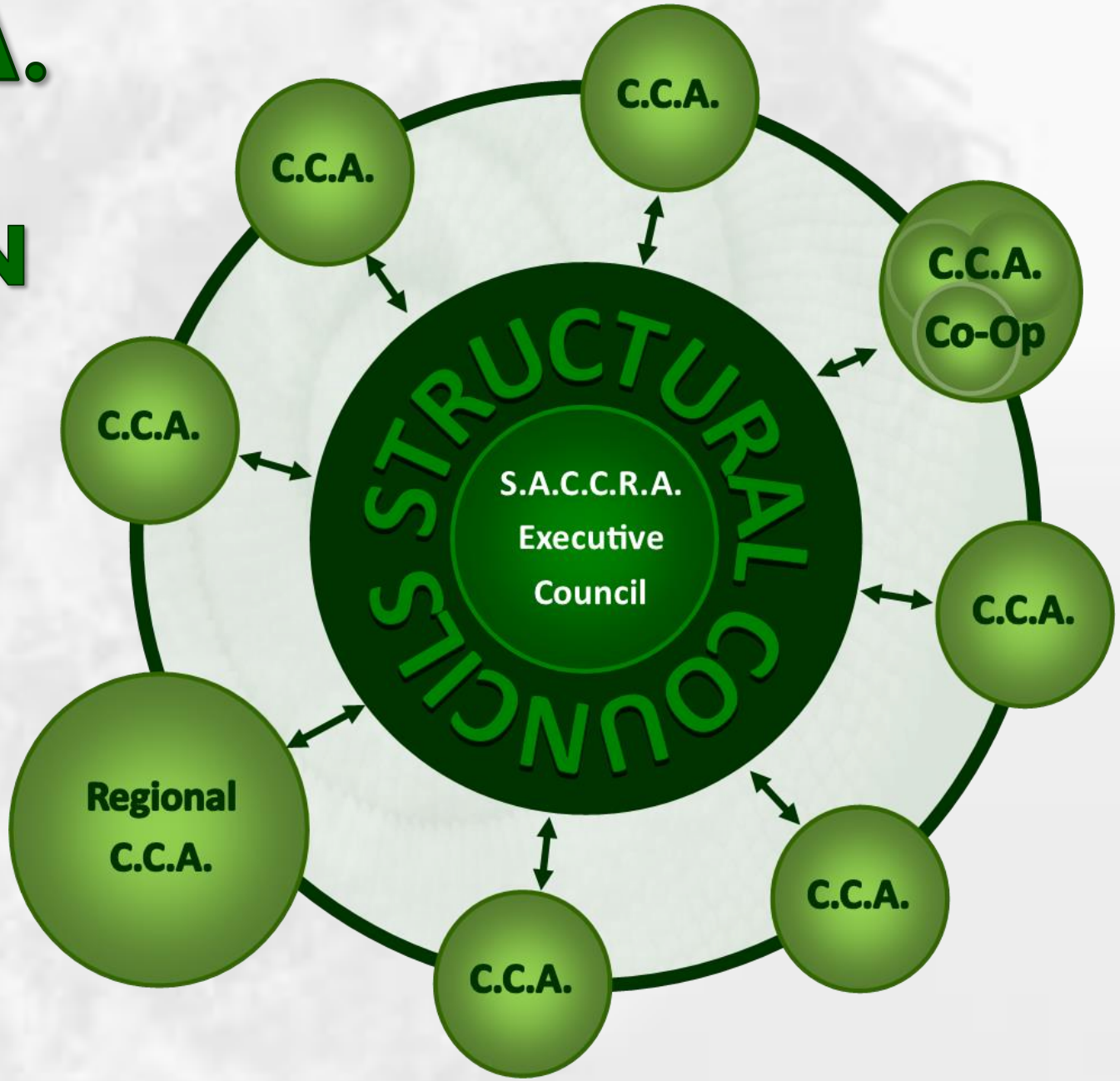
Cannabis is a prohibited narcotic substance in South Africa, and cultivation for any purpose other than that explicitly allowed for through the licence and permit system under the Medicines Act, is a criminal offence. Likewise, cultivation by non-licensees remains a criminal offense under this legislation.

cultivation by non-licensees remains a criminal offense

WHAT IS THE ALTERNATIVE?

S.A.C.C.R.A.

SOUTH AFRICAN CANNABIS COMMUNITY & REGULATORY ASSOCIATION



THE LOBBY

FREE AND FAIR ACCESS
TO RESPONSIBLE USE
OF THE CANNABIS PLANT
FOR ALL

"IN AN INFORMATION SOCIETY, NO THOUGHT, DEBATE OR DREAM IS WASTED – WHETHER CONCEIVED IN A TENT CAMP, PRISON CELL OR THE TABLE FOOTBALL SPACE OF A STARTUP COMPANY. " 2015 - PAUL MASON

SACCRA

S.A.C.C.R.A. PURPOSE

- DOMESTIC USE REQUIRES SIMPLE RESPECT AND COMMON SENSE ACHIEVED THROUGH EDUCATION
- COMMERICAL REGULATION OF LEGAL CANNABIS BASED INDUSTRY
- IMPLEMENTED VIA CCA'S
- SIMPLE REGULATORY AGREEMENTS
- COMMUNITY EMPOWERMENT AND INDEPENDENCE

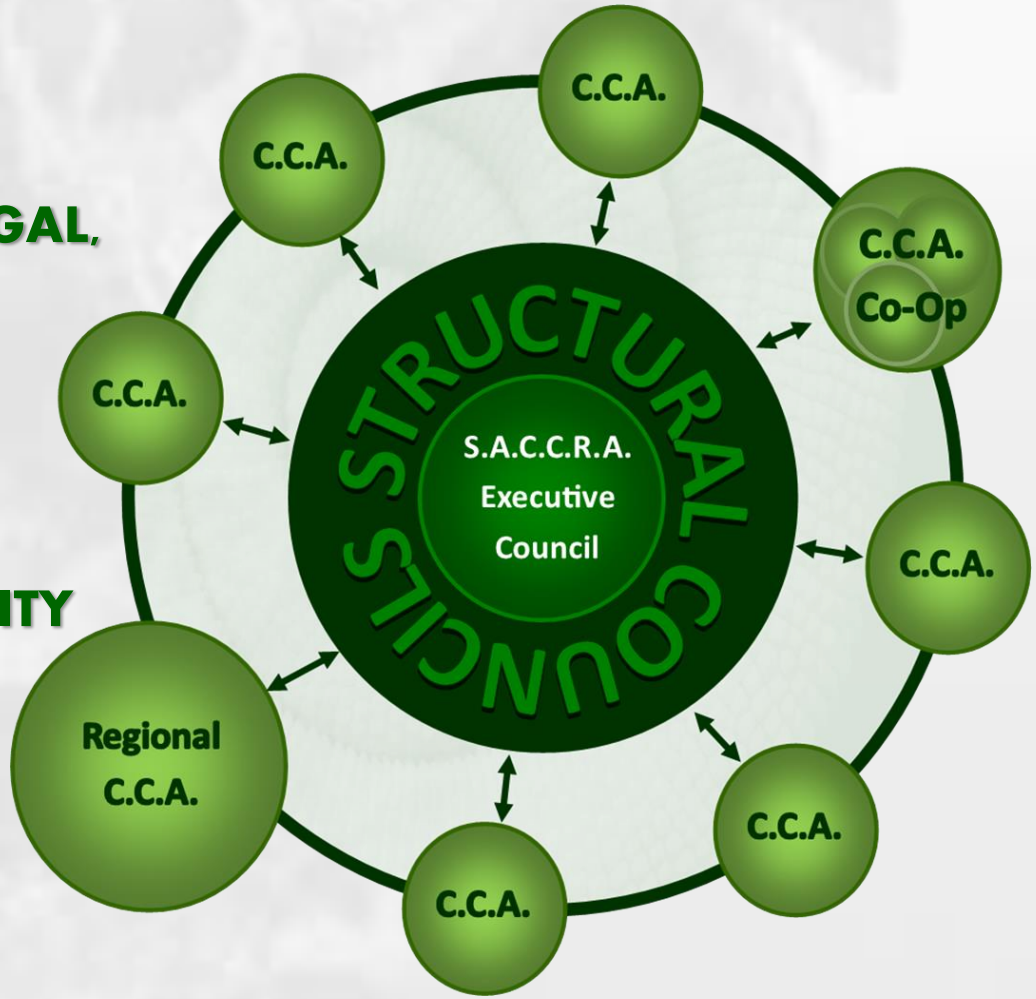
SACCRA

S.A.C.C.R.A. STRUCTURE

- S.A.C.C.R.A. DEVELOPMENT TRUST
- EXECUTIVE COUNCIL AND TRUSTEES
- STRUCTURAL COUNCILS - MEDICAL, AGRICULTURAL AND ENVIRONMENTAL, LEGAL, INDUSTRIAL, SOCIAL DEVELOPMENT AND YOUTH COUNCILS

LOCAL

- MEMBERS FORMING CANNABIS COMMUNITY ASSOCIATIONS
- LOCAL COMMUNITY TRUST
- REPRESENTATIVE COUNCIL AND LOCAL TRUSTEES



PARTICIPATION

- CONTRIBUTOR
- STANDARD MEMBER
- ACTIVE MEMBER
- COMMERICAL CONTRIBUTIONS FROM CANNABIS BASED AND OTHER BUSINESSES

CANNABIS RELATED PRIVATE ENTERPRISES	CONTRIBUTE 10% OF NETT PROFIT TO	LOCAL COMMUNITY TRUST RUN BY C.C.A.
LOCAL C.C.A. TRUSTS	CONTRIBUTE 1% OF NETT INCOME	S.A.C.C.R.A. DEVELOPMENT TRUST
INDIVIDUALS AND BUSINESSES	VOLUNTARY CONTRIBUTIONS	GREEN RIBBON FOUNDATION

C.C.A.

- **ACTIVE MEMBERS**
  - **Representative council**
  - **Trustees of local trust**
- **STANDARD MEMBERS**
- **Unaffiliated community members**

S.A.C.C.R.A.

SOCIAL DEVELOPMENT MODEL

S.A.C.C.R.A. SOCIAL DEVELOPMENT MODEL