

LEGISLATIVE ASSEMBLY OF

COSTA RICA REPUBLIC

DRAFT LAW

**RESEARCH LAW, REGULATION AND CONTROL OF CANNABIS PLANTS AND
HEMP for medical use,**

E INDUSTRIAL FOOD

MARVIN ATENCIO DELGADO

DEPUTY

Docket No. 19,256 _____

DRAFT LAW

**RESEARCH LAW, REGULATION AND CONTROL OF CANNABIS PLANTS AND CANNABIS
USE FOR MEDICINE, FOOD AND INDUSTRIAL**

___ N.º __19.256 record EXPLANATORY STATEMENT:

Brief history of the medicinal uses of cannabis and cannabis plants.

Medicinal use of medicinal herbs dates back to the beginnings of mankind. Various studies on ancient cultures in Central Asia, Egypt, China, India and Persia, demonstrate the use of cannabis as an anesthetic for performing surgeries. Similarly, the use of cannabis in medical prescriptions is recognized.

Also, the Greeks and Romans used cannabis and hemp for multiple purposes including medical treatment for stomach and head pains, impotence and pain in general and for the manufacture of

textiles and as food are. Even discomfort or side effects caused by these plants compared to those produced by opium were lower.

In the tenth century, this knowledge about the use of cannabis and hemp were integrated into Islamic culture (Arabic) from India.

During the Middle Ages in Central Europe medical cannabis for lung problems, arthritis, joints, gout and tumors it was used.

In 1811, Samuel Hahnemann, a German physician, was the first to mention in his book entitled "Reine Arzneimittellehre" homeopathic use of cannabis sativa.

In the early nineteenth century, the use of native hemp, predominantly seeds and occasionally other parts of the plant were used pharmacologically. One of the most extensive descriptions of implementation of hemp was provided in 1830 by the chemist and botanist Theodor Friedrich Ludwig Nees saying: "*Many doctors, including **Hahnemann**, used the extract came in patients with nerve problems instead of using the opium and hemp produced less discomfort or side effects.*"

In Europe, cannabis was introduced by Napoleon's soldiers after the Egyptian campaign in 1797.

In 1839, Dr. William B. Irish O`Shaughnessy published several studies that looked possible therapeutic effects in humans using hemp and won many adherents in the European medical academy. He prepared several presentations of hemp were applied with high levels of success in the following diseases: rheumatism, rabies, tetanus, trembling delirium and spasms.

This scientist wrote in his findings as follows: "***the preceding cases Constitute an abstract of my experience on this subject, and Which has led me to the belief That in Hemp the profession you have Gained an anti-convulsive remedy of the greatest value.***" [1]

In 1845, psychiatrist Jacques-Joseph Moreau de Tour experimented with cannabis and hemp and described the therapeutic uses of these plants in psychiatric illnesses.

After more than thirty years of being frozen numerous studies around the uses of cannabis, in 1964, the chemist R. Mechoulam, University of Jerusalem, succeeded in isolating the active ingredient of cannabis, tetrahydrocannabinol or THC on and explained their mechanisms of action.

And in 1992, Mechoulam was isolated a substance produced by the human brain, able to reproduce the effects of THC, which he called anandamide or "molecule of happiness" neurotransmitter whose study announced very interesting perspectives at the level of neuronal behavior.

From the analysis of all the aforementioned investigations, there is a need to generate two major changes: first, it is necessary to create a law that encourages scientific research taking up the results obtained through studies in the past and today, researchers have been conducting various countries of the world in relation to the therapeutic uses of cannabis and cannabis plants; where Costa Rica has not yet causes strictly political regulations and should open ground to get back to the forefront, taking the country a chance to have a tangible international scientific reputation for transcendental medical contributions, such as the case of research and discoveries in antivenoms made by the Costa Rican medical chlorite Picado Twilight. Our country is bound by ethical and social reasons to promote the intellectual talents of our young scientists opening the doors to new fields of research. The Act establishes the obligation to build new pharmaceutical laboratories for the preparation of cannabinoid drugs and cannabis extracts which could be incorporated new professionals in addition to existing laboratories in public universities.

Secondly, it is crucial advance in the international level, appropriate modification of the list of international classification of drugs to be evident and clear that the cannabis, its cannabinoids and other extracts, plant have scientifically proven therapeutic effects.

Then a picture that exposes a historical scientific injustice that occurred from a biased legal framework on the effects of cannabis plant established a focused regulation, prevalently, from the point of view of international policies of persecution shown and control of illicit drug trafficking:

Table: "The history of cannabis in the system of international drug control".

Source: Global Drug Policy Observatory. Reportingmonitoringanalysis, May 2014.

Current situation.

- **International policies.**

Food and Drug Administration (FDA).

The FDA has publicly supported scientific research valid regarding the medicinal use of cannabis, provided they are under the requirements of the application of research into new drugs. and it has raised the possibility of reassessing the current classification of cannabis in the lists placed it from the start without further justification in Schedules 1 and 4.

Since 1992, the FDA has approved several medications containing Delta 9 THC and CBD for the treatment of cancer, epilepsy and neuropathic pain, among others.

US states for the medicinal use of cannabis

In 1996, California voters approved Proposition 215, the Compassionate Use Act, which exempts the medical use of cannabis criminal sanctions. This does not legalize the substance, but modifies its treatment of the judicial system to patients and their caregivers. California law allows individuals to possess, grow and transport cannabis, as long as it is for medicinal purposes and is justified by a "recommendation" written by a doctor (unlike a prescription or prescription). Since 1996, other states have followed California's lead in varying degrees. Currently, there are 23 states in the US with laws regarding medical cannabis.

Registered in the US Patent

Currently, the government of the United States of America has patents US6630507 B1, CA2329626A1, DE69936640D1, EP1071419A1, EP1071419B1 and WO1999053917A1, which patented the use of cannabinoids for the treatment of diseases such as antioxidants and neuroprotective. These were completed in April 1999 and published from October 7, 2003.

Wave American countries regulations.

Following is a table showing the different types of regulations established in Latin on the use of cannabis:

Country	Year	State	Regulation
Argentina	2009	decriminalized	Consumption in private areas for medicinal and personal purposes.
Canada	nineteen ninety six	Legal Use Medicinally Industrial Use	Consumption allowed under medical authorization. Industrial use is not controlled
Chile	2011	decriminalized	Allowed personal use in private areas.

USA	N / A	It varies by state	Each state decides its policy. 23 states allow the medicinal use under medical authorization. Investigations are supported by the Federal State and the FDA. The last state to approve the medicinal use of cannabis has been New York.
Peru	2003	decriminalized	Personal use. Consumption in private areas.
Uruguay	2013	Legal	personnel and medical use. Production and distribution under the responsibility of the state. It requires state authorization to access.
Paraguay	2005	decriminalized	Personal use. Consumption in private areas.
Ecuador	1990	decriminalized	Personal use. Consumption in private areas.

Here it is also shown a picture with the main scientific studies on the medical use of cannabis:

Table of scientific studies on the use of medicinal cannabis (1975-2014)

<i>category</i>	MCCRID	Title	publication
<i>Asthma</i>	X5ZLGBZU6U	Effects of smoked marijuana in experimentally induced asthma	1975
	TUQNL9BKI	Neuroprotective antioxidants marijuana.	2000
<i>neuroprotection</i>	RC56R78AFP	Cannabinoids provide neuroprotection against toxicity of 6 hydroxydopamine in-vivo and in-vitro: relevance for Parkinson's disease	2005

	HG9GFNFUQU	Endocannabinoids acting on cannabinoid receptors that regulate one cardiovascular function in hypertension	2004
<i>Cardiovascular / Heart</i>	XIEPG53ZM5	Study shows that cannabinoid (CBD) provides heart protection	2006
	OKFHDHZ6FS	Cannabidiol, a component of non-psychoactive cannabis, protects against myocardial ischemia-reperfusion injury	2007
<i>Migraine</i>	K9PWR3JJ9G	Endocannabinoid deficiency Clinic (STEL): this concept can explain the therapeutic benefits of cannabis in migraine, fibromyalgia, irritable bowel syndrome and other diseases resistant to treatment?	2004
	4A0AWJZP6C	Effect of Delta-9-tetrahydrocannabinol and cannabidiol on nocturnal sleep and early morning behavior in young adults.	2004
<i>Sleep disorder</i>	9AZQ1I1ARS	Cannabidiol, a component of Cannabis sativa, modulates sleep in rats.	2006
	3ZPKLOI6HV	The non-psychoactive constituent of cannabis, cannabidiol, is an inducer agent attention.	2008
	EZGBKWTR7R	Effects of acute systemic administration of cannabidiol in the sleep cycle in rats.	2013
<i>Alzheimer</i>	GSJA0M97KN	Cannabinoid receptor stimulation 2 (CB2) suppresses microglial activation.	2005

	MV1P0YQHNN	Cannabidiol as an emerging therapeutic strategy to ameliorate the effects of inflammation in oxidative stress.	2011
	P7YIXJ5JE4	Role of the cannabinoid system in the transition from beta-amyloid through the blood-brain barrier.	2013
	DCQ6PMZDID	-tetrahydrocannabinol Delta9 inhibits cell cycle progression in cells of human breast cancer through regulation of Cdc2.	2006
	ZJO2LKAQN4	Cannabidiol induced apoptosis in leukemia cells - cannabidiol An unusual role in the regulation of expression and p22phox Nox4	2006
	OOIQWSSPP6	Cannabidiol as a novel inhibitor of Id-1 gene expression in cells of aggressive breast cancers	2007
<i>Cancer</i>	QYKHU8GZ0T	The cannabinoid delta (9) -tetrahydrocannabinol inhibits RAS-MAPK signaling and PI3K-AKT survival and induces apoptosis mediated-BAD in colorectal cancer cells.	2007
	HZUTEL5FKL	Cannabinoids for Cancer Treatment: Progress and promise	2008
	TLXVL66LIA	Cannabinoids for Cancer Treatment: Progress and promise	2010
	WHHW4RGN97	Cannabidiol enhances the inhibitory effects of delta9-tetrahydrocannabinol on cell proliferation human glioblastoma and survival.	2010

	YQ7E2KAPXX	Cannabidiol prevents angiogenesis by multiple mechanisms	2012
	MJ89E3QHXX	Cannabidiol as a potential anti-cancer drug	2013
	LCS3B0VPVQ	Cannabidiol inhibits neuropathic pain induced by paclitaxel 5-HT1A receptors without decreasing nervous system function or efficacy of chemotherapy	2014
	TG8WNQ9KRM	crucial role of CB2 cannabinoid receptors in the regulation of immune responses during Central neuropathic pain	2008
<i>Pain / Chronic Pain</i>	UB0JQD2AB9	Smoked cannabis for neuropathic pain - A randomized controlled trial	2010
	I8HTOQK6L5	Cannabinoids for treatment of chronic noncancer pain, a systematic review of randomized trials	2011
	MXO99OBA73	Cannabis as a supplement or substitute for opioids in the treatment of chronic pain.	2012
<i>Acne</i>	THZOQRT37Y	The skin endocannabinoid system in health and disease: new perspectives and therapeutic opportunities	2009
	WUQ5Q25T32	¿Cannabidiol as a treatment for acne?By Fred Gardner	2010
<i>Inflammation</i>	IY37CVV21R	Cannabinoids as new anti-inflammatory drugs.	2009

	QJVQUGZ6GX	Cannabinoids and skeleton: marijuana to the reversal of bone loss.	2009
<i>Osteoporosis</i>	KXT8O4H6C4	Cannabinoid receptors as a target for the treatment of osteoporosis: A Tale of Two Therapies	2010
	YE7VEIOLV	Role of cannabinoids in the regulation of bone remodeling	2012
<i>Immune system</i>	E75WWMJNRZ	Emerging role of CB2 cannabinoid receptors in immune regulation and therapeutic perspectives	2009
<i>Diabetes</i>	WW5BIATG45	Cannabidiol attenuates cardiac dysfunction, oxidative stress, fibrosis, inflammatory and death of cell signaling pathways in diabetic cardiomyopathy.	2010
	B08REU5QXM	The impact of marijuana use in glucose, insulin and insulin resistance among Adults.	2013
<i>Gastric diseases</i>	ERAP0Q648W	Alternative objectives within the endocannabinoid system for the future treatment of gastrointestinal diseases.	2011
<i>Anxiety</i>	AGVLBF8S4	The endocannabinoid system in anxiety, fear memory and habituation	2012
<i>Epilepsy / Seizures</i>	FMT0F27V74	Cannabidiol exerts anti-convulsant effects in animal models of temporal lobe and partial seizures.	2012

	CVDXXHBMZJ	Cannabis extract rich in anti-convulsants cannabidiol are in mice via receptor-independent mechanism CB1	2013
	JOMI9DG8GB	Effects of WIN 55,212-2 (a cannabinoid CB1 and non-selective CB2 receptor agonist) in the protective action of various classical antiepileptic drugs in mice 6Hz, psychomotor seizure model.	2014
<i>Psychosis / Schizophrenia</i>	LWER6WP3KW	A controlled study Family cannabis users with and without psychosis.	2014

Source: Prepared by Medical Cannabis Costa Rica Org with data from the National Library of Medicine, USA (<http://www.nlm.nih.gov/>), 2014.

· **National and institutional policies.**

The Supervisory Board Narcotic Drugs Ministry of Health, the Costa Rican Institute on Drugs, the Institute on Alcoholism and Drug Dependence and the Ministry of Public Security meet objectives linked to a National Policy on Drug Control does not include research, regulatory and control of cannabis-based medicines and medicinal hemp.

In view of the above, it is necessary to form a specialized institute which will be composed of representatives of public institutions linked to public health research as well as a small sector of private parties involved in the cultivation, production and research phytopharmaceuticals leaving as technical advisers to public institutions dedicated to the control of illicit drugs and drug trafficking whose platform is already established.

The **National Policy for Cancer Prevention and Control (2011-2017)** of the Ministry of Health, contains a declaratory cancer as a priority or institutional interest was issued by the CCSS where the Institutional Cancer Council is also created as a "technical coordination cancer. " This policy includes among its objectives one that is geared towards research in cancer, which would be feasible to allocate resources for conducting research with cannabis and cannabis plants to treat and cure cancer, if approved this initiative law.

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Block of Constitutionality.

Wrongfulness typified in our legal system of the plants indicated is based on a designation of object prohibited without considering the qualitative conditions and positive uses for the health of cannabis plants and cannabis.

So, even though the Costa Rican State allows the medical use of cannabis and hemp as limited and strictly controlled activity which has prevailed fear, myths and ignorance. Above they have been identified scientific studies on the beneficial uses of substances containing these plants for the treatment of multiple diseases internationally.

In the 1961 Single Convention on Narcotic Drugs, as amended by the Protocol of 1972 on Narcotic Drugs, in its preamble, states in relevant part , that the Parties concerned for the physical and moral health of humanity, recognizes ***"that the medical use of drugs continues to be indispensable to mitigate the pain and that the necessary measures be taken to ensure the availability of narcotic drugs for this purpose (...)" [2]*** .

The prohibitions and limitations that our legislation established around the cultivation, production, marketing and general use of cannabis and hemp are contained in the *General Law of Health, the Organic Law of the Ministry of Health and the Law on narcotics, psychotropic substances, drugs unauthorized use, related activities, money laundering and terrorist financing, N°8204 Act.*

· Regulatory Void: problems detected.

The legal reality is that our legislation strictly punitive referring to illicit drugs or limited also allows limited and discouraging use for research purposes and medical, providing that is the Ministry of Health the competent authority in human health, to validate and authorize investigations, treatments and medications. However, there are no regulations to properly regulate the activity of medical production from cultivation of cannabis and hemp where the parameters, purposes, uses, controls, infringements and penalties needed to be defined.

In other countries, it has been legislating in favor of the general legalization of "marihuana" for recreational use. However, our proposal does not walk in that line but the aim is to regulate the research, control and medicinal, food and industrial use of cannabis and cannabis plants through regulation of the entire production chain from seed and crop, in the case of the cannabis plant will be in controlled environments, to the sale, use and consumption of drugs based on the active compounds cannabinoids and CANANO by duly authorized and registered patients Research Institute, regulation and control that is created by this Act.

The 1961 Single Convention, Article 23 requires Parties interested in promoting research and use of medicinal cannabis must meet the requirement of creating a regulatory state institute responsible for investigating, controlling, market and distribute products made cannabis base. No

reference to the use of cannabis is made but it was included in this bill because of the many beneficial uses has this plant within which are regulating medicinal, food and industrial and also because of the irrational confusion existing in Costa Rican legislation prohibits it.

Our public institutions and legal framework does not understand or establish clear and comprehensive regulations on the cultivation and production of cannabis and hemp for research and medicinal, food and industrial use, does not indicate what are the procedures for granting the authorization certificates for different activities authorized, including the establishment of offenses and penalties and the creation of a tax, as we said in this proposal. Moreover, it is necessary to make this Act a link with health and criminal legal regulations in force for its effective implementation.

In addition, currently there is no clear procedure for researchers from public universities that despite that they have highly qualified personnel and appropriate equipment can not conduct research with cannabis and cannabis plants for medicinal purposes (drug), food or industrial in reason that they are not allowed to cultivate them for analysis and then are forced to raise burdensome requests to the institutions responsible for control and seizure of drugs, whose raw material does not have the best conditions of safety and quality required. This prevents the development of research that could yield positive results for the economy and the health of the sick.

Then a picture with major therapeutic effects of different cannabinoids cannabis plant shown:

A table showing the cannabis plant cannabinoids with therapeutic effects for the treatment of various diseases

Hence, we believe that the theme that is intended to regulate covers where the central axis revolves around the legal right health of patients of diseases such as multiple sclerosis, cancer, medical, social, agricultural, environmental, economic and legal sciences, epilepsy and AIDS, among others.

For all the above, I submit to analysis and consideration of the ladies and gentlemen of this bill to be passed by the Legislative Assembly and can bring benefits on public health not only for the health of patients but in the framework of a public policy that would model in the world, could also generate economic benefits for our country.

THE LEGISLATURE OF THE REPUBLIC OF COSTA RICA

DECREES:

RESEARCH LAW, REGULATION AND CONTROL OF CANNABIS PLANTS AND CANNABIS USE FOR MEDICINE, FOOD AND INDUSTRIAL

TITLE I

GENERALITIES

CHAPTER I

GENERAL DISPOSITION

Section 1. Purpose and scope.

The purpose of this Act is to establish the scope and mechanisms of regulation of activities of planting, cultivation, harvesting, production, processing, storage, distribution, processing, marketing, transportation, sale, use and consumption of cannabis plants (*cannabis indica*, *cannabis sativa* and *cannabis ruderalis*) and hemp plant, in accordance with the uses, ranges, presentations and authorized by this law purposes.

They are subject to this Act and the Costa Rican jurisdiction, persons, physical or legal, public or private, national or foreign, that produce, market, used or consumed medicines, foods and industrial materials from the cannabis plant and the plant hemp originating, ending or transiting through the country and even those that can be exported.

Article 2. Uses and public interest.

Declare public interest and state actions aimed at the research, production and industrialization of the cannabis plant and cannabis plant authorized for medical, food and industrial use as determined by this Law competent public authority.

Article 3. Purposes

The purpose of this law are as follows:

- a) Promote research and medicinal, pharmaceutical and food uses of cannabis and cannabis plants duly authorized.
- b) Encourage research and development of agribusiness cannabis and hemp and its many industrial applications in the country.
- c) Cooperate with the reduction of drug use, illegal trade, drug trafficking and organized crime.
- d) To educate the public about the health, environmental and socio-economic benefits of the industry linked with cannabis and cannabis plants covered by this Act.
- e) Create new jobs and wealth for the country.
- f) Provide alternative drug treatments from the active components and cannabinoids derived from cannabis and cannabis plants for treatment of various ailments.
- g) To improve the quality of life and the family environment of patients suffering from treatable illnesses diagnosed with medicinal cannabis and hemp.
- h) Strengthening health tourism in the country through the provision of medical services using cannabis and hemp products and medicinal cannabinoids for the treatment of diseases.

Article 4. State Regulation

The State will assume control and regulation of the activities of seed import, export, planting, cultivation, harvesting, production, acquisition in any capacity, storage, marketing, distribution, use and consumption of cannabis and non-psychoactive medicinal cannabis and cannabinoids or cannabis and hemp for food and industrial purposes, according to the parameters and authorized by this Act ranges, through the Institute created by this Act, which is given the legal mandate, in accordance with the provisions of this Act and its regulations.

The measures to control and regulate psychoactive cannabis and its derivatives which exceed or transgress the parameters and authorized ranges are excluded from this law and will be regulated in the manner and by the competent authorities in accordance with the Organic Law of the Ministry of Health, law No. 5412, the General Health law, No. 5395 and the law on Narcotics,

Psychotropic Substances, Drugs of unauthorized Use, Related Activities, Money Laundering and Financing of Terrorism Act 8204.

Article 5. Infrastructure.

The Ministry of Health through the Institute in charge must have adequate research infrastructure, production, control, monitoring and proper marketing of medicines, food and other industries that are generated from the use of cannabis and cannabis plants regulated by this Act.

Article 6. Definitions.

For the purposes of this Act the following definitions apply:

Cannabis for medicinal or therapeutic effect use: It is considered as cannabis for medicinal use any variation of the female cannabis plant indica, sativa and rudelaris, its cannabinoids and active compounds in the ranges permitted by this Act, grown and used in organically and processed in authorized for strictly therapeutic purposes presentations, not recreational, treat or alleviate a symptom, an illness or a disease previously diagnosed by a physician. These plants, their cannabinoids and other substances do not produce physical or psychological dependence in people.

Cannabis and hemp for food use: any part of the cannabis plants and cannabis that can be linked or associated with food or food processing and possessing the amounts of CBD and THC appropriate in accordance with the studies and regulatory provisions established the IICBA for normal and complying with accessible food for public consumption.

CBD or Cannabidiol: is a component **non-psychoactive** containing the cannabis plant and is considered to have a broader scope for medical applications than THC, including epilepsy, multiple sclerosis, cancer, acquired immune deficiency syndrome and other diseases. It causes a sedative effect in most cases and inhibits the transmission of nerve signals associated with pain. According to scientific studies, the cannabis plant has more than sixty cannabinoids none of which are found in other plants. They do not produce physical or psychological dependence in people.

Diagnosis or clinical propaedeutic for the use of medicinal cannabis and hemp:

It is the process by which a doctor examines a patient and identifies a treatable disease with cannabinoids or cannabis extracts or medicinal hemp drugs. These diseases can be cancer,

epilepsy, acquired immune deficiency syndrome of cachexia, multiple sclerosis or any other disease that has national or international scientific studies validated by IICBA.

Written Documentation: refers to a signed statement (Medical Certification) by the patient's physician or copies of the relevant medical record.

Usable form of cannabis refers to seeds, leaves, buds, flowers and roots of the Cannabis plant, which are appropriate for medical or food use in accordance with the provisions of this law.

Hemp usable form: refers to seeds, leaves, buds, stems, flowers and roots of the hemp plant, which are suitable for medical, food or industrial use in accordance with the provisions of this law.

Presentations and routes of administration authorized for the medicinal use of cannabis and hemp refers to oil, tablets (tablets and coated tablets), capsules, troches, suppositories, pessaries, transdermal patches, lozenges, ointments, lotions, soaps, ointments, gels, creams, jellies, pastes, tinctures, sprays, elixirs, powders for suspensions or solutions, syrups, injectable into ampoules, prefilled syringes, emulsions and the like as well as pure flowers that can be administered by oral, intravenous, transdermal or inhaled route.

Base salary: for the provisions of this Act, the term "base salary" concept used in Article 2 of Law No. 7337 of May 5, 1993

Card or ID card registration: It is one document or license issued by the legally authorized Institute, which identifies and authorizes a patient or a primary caregiver or legal guardian of the patient to use the cannabinoid drugs or extracted hemp in accordance with established by IICBA.

THC or Delta-9 Tetrahydrocannabinol: it is a psychoactive component containing the cannabis plant and exerts effects on the central nervous system, which can inhibit pain, modify the mood or alter perceptions. **THCA or acid tetrahydrocannabinolic:** it is one of the active components containing cannabis naturally and **is non-psychoactive**, so no adverse effect on user behavior. It has been shown to contain anti-inflammatory and neuroprotective properties. **Article 7 allowed ranges**

For the purposes of this Act, seeds and cannabis plants must have at least 1.5% (one point five percent) of CBD and up to 21% (twenty percent) of THC or Delta-9 Tetrahydrocannabinol to be considered authorized for medicinal use.

The authorized medicinal use is based on cannabinoids and other active compounds with therapeutic effect.

Because of its natural composition and beneficial effects nonpsychoactive limitations for THCA containing the cannabis plant is established.

Seeds and plants authorized non-psychoactive hemp may not exceed 0.5% (zero point five percent) of Delta-9 THC or Tetrahydrocannabinol.

Article 8 Prohibitions.

The following activities are established as prohibited:

- a) authorized medicinal cannabis smoking in public and private spaces or places indicated in the Article 5 of the General Law for the Control of Snuff and its harmful effects on Health, Law No. 9028.
- b) Commercialize permitted under license seed planting and production unauthorized individuals.
- c) Plant cannabis seeds in the country without proper authorization of IICBA.
- d) To cultivate and use cannabis male plants for purposes other than seed breeding and research.
- e) Use pesticides and herbicides that are not organic in cannabis and hemp plantations authorized in this Act and in accordance with the Law on Development, Promotion and Development of Organic Farming Activity Act 8542.
- f) Mix substances or products of the cannabis plant and cannabis for medicinal use with other synthetic substances.
- g) Any form of advertising and promotion of drugs and medicinal cannabis hemp, when misleading; use false information or no scientific basis; when it has done in contravention of the regulations, authorizations obtained or restrictions imposed by the competent authority, in view of the nature of the drug and the type of disease, disorder and physical symptoms for which it is used.
- h) Commercialize drugs cannabis and cannabis without the appropriate license.

TITLE II

RESEARCH, REGULATION AND CONTROL

CHAPTER I

RESEARCH INSTITUTE, REGULATION AND CONTROL OF CANNABIS AND HEMP

Article 9. Creation.

Créase Research Institute, Regulation and Control of Cannabis and Hemp (IIRCCA) as a part of the Ministry of Health body with maximum concentration and instrumental legal personality to manage funds, underwrite national or international agreements, cooperation agreements or transfer resources, and receive donations from public or private, national or foreign entities required to perform their duties in strict compliance with its material purpose and in accordance with this Law of its creation. Shall have jurisdiction throughout the national territory.

The IICBA will exclusively responsible for conducting all investigations and the granting of permits for the use and marketing of cannabis and cannabis plants, their uses and products authorized in this Act and licenses.

The Institute will administer its own funds through current accounts, strictly necessary, in any of the banks of the National Banking System; and you are authorized to borrow or trust funds to finance their activities. All these activities will be subject to oversight and financial controls of the corresponding internal audit and the other provisions governing the matter.

Article 10. Hallmarks.

The Institute of Research, Regulation and Control of Cannabis and Hemp (IIRCCA) will, for official use, stamps, means of identification, badges and emblems own.

Article 11. Powers of IICBA.

The IICBA shall have the following powers:

A) Research and validation exclusively of medical, therapeutic and nutritional use of cannabis and cannabis plants.

B) Potestad control of all mechanisms and protocols for obtaining concessions, licenses and permits, including security protocols to control seeds, the administration of clinics, laboratories, manufacturing standards of pharmaceutical and food products, farms culture and the types of presentations of medicines and authorization and certification of concentrations of THC and CBD.

C) Potestad control of all mechanisms designed for the authorization of agro-industrial uses and marketing of hemp.

D) power to sanction offenders in accordance with the prohibitions, offenses and penalties laid down in this Act.

E) The control and supervision of planting, cultivation, harvesting, production, reproduction, storage, distribution, processing, marketing, export, transport and sale of cannabis and hemp, in accordance with the provisions of this law and the law, without prejudice to the powers of other bodies and public entities.

F) Coordinate with public and private, national or foreign institutions of the health and education sectors.

G) To advise the Executive on:

1) The formulation and implementation of public policies for the regulation and control of distribution, marketing, sale, offering and use of medical cannabis.

2) The coordination of technical cooperation offers made to the country in this area.

3) The contribution of scientific evidence, through research and evaluation of the strategy for targeting cannabis public policy.

Article 12.- Powers of IICBA.

The duties of the IICBA the following:

A) To grant concessions, licenses and permits and their extensions, modifications, transfers and cancellations in accordance with the provisions of this Act and its regulations.

B) Export medicinal cannabis and hemp and other food and industrial products that are made from these plants in accordance with this Law.

C) Create a user registry, protecting your identity, maintaining the anonymity and privacy in accordance with the current legislation and the corresponding regulations. Information regarding the identity of the holders of acts of registration shall character of sensitive data.

D) Create and maintain a specialized food and medicines produced from plants of cannabis and hemp authorized by this Act registration.

- E) Create and maintain a seed bank cannabis and hemp authorized for research, production, cultivation, processing, marketing.
- F) proceeding directly to public bodies to seek and receive information necessary to fulfill the tasks assigned.
- G) enter into agreements with public or private institutions for the purpose of carrying out their duties, especially those who already have assigned jurisdiction in the matter.
- H) Monitor compliance with the provisions in force in charge.
- I) To issue administrative acts necessary for the performance of their duties.
- J) Identify and implement appropriate sanctions for violations of regulatory standards set in this law and its regulations.
- K) enforce the sanctions imposed.
- L) Create and maintain a computer system that allows for cross-checking the information on medicines and foods containing cannabis at least accurate inventory data for each clinic, sales of products and users running.
- M) Create a record export of products and drugs derived from cannabis and cannabis plants.
- N) Certify for purposes of control, transparency and banking control the rotation or origin of the regulated activities and resources obtained through concessions, licenses and permits regulated under this Act.

CHAPTER II

MANAGEMENT

Article 13. Structure of the Institute.

The organs of the Institute shall be:

- a) Board of Directors
- b) Executive Director

c) Honorary Technical Council

d) Internal Audit Unit

Article 14.- Board.

The Board shall be the chief of the Institute and its members shall be persons of recognized moral and technical solvency. It shall consist of seven members:

1. A representative of the Ministry of Health who will preside.
2. A representative of the Ministry of Agriculture and Livestock.
3. A representative of the National Seed Office.
4. A representative of the University of Costa Rica.
5. A representative of the College of Physicians and Surgeons.
6. A representative of the College of Pharmacists.
7. A representative of dealers cannabis growers class A.

The representative of the dealers shall be appointed by a General Assembly must convene all the IICBA authorized dealers.

Among the members of the Board shall be at least one professional in toxicology, one in biology, one in biochemistry and one in medicine.

The appointment of members of the Board include that of their corresponding alternates.

The term of office of the members of the Board shall be three years and may be reappointed for one consecutive term.

Retiring members shall remain in office until the new appointed members assume.

Board members receive an adequate remuneration to be fixed by the Board itself.

The Board shall determine its regime session. Resolutions are taken by simple majority.

Article 15.- Powers of the Board.

The Board, in its capacity as supreme administrative body of the Institute (IICBA) shall have the following powers:

- A) Projecting the General Regulations of IICBA and subject to approval by the Ministry of Public Health.
- B) To prepare and approve the regulation of agriculture under controlled for planting and production of cannabis and cannabis for medicinal, food and industrial environments.
- C) To approve the status of its employees within six months of installation. It shall be governed, as provided by the rules of private law.
- D) Set the cost of each authorization certificates.
- E) To approve its budget and submit it to the Executive for knowledge, together with the business plan.
- F) To authorize each independently export cannabis or hemp medicinal, food or industrial use.
- G) To approve the plans, programs and special projects.
- H) Raise the memory and the annual balance IRCCA.
- I) Managing resources and assets IRCCA.
- J) To acquire, encumber and dispose of all kinds of goods. In the case of real property shall be resolved by a qualified majority of at least five members.
- K) To delegate the powers it deems appropriate and reasoned decision by a majority of its members.
- L) Generally perform all civil and commercial acts, issue acts of internal administration and perform its general powers inherent in materials management operations under the tasks and specialization of IICBA with.
- M) Select, at the first session of each year, a secretary, a treasurer and four members. The first vowel replace the chairman in his absence, temporary impediments and excuses; when missing both, the Board shall appoint an interim president. If the secretary is missing, you appoint an ad hoc.

N) appoint and remove the CEO.

O) appoint and remove the auditor, for which you should follow the procedure outlined in the law.

P) To determine the general policy of the Institute, within the fields of action assigned laws and regulations.

Q) To examine and approve the annual work plans, budgets and amendments thereto, as well as monitor their agreement.

R) approve the regulations of organization and operation.

S) Know the semiannual reports of work of the Executive Directorate and Internal Audit. These reports shall be published in electronic media to be accessible to the public and may be subject to oversight and public control.

T) Supervise through coordination and collaboration of the College of Pharmacists and the Ministry of Health all clinics and pharmacies in the Costa Rican Social Security issued cannabis or drugs derived from hemp.

Article 16.- Executive Director

The Executive Directorate is a subordinate body of the Board; It will be headed by an executive director, who will be the highest ranking official, for purposes of management and administration of the Institute. It will be up work, immediately, with the Board in planning, organization and control of the institution; as well as the formalization, implementation and monitoring of its research and policy. In addition, it shall fulfill the tasks assigned to it by the regulations and shall initiate legal proceedings in defense of the rights of the Institute, as determined by the Board.

He shall be appointed by agreement of two-thirds of the Board. It will be hired for periods of three years renewable. For dismissal or non-renewal of the Board shall require the same majority of votes required for appointment.

The Executive Director shall be subject to the obligation under Article 4 of Law 8422, Law against corruption and illicit enrichment in the civil service.

Their remuneration shall be fixed by the Executive Board under the Institute's resources.

The Executive Director shall attend the meetings of the Board with no voting rights and shall have the following powers:

- A) To comply with and enforce the existing rules on competition of IICBA.
- B) To implement plans, programs and resolutions adopted by the Board.
- C) Perform all tasks related to personnel management and the internal organization of IICBA.
- D) accountable through semiannual reports to the Board of IICBA.
- E) Any other that the Board entrusted or delegated to him.

Article 17. Honorary Technical Council

The Honorary Board shall consist of one representative from each of the following organizations:

- A representative for each Category dealers for cannabis cultivation.
- A representative for licensees to dispensaries.
- A representative from licensees for hemp cultivation.
- The Monitoring Board Drugs and Narcotics.
- A representative of the Institute of Alcoholism and Drug Addiction.
- A representative of the Costa Rican Institute on Drugs.
- Any other member authorizing the Board of IICBA.

Article 18. Technical Proceedings of the Honorary Council.

Honorary Technical Council, in its capacity as consultative organ of the Institute, will perform:

- A) Advise on the drafting of the General Regulations of IICBA.
- B) Advise on the drafting of plans and programs prior to approval form.
- C) Advise on anything that the Board may request.

D) Advise on safety, quality, safety and traceability of cannabis seeds and plants to fulfill the purposes set out in this law.

E) Sounding on any other matters relating to the tasks of IICBA, when appropriate.

Article 19 Internal Audit

The IICBA will have an internal audit, which will work under the direct supervision and responsibility of an audit person who must be authorized public accountant with extensive experience in information systems. Internal Audit will have the resources necessary for the proper performance of their duties.

The technical and administrative structure of the Internal Audit Unit to regulations.

The Internal Audit shall exercise its functions with independence and functional criteria with respect to the hierarch and other government bodies. Its organization and functioning shall be governed in accordance with the provisions of the Organic Law of the Comptroller General of the Republic, the Manual for the exercise of internal audits and any other provisions issued by the comptroller.

Article 20. Appointment of the auditor person

The auditor will be appointed by the Board, by the affirmative vote of two thirds of its members. It will remain in office six years and may be reappointed. It is subject to the same limitations as this Act and its Regulations provide for the Executive Board, as may be applicable.

The audit person may be suspended or removed from office for just cause and by the supreme decision of the Board, with observance of due process. For the dismissal the same number of votes required to appoint, in accordance with the provisions of the Comptroller General of the Republic will be required.

Article 21.- Powers of the Internal Audit

Internal Audit, in addition to operational and financial audits special character, have the following powers:

a) Monitor and evaluate the internal control system and propose appropriate remedial measures.

- b)** Comply with the technical auditing standards, the provisions issued by the Comptroller General of the Republic and the law.
- c)** Conduct audits or special studies, in relation to any of the bodies subject to its institutional jurisdiction.
- d)** Provide advice on matters within its competence, the hierarchs of IICBA and also warn liabilities fiscalicen bodies, on the possible consequences of certain behaviors or decisions, when they are of their knowledge.
- e)** Perform such other powers that include standards system of control and supervision.

Article 22.- Powers of Internal Audit

To fulfill its duties, the Internal Audit shall have the following powers:

- a)** To have free access at any time to all books, records, assets and documents, as well as other sources of information related to their activity.
- b)** request any official or employee of any hierarchical level, in the form, conditions and the time it deems appropriate, reports, data and documents necessary for the proper fulfillment of its purposes.
- c)** To request officials and employees of any hierarchical level, collaboration, advice and facilities required the exercise of Internal Audit.
- d)** Any other powers necessary for compliance and control and audit manuals issued bythe Comptroller General of the Republic.

Article 23. Implementation of the recommendations

The Board of IICBA will be responsible for implementing the recommendations issued by the Internal Audit Unit. If the Administration disagrees with these recommendations shall issue a reasoned written agreement within thirty working days, which will contain an alternative solution.

To keep the divergence of opinion between the Administration and the Internal Audit Unit will correspond to the Comptroller General of the Republic clarify the differences, at the request of interested parties.

The Board shall be responsible for establishing, maintaining and improving its internal control systems.

The rules dictate that the Board thereon, shall be binding upon the administration responsible for implementing and operating the system.

CHAPTER III

ENABLING THE TITLES

ARTICLE 24.- Concessions

concession for activities related to the cultivation, production and industrialization of the cannabis plant and medicinal hemp regulated in this Act shall be granted. This concession shall entitle its holder for the cultivation, production, processing, transportation and marketing of cannabis plants and medicinal hemp authorized in accordance with the uses and purposes provided in this Act. the concession will be granted for an area of particular, local, regional or national coverage, so that the necessary and adequate production for domestic demand and conditions guarantee morbidity of the country's inhabitants.

ARTICLE 25.- Bankruptcy proceedings

Concessions will be granted by the IICBA through tender procedure in accordance with the Public Procurement Act and its regulations.

For a grant interested parties must demonstrate financial solvency, transparency in the origin of their capital and business philosophy in line with the development policies of the country and the 8402 Act.

Article 26.- Conditions and types of concessions

I. There will be three types of grants (categories) available to allow a wider range of beneficiaries and improve socio-economic conditions of domestic producers.

II. For purposes of state control, 42 concessions will be available to farmers throughout the country, this in order to avoid creating any kind of monopoly. However, IICBA shall be entitled to that, the fact that the licensed production of medicinal cannabis or hemp is not enough because of the demand for drugs, increase the authorized number of production or concessions.

III. Any licensee may develop food plants indicated compliance with health legislation and other regulations established by the Ministry of Health.

IV. Each applicant and its employees shall comply with background checks established by IICBA.

V. The IICBA define specific areas of the country and adequate minimum size for each type of grant.

SAW. It is only allowed a concession by natural or legal person.

VII. Any dealer of cannabis cultivation and medicinal hemp is eligible for a license to grow industrial hemp payment of the respective fee.

VIII. All grants are subject to the rules and regulations established by IICBA.

IX. All dealers will be forced to sell, primarily, to IICBA all stocks of cannabis or cannabis for medicinal use at the price established in this Act, to meet the demand for drugs agreed with CCSS and authorized presentations. The IICBA, in coordination with the CCSS shall identify and maintain an inventory of medicines to meet the demand of patients who come to the CCSS to receive alternative treatments covered by this Act.

X. Any licensee may export cannabis or hemp for medicinal or food use in accordance with what is authorized for each category prior authorization granted by the IICBA and once they have provided adequate supply for the country.

XI. Concessions will be divided and classified into three categories.

- Category A: 50% of the total domestic production will be in charge of this category and will be available in August concessions for growers.

- Category B: 35% of the total domestic production will be in charge of this category and will be available 13 concessions for growers.

- Category C: 15% of the total domestic production will be in charge of this category will have available 21 concessions for growers.

GROWER AWARDS CATEGORIES

CATEGORY A

I. The cost of each grant available for this category is US \$ 150,000.00 (one hundred fifty thousand US dollars) or its equivalent in colones. The concession period will be four years, renewable at the end of each period.

II. This concession allows the grower be licensed dispensary within their own facilities whose cost would be included in the fare paid. These licenses do not apply or be deducted from the number of licenses provided in this Act for regular clinics.

III. A requirement for dealers in this category is able to produce up to one ton per year with the farming system under controlled in accordance with the regulatory provisions of this Act and the regulations shall issue the IICBA environment. The production is subject to the requirements of IICBA.

IV. It is also a mandatory condition for this category dealers have adequate laboratory for plant breeding, reproduction and research of seeds and for the processing and preparation of medicines in the various presentations and routes authorized by this Act to be required by the IICBA for purposes of distribution in pharmacies and clinics CCSS.

V. Grantees under this category may produce those drugs cannabis and hemp indicating this Act and the IICBA required.

CATEGORY B

I. The cost of each grant available for this category is US \$ 75.000,00 (seventy-five thousand US dollars) or its equivalent in colons, valid for a period of four years and may be renewed at the end of each period.

II. A requirement for dealers in this category is able to produce up to 450 kilograms per year, with farming system under controlled in accordance with the regulatory provisions of this Act and the regulations shall issue the IICBA environment. The production is subject to the requirements of IICBA.

III. These dealers may not have a laboratory for breeding, reproduction and research of seeds and for industrialization, processing or preparation of pharmaceutical drugs for distribution in dispensaries and only be processed cannabis flowers and oils

CATEGORY C

I. The cost of each grant available for this category is US \$ 35.000,00 (thirty-five thousand US dollars) or its equivalent in colones, valid for a period of four years and may be renewed at the end of each period.

II. A requirement for dealers in this category is able to produce up to 120 kilograms per year with the farming system under controlled in accordance with the regulatory provisions of this Act and the regulations shall issue the IICBA environment. The production is subject to the requirements of IICBA.

III. Dealers in this category may not have a laboratory for breeding, breeding and seed research.

IV. Grantees under this category can only produce cannabis for medicinal use in the oil and flower forms.

ARTICLE 27.- Poster Contest

The poster contest shall establish at least the following:

- a) The date, time and place of submission of bids, and the requirements to be met suppliers and other records to be delivered.
- b) The types of activities under concession, their use patterns and coverage area.
- c) The obligations of dealers in accordance with each authorized activity, as appropriate.
- d) The deadlines for consultations and clarifications to the cartel.
- e) The amount of the annual fee and the financial, technical and legal requirements that are valued in qualifying tenders and the methodology to be used.
- f) The duration of the concession.
- g) The conditions and timing of payment of the consideration, as appropriate.
- h) The participation and compliance guarantees available to the IICBA.
- i) Fines and penalties for breach of the concession agreement.
- j) The draft contract to be signed with the dealer.

ARTICLE 28.- OBJECTION TO POSTER

It may be brought against the cartel objection within the first third of the deadline for bids. The application, duly founded, be submitted to the Office of the Comptroller General of Colombia.

All potential bidder or his representative may file an appeal for objection to the poster when deemed to have been incurred vices procedures or any violation of the fundamental principles of government contracting, they have been omitted technical specifications, or has broken, somehow, the regulatory system of the subject.

The appeal of objection shall be resolved within ten working days of presentation.

Who can turn to and not to do it or not alleged violations or losses to which you are entitled, you cannot use these arguments in the appeals lodged against the award process.

ARTICLE 29.- Tendering

Tenders must be submitted to the IICBA, in accordance with the terms of the cartel. The presentation of the offer implies the full submission of the offeror, both Costa Rican law as to the general rules and particular contest.

ARTICLE 30. SELECTION OF THE CONCESSIONAIRE AND AWARD

The concessionaire will be selected from among the bids according to the rules of the cartel and according to the system set out in the contest.

Eligible offers will be evaluated by the IICBA, which will then determine whether or not the award.

The award agreement shall be published in the Official Gazette within ten (10) business days.

ARTICLE 31.- APPEAL AWARD

Award against the act may be appealed, within the publication of the agreement in the Official Gazette ten working days. The application, duly substantiated, be submitted to the Office of the Comptroller General of Colombia.

You may file an appeal any party with a legitimate, current, own and direct interest. It shall also be entitled to appeal who has submitted a bid, by any representation on behalf of third parties.

The appeal shall be settled within forty working days of the initial order of removal. This period may be extended by a reasoned decision up to twenty working days in very special cases, when needed seek especially important to resolve the resource expert evidence, and that complexity cannot be rendered within the normal period for withdrawal.

The reallocation also may be challenged when the causes of nonconformity of the subject have arisen based on the award ceremony.

The final resolution or order to put an end to the resource will be exhausted administrative remedies. Within three after communication business days, the applicant may challenge the final act without suspensive effect in accordance with the provisions of the administrative law.

If the contract whose award is contested has been implemented or is in progress, the judgment favorable to plaintiff may only recognize the damages caused.

ARTICLE 32.- Concession Contract

Sign the award process, and having the agreement authorization of the Board of IICBA, the executive director of that institution concluded with the dealer the respective contract, which shall specify the conditions and obligations that the licensee shall, in accordance with this Act, its regulations, the rules of the competition, supply and award process. The contract must be approved by the Comptroller General of the Republic.

ARTICLE 33.- ASSIGNMENT

Concessions can be transferred with the prior approval of the Board of IICBA.

To approve the assignment should observe the following minimum requirements:

- a) That the transferee meets the same requirements as the transferor.
- b) the transferee undertakes to fulfill the same obligations acquired by the transferor.
- c) That the transferor has exploited the concession by at least two years and has fulfilled the obligations and other conditions laid down for that purpose in the concession contract.
- d) That the assignment does not affect effective competition in the market.

Authorized the transfer, you must subscribe the respective contract with the new concessionaire.

Article 34.- Licenses.

To obtain a license stakeholders must demonstrate financial solvency and transparency in the origin of their capital.

The IICBA held a call for expressions of interest to select natural and legal persons interested in obtaining a license for dispensary or for growing hemp.

Article 35. Types of licenses.

The IICBA establish the corresponding procedure for granting the following licenses:

1) import license seeds

Only holders of a concession to growing class may import cannabis seeds and hemp seed and reproduction for which will require the prior approval of IICBA. They will be required to share the investigations carried out on seeds with IICBA and donate a percentage of their seeds to IICBA for the latter's use in research, breeding and seed distribution among the other growers who require it.

2) LICENSES DISPENSARY.

I. The cost of each annual license is \$ 10.000,00 US (US dollars) or its equivalent in colones.

II. Each license shall be valid for four years, renewable for the same period and must be renewed before the end of the previous period.

III. There will be 55 licenses dispensaries throughout the country. This based on an average of 70,000 people market, where every business has the potential of 1,500 patients.

IV. Each applicant shall comply with background checks established by IICBA.

V. Licensees may establish their business anywhere within the country but no establishment may be located within a range of 500 meter radius of a school.

SAW. It is allowed only one license per physical or legal person.

VII. All licenses are subject to the rules and regulations established by IICBA.

3) LICENSES FOR INDUSTRIAL AND FOOD HEMP.

I. For the cultivation of hemp will be available one hundred seventy-eight (178) licenses.

II. Each license shall be valid for two years and may be renewed before the end of the corresponding period.

III. For food processing must meet the requirements of health legislation and other regulations established by the Ministry of Health.

IV. Each applicant and its employees shall comply with background checks established by IICBA. They must also comply with the provisions on safety and production control available, by regulation, the IICBA.

V. is only allowed a license for natural or legal person.

SAW. Each applicant must register with IICBA the GPS (Global Positioning System) in the area licensed for hemp cultivation coordinates.

VII. The seeds used by the licensee must be registered with the National Seed Office and may not submit more than 0.5% THC.

VIII. Any seed that will be sold to the end user must be processed in such a way that it can not germinate.

IX. All licenses are subject to the rules and regulations established by IICBA.

X. Licenses are divided and classified into three categories according to the size of the crop:

Category D: 10 hectares or more available for cultivation. 34 licenses available for this category.

Category E: from 3.1 to 9.9 hectares available for cultivation. 55 licenses available for this category.

Category F: 1 to 3 hectares available for cultivation. 89 licenses available for this category.

Licensing categories hemp cultivation

CATEGORY D

i. The cost of each license available for this category is US \$ 30.000,00 (thirty thousand US dollars) or its equivalent in colones.

ii. Each license shall be valid for two years and may be renewed before the end of the corresponding period.

iii. Mandatory requirement is to have at least ten (10) hectares available for cultivation of hemp.

CATEGORY E

i. The cost of each license available for this category is US \$ 15.000,00 (fifteen thousand US dollars) or its equivalent in colones.

ii. Each license is valid for two years and may be renewed before the end of the corresponding period.

iii. Mandatory requirement is to have at least three point one (3.1) hectares available for cultivation of hemp and a maximum of nine point nine (9.9) hectares.

CATEGORY F

i. The cost of each license available for this category is US \$ 5.000,00 (five thousand US dollars) or its equivalent in colones.

ii. Each license is valid for two years and may be renewed before the end of the corresponding period.

iii. Mandatory requirement is to have at least one (1) hectare available for the cultivation of hemp and a maximum of three (3) hectares.

Article 36.- Permits for Transportation

Dealers and licensees must apply for special permits to transport the products of cannabis and hemp in accordance with safety requirements, safety, labeling and packaging must establish, by regulation, the IICBA.

These permits are valid for up to one year and are renewable.

ARTICLE 37.- Revocation and termination of concessions, licenses and permits

For purposes of this Act, they are causes for termination and termination of the concession contract the following:

1) The termination of the concession proceeds for the following reasons:

a) When the licensee has not authorized activities to fulfill the purposes requested after a year of being assigned or extension has been granted.

b) Breach of the obligations and conditions set out in this Act, the regulations issued for that purpose or those imposed on the concession contract, unless unforeseen circumstances or force majeure is checked.

c) Failure or delay of at least two months in the payment of annual, biennial or multiannual rate permit, license and concession, as appropriate to IICBA and tax obligations.

d) Failure to cooperate with public authorities in cases provided in this Act and the General Health Law.

and) Recidivism of very serious offenses, in accordance with Article 51 of this Law, during the term of the authorization certificate.

The declaration of termination of the contract will be preceded by an administrative process that will respect the rules of due process. The concession holder whose decision has been declared a serious breach of its obligations, be unable to keep new concessions and authorizations from those provided in this Act, for a minimum period of three years and a maximum of five years, counted from firmness of the resolution.

2) The concessions, licenses and permissions are extinguished for the following reasons:

a) The expiration of the agreed term.

b) Impossibility of performance as a result of measures taken by the State authorities.

c) The rescue because of public interest.

d) The mutual agreement of the granting authority and the concessionaire. This agreement shall be reasoned due regard to the public interest.

e) The dissolution of the concessionaire legal person.

If the termination occurs for reasons beyond the dealer, he will be safe their right to receive the compensation due under this Act and the concession contract.

Article 38.- Carnet for patients of medical cannabis products.

A patient who no longer has a diagnosed medical condition for medicinal use of cannabis or hemp must return your ID card registration to IICBA within twenty-four hours of receiving such a discharge diagnosis by your doctor.

The IICBA will be responsible for approving the implementation of each patient and process identification cards patient record prior medical recommendation of at least one physician with knowledge of the uses of cannabis and medical cannabis and view the patient's medical record.

ID cards may not be granted for consumption of cannabis or hemp drugs to persons who have been convicted of crimes linked to drug trafficking unless it is able to demonstrate that there is no risk to patient health.

The license or ID card patient access to drugs cannabis and / or hemp is renewable by prescription individualized case by case basis in accordance with the provisions established by regulation the IICBA.

CHAPTER IV

RECORDS

Article 39.- Register of Medicinal Products.

For registration of herbal medicinal cannabis and hemp apply the provisions of the General Health Law, Law N°5395. It will be indispensable technical and scientific compliance with the CBD and THC ranges set out in this Act verification.

Article 40.- Registration patients.

The IICBA shall create and maintain a confidential computerized records of patients who have applied and are in the right to receive an ID card registration.

This record shall be restricted only to dispensaries duly authorized by the IICBA for release drug access.

In no particular you will be allowed to access any patient information in the confidential registry that will manage the IICBA, or any information otherwise maintained so by IICBA on physicians and primary caregivers, unless authorized by the IICBA in the course of their duties employees health officials and police officers authorized by the IICBA, which have stopped or arrested a person claiming to be participating in the medicinal use of cannabis and / or medicinal hemp in possession of an iD card registration or its functional equivalent. The agents of state and local law enforcement or should have access to the information contained in the confidential record of IICBA solely for the purpose of verifying that the individual who submitted the ID card registration to an official state or local law enforcement , it is legally in possession of the card.

To be incorporated into the record the patient must provide the following information to IICBA:

(I) Original or copy of the written documentation (Medical Certification) which states that the patient has been diagnosed with a medical condition for use of cannabis and / or medicinal hemp and the conclusion of the physician that the patient may benefit from the medical use of cannabis and / or hemp;

(II) The name, address, phone, email and date of birth. To be attended by the CCSS must be properly secured and in good standing;

(III) The name, address, and telephone number gives the patient's physician; Y

(IV) The name and address of the first caretaker of the patient, if someone goes designated at the time of the application.

(V) The approval of the National Child Welfare Agency in case concerned a minor.

(VI) The consent of at least one parent in the case concerned a minor.

You must surrender to the IICBA completed application form in accordance with the requirements established by the Institute.

Within thirty calendar days of receiving the information referred to in sub-paragraphs, the IICBA shall verify the medical information contained in written documentation. The IICBA shall notify the applicant that the application for an ID card registration has been denied if the result of the review by the ombudsmen of IICBA reveals that: the required information was not provided or if it contributed has been falsified; documentation fails to state that the patient has a medical condition specified in this Act or the regulations IICBA; or the doctor does not have a license to practice medicine issued by the appropriate professional association. If found everything in order, no later than five days after we verify this information, the IICBA shall issue a registry identification card with serial number to the patient, stating:

(I) The patient's name, address, date of birth and social security number, if any;

(II) The patient's name has been certified by the IICBA as a person who has a medical condition for the use of medicinal cannabis, so the patient can cope with such conditions with the medical use of cannabis authorized;

(III) The date of issuance of the ID card registration and expiration date of the card, which must be one year after the date of issue; Y

(IV) The name and address of the patient's primary caregiver, if any was designated at the time of application.

A patient who applied for a card has been denied by the IICBA can not apply again for six months from the date of denial. This act of denial of an ID card registration will be considered as a final act of IICBA. Only the patient whose application is rejected will be entitled to challenge the final act.

When changes occur in the name, address, doctor or primary caregiver of the patient in possession of an ID card registration, it shall notify the IICBA within ten working days to the knowledge of that fact.

A patient who has not designated a primary caregiver when applying to the IICBA may do so, in writing, at any time during the effective period of the ID card registration, and the primary caregiver may act in this capacity after such designation.

To keep an ID card registration, the patient must forward annually, at least thirty days before the expiration date established in the ID card registration, written documentation updated to IICBA, and also, the name and address of the primary caregiver patient, if one is designated for that time.

A patient is questioned by any police authority on the medicinal use of cannabis and / or hemp shall provide a copy of the application submitted to the IICBA, including written documentation and proof of the date of mailing or other transfer of documentation written for submission to IICBA, which will be granted the same legal effect as ID card registration until the time the patient receives notification that the application has been denied.

Agents health or public order shall notify immediately to IICBA by the established media, when a person in possession of an ID card registration has been determined by a court of having violated intentionally provisions this Act or its regulations.

TITLE III

PATIENTS AND DUTIES Medical Professionals

CHAPTER I

DUTIES OF PATIENTS

Article 41. Duties of cannabis and cannabis patients for medicinal use.

No patient should:

- Participate in the medicinal use of cannabis or hemp in a way that endangers the health or safety of any person; or
- Participate in the medicinal use of cannabis in plain view, or on a site banned smoking in accordance with the provisions in Article 5 of the General Law for the Control of Snuff and its harmful effects on Health, Law No. 9028.
- No patient is **under eighteen years** of age should participate in the medicinal use of cannabis or hemp unless there:

- a) Medical Certification of patient diagnosis that reflects the disease and is treatable with medical cannabis;
- b) Medical Explanation of potential risks and benefits of medical cannabis patients and the parents or legal representatives of the patient by scientific documentation (informed consent).
- c) One or both parents of the patient gives written consent to the IICBA to allow the patient to participate in the medicinal use of cannabis;
- d) The parents state in writing that will serve as caregivers of the patient and apply for an ID card registration medication approved for patients cannabis products,
- e) The IICBA will be responsible for approving the application and process patient ID card patient record to the parent designated as primary caregiver; Y
- f) The primary caregiver must control the acquisition of such medicinal cannabis medication, dosage and frequency of use by the patient.
- g) The National Children's Trust provide their written endorsement to the file on the basis of current scientific medical and diagnostic studies.

Article 42.- Causes of justification.

A patient or primary caregiver accused for violating any provision of criminal law relating to the medicinal use of cannabis patient may have established an affirmative defense or justification demonstrating that:

- (I) The patient was diagnosed previously by a duly authorized to recommend an alternative treatment with use of cannabis and / or hemp medical doctor.
- (II) The patient was recommended by your doctor, in the context of a doctor-patient in good faith statement that the patient may benefit from the use of medicinal cannabis or hemp for its clinical diagnosis; Y
- (III) The patient and primary caregiver were collectively in possession of quantities of cannabis only as permitted in this section.

These allegations do not exclude any other defense where a patient or primary caregiver are accused of violating the criminal law related to the medical use of cannabis or cannabis patient.

It will be an exception to the criminal law for any patient or primary caregiver who is in lawful possession of an ID card registration to employ or assist in the medical use of cannabis or hemp.

CHAPTER II

PRESCRIPTION AND MEDICAL SURVEILLANCE

Article 43 Medical prescription.

Medications made cannabis and hemp can be sold only by prescription. This is done using special recipes with a distinctive color must issue the Ministry of Health.

Article 44.- professional duty.

It should be an exception to the criminal law for any doctor:

(I) advise a patient whom the doctor has diagnosed with a disease, the risks and benefits of medicinal use of cannabis and / or hemp, provided that such advice is based on the evaluation of the patient's medical history and condition current medical and doctor-patient relationship in good faith; or

(II) provide a medical certificate to a patient where noted clinical diagnosis that allows you to benefit and receive a treatment with cannabis and / or medicinal hemp, in presentations and routes of administration authorized under this Act is made.

However, doctors may perform therapeutic alternative procedures using the technique of inhalations of cannabis administered directly to the patient within those health centers that have adequate facilities and trained support staff.

All pharmaceutical professional who works for the CCSS or exercising as regent of this law authorized dispensaries have appropriate knowledge about these drugs, the various presentations and routes of administration and the effects they produce.

Article 45.- Incorporation in the official list of medicines.

Medications made cannabis and hemp regulated under this Act shall be available on the official list of medicines.

Article 46.- Pharmacies CCSS.

The IICBA will be responsible for providing CCSS pharmacies cannabinoids extracted drugs and cannabis.

The Costa Rican Social Security Fund is authorized to issue them in their pharmacies in presentations and routes of administration authorized. To do this you must have the infrastructure and exclusive and adequate space for safe and secure storage of these drugs.

CCSS pharmacists must issue cannabinoids extracted drugs and cannabis in accordance with the prescriptions can not deliver pure cannabis plant flowers.

TITLE IV

PRICE

CHAPTER I

RULES FOR FIXING THE FOOD AND DRUG PRICE cannabinoids

Article 47. Price of cannabis and cannabis products for medicinal use

The rules for the pricing of medicinal cannabis products are as follows:

1. Farmers must sell directly to IICBA the entire stock or distribute in turn directly to clinics, as long as authorized by the IICBA.
2. The average price is \$ 6 US or its equivalent in colones per gram of crude product or flower that is sold to IICBA.
3. The IICBA and authorized to sell or provide growers directly sell finished products to clinics with an aggregate value of \$ 1.5 or its equivalent in colones per gram, ie, to \$ 7.5 or its equivalent in colones.
4. The average price of cannabis oil concentrate is about eight times the price of a gram of crude product or flower, around \$ 48.00 US or its equivalent in colones per gram.
5. Prices in clinics will be adjusted by the IICBA, which will be the selling prices of IICBA more added value of \$ 0.5 or its equivalent in colones per gram, ie, \$ 8 or its equivalent in colones.

These prices will be adjusted in accordance with the rules set out by the IICBA by price regulation cannabinoid medicines and medicinal hemp authorized by this Act.

Article 48. Price of cannabis products for food use.

The price of cannabis products for food use will be regulated by the IICBA.

CHAPTER II

RULES FOR THE PRICING OF HEMP PRODUCTS FOR FOOD AND INDUSTRIAL USE

Article 49.- The price of hemp products for food and industrial use will be regulated by the IICBA.

TITLE V

TAX

CHAPTER I

CREATION OF TAX CANNABIS

Article 50. Creation of tax cannabis.

a tax on profits of enterprises and individuals to develop lucrative activities associated with each of the concessions, licenses and regulated by this law permits set.

The generator of tax on profits referred to in the preceding paragraph, the fact is the perception of income in cash or in kind, continuous or occasional, from the lucrative activities associated with each of the concessions, licenses and permits regulated by this law . **Article 51 .- Taxpayers.**

Will taxpayers of this tax individuals and legally constituted, regardless of nationality, legal persons of domicile and place of the constitution of legal persons or meeting of their boards or the conclusion of contracts, performing business activities or profit status in the country linked to each of the activities associated with each of the **concessions and licenses** covered by this law.

Article 52.- Tax Rate

A fee imposed on taxable income contained in Article 15 of the Law on Income Tax Law N°7092, will apply an additional 7% for activities associated with each of the concessions, licenses and permits regulated in this law.

Article 53. Entities not subject to tax.

Exenciónese tax payment:

a) When IICBA by income received from the sale of cannabis products or hemp.

Article 54 Destination of the tax.

The resources collected from the tax should be handled in a specific account in one of the state banks in the Republic, in accordance with the Financial Administration Act, in order to facilitate handling and to the National Treasury may rotate them, direct and timely be monthly and will be distributed as follows:

- a) Twenty percent (20%) of the resources will be allocated to the Costa Rican Social Security Fund (CCSS), to be used in the modernization of equipment, purchase of medicines and construction of new hospital facilities and clinics.
- b) A ten percent (10%) will go to IICBA, to fulfill the functions entrusted by this law.
- c) Five percent (5%) will go to the College of Pharmacists to perform the audit of all clinics in conjunction with inspectors from the Ministry of Health and report to IICBA its results for the appropriate, in accordance with the provisions Article 100 of the General Health Act and this Act and its regulations.
- c) Five percent (5%) will be allocated to the Ministry of Health to fulfill the tasks entrusted in this Act and the General Health Law related to the effective control of dispensaries, expedited registration of cannabinoid drugs and extracted from hemp, food and respective labeling, among others.
- d) A five percent (5%) will be allocated to the Ministry of Agriculture to carry out activities related to the control of cultivation, production, processing, planting and production of medicinal cannabis and hemp for industrial use .
- e) A three percent (3%) will go to the Costa Rican Institute of Sport and Recreation (ICODER) to fulfill their duties related to sports and recreation.
- f) A two percent (2%) will go to the Institute on Alcoholism and Drug Dependence (IAFA) for the performance of their duties.
- g) Five percent (5%) will be allocated to the Ministry of Public Works and Transport for the construction of new road infrastructure works as well as works for compliance and improving access for people with disabilities.
- h) Five percent (5%) will be allocated to the Ministry of Science and Technology research, infrastructure and technical and scientific equipment.
- i) A ten percent (10%) will be allocated to municipalities across the country equitably for improving public services and municipal infrastructure.

j) Five percent (5%) will be allocated to the Ministry of Education for the construction of new educational and sports infrastructure.

k) A five percent (5%) will be allocated for financing the National Network of Care across the country to fulfill its tasks related to infrastructure, care professional and feeding of minors beneficiaries in an attempt to hold harmless the largest possible population.

l) Five percent (5%) will go to the Costa Rican Institute of Aqueducts and Sewers for the construction of the necessary infrastructure for the strengthening and modernization of adequate water system and protection of water sources.

m) A five percent (5%) will go to the University of Costa Rica for purposes of conducting joint research with the IICBA on technical and medical governed by this Act, scientific.

n) A ten percent (10%) is allocated for non-governmental organizations dedicated to treating people with addiction problems.

The Office of the Comptroller General of Colombia supervise the use of these funds, as provided in this law.

Furthermore, all beneficiary institutions must render a detailed and complete to the Board of IICBA on the effective implementation of the destinations assigned for each of the resources derived from the tax created by this Act annual report.

TITLE VI

VIOLATIONS AND PENALTIES

CHAPTER I

SEIZURE

Article 55.- Confiscation of cannabis products

The Ministry of Health, IICBA, the Costa Rican Institute on Drugs (ICD), the police authorities, the Ministry of Public Security, the Ministry of Economy, Industry and Commerce (MEIC) and municipalities are empowered to conduct seizures cannabis and hemp products not authorized by the IICBA. All items seized will be sent to the competent judicial authority within three days, which shall order the deposit in place that has provided the Ministry of Health to guard evidence until such authority determine the procedure. If within three months after the end of the trial, having passed the rightful owner a persona not in court to enforce their rights, the court shall order the Ministry of Health destruction of property. When proceeding to the destruction of these goods should be taken appropriate steps to avoid health risks and environmental measures.

All this notwithstanding the procedure of destruction of plantations established in Article 95 of the 8204 Act which applies only to the case of cannabis and hemp plantations that are not properly covered in this law.

ARTICLE 56.- Confiscation Act

Health authorities; research, regulation and control; of cop; drug control; commercial and municipal come to confiscate the proceeds of cannabis and / or hemp irregular conditions up a written report the presence of two witnesses. That document shall contain the date, place, name and surname of persons acting indicating the steps taken and the signature of all participants or mention that one can not or want to sign.

copy of the person to whom the goods confiscated or who is in the place of seizure was issued. The seized products will be made immediately, the order of the competent judicial authority.

CHAPTER II

VIOLATIONS AND PENALTIES

ARTICLE 57.- Sanctions

According to the offense, the sanction IICBA:

a) A fine of ten percent (10%) of a base salary, to individuals who smoke cannabis products on sites banned in accordance with the provisions of Article 5 of Law 9028 which is mandatory in the this Law. in addition to this, the IICBA shall revoke for a period of one year iD card registration of any patient found intentionally violating the prohibition stipulated on products prohibited for smoking cannabis sites.

b) A fine of a base salary (100%) who commits any of the following behaviors:

i. A person occupying the position of director, director, curator, trustee, guardian and other individuals with decision - making powers in any company or public or private institution, where it is found that have allowed the product smoked cannabis sites prohibited under Article 5 of Law 9028 which is mandatory according to the provisions of this Act.

ii.- Who sells or supplies cannabis products higher than those indicated in the prescription quantities.

iii.- Who sells or supplies cannabis products using any means that does not allow verification of the identity of the purchasing people.

- c)** A fine of twenty (20) base salaries who commits any of the following behaviors:
- i.** Whoever contravenes any of the provisions on the sale of seeds of cannabis plants.
 - ii.-** Who cannabis seeds play in the country without proper authorization of IICBA.
 - iii.-** Who authorized the IICBA seeds or seeds or plants reproduce male cannabis for purposes other than seed reproduction or research.
 - iv.-** Whoever fails to comply with the regulations and technical specifications of packaging and labeling of cannabis products.
 - v.-** A party that breaches any of the provisions relating to advertising and promotion of medicines and medicinal cannabis hemp established in this law.
 - vi. -** Who sow, cultivate, produce, industrialize, market, distribute, free or grievously, products cannabis or hemp for any use authorized in places not allowed, under conditions unauthorized or without the proper concession, license or permit the IICBA.
 - vii.-** Who sells or supplies cannabis products to people without proper medical prescription and meat identification stipulated in this Law.

In addition to the sanctions mentioned fine, municipalities, IICBA and the Ministry of Health will close down premises comply with the obligations under this law. In cases required to renew permits or licenses to those entities or any other state institution must demonstrate through certification duly issued by the IICBA, which are up to date in payment of fines set out in this article.

ARTICLE 58.- Collection and fines destination

Fines will be levied by the IICBA. The resources collected under this heading shall be used for the control and supervision work for the effective implementation of this law.

the IICBA is authorized to recruit staff for these purposes.

ARTICLE 59.- Deadline for payment of fines

The financial penalties provided for in this law must be paid within a maximum period of thirty days from its application.

ARTICLE 60. The administrative procedure

All actions and actions of this Act shall be processed in accordance with the summary procedure established in the General Law of Public Administration.

TITLE VII

BUDGET AND FINANCE IICBA

CHAPTER I

FINANCING

Article 61.- Financing IICBA.

To fulfill its purpose, the IICBA be financed from the following resources:

- a) The proceeds from concessions, licenses and permits issued under this Act.
- b) The percentage of the tax created by this Act.
- c) The percentage CCSS allocate funds administered by the Cancer Council for the purchase of drugs made from cannabis and hemp extracts and cannabinoids for the treatment of cancer and other diseases.
- d) The resources available to the Ministry of Health for the start of the activities of IICBA.
- e) Any other form of income or credit transactions authorized by this Act.
- f) Headings are allocated annually in budgets, ordinary and extraordinary, and their modifications.
- g) Contributions and grants from other institutions, natural or legal, national or foreign, public or private, as well as special laws.
- h) The product of internal or external loans contracted.
- i) The interest generated by the financial records of the Institute.
- j) The funds and other resources collected from sales.
- k) Other sums collected under this Act.

Article 62.- Exemption. The IICBA shall be exempt from all taxes, fees and stamps and any other form of contribution.

Article 63 Budget

The liquidation of the budget IICBA will join the Ministry of Health.

All IICBA goods and resources should be itemized and recorded accurately and precisely, and shall be used exclusively to fulfill the purposes of the Institute.

TITLE VIII

AMENDED PROVISIONS, FINAL AND TRANSITIONAL

CHAPTER I

AMENDED PROVISIONS

Article 64. Amendments to the Organic Law of the Ministry of Health, Law No. 5412.

Adiciónese a new subsection h) in Article 5 and Article 18 Refórmese located in "Section VII Monitoring Board Narcotic Drug" both of the Organic Law of the Ministry of Health, Law No. 5412, for hereinafter read as follows:

"Article 5. They will be assigned to the Office of the Minister organs, as follows:

(...)

h) The Institute of Research, Regulation and Control of medicinal cannabis and hemp. "

"SECTION VII

Board Narcotic Drug Monitoring

ARTICLE 18.- The Board of Narcotics Drug Monitoring will be the body responsible for monitoring and controlling the importation, supply and sale of any narcotic drugs and products that use may produce physical or psychological dependence on people, determined in accordance with the law, **non - exclusive jurisdiction of the Institute of Research, Regulation and Control of Cannabis and Hemp. "**

Article 65. Amendments to the General Health Law, Law No. 5395.

Reformense Articles 95, 96, 97, 100, 101, 102, 103, 106, 120, 124, 127, 128, 129, 130, 131, 132, 133, 134, 135, 136, 137, 371, 376 and 382 as well as the title of "Paragraph VI" and the content of articles 140 and 141 there regulated, all of the General Health Law, Law No. 5395, hereinafter to read as follows:

" ARTICLE 95.- Pharmaceutical establishments are:

- a) Pharmacy, who is dedicated to the preparation of recipes and direct sale and supply of medicines to the public.
- b) Droguería, who operates in the import, storage, distribution and wholesale of drugs is forbidden perform in these direct supply to the public and preparing recipes.
- c) Pharmaceutical Laboratory or Pharmaceutical Factory: one that is dedicated to handling or preparation of medicines, raw materials whose exclusive destination processing or preparation thereof and the handling or processing of cosmetics and
- d) Dispensary: one that is dedicated exclusively to the preparation of recipes and the sale and direct supply to the public of medicines made from the cannabis sativa plant, indicates or rudelaris well as the hemp plant ranges and presentations authorized by the law. "**

" ARTICLE 96.- Every pharmaceutical establishment requires the regency of a pharmaceutical for its operation, **except for** pharmaceutical companies that are dedicated exclusively to the manufacture of cosmetics that do not contain drugs. Establishments exclusively of veterinary drugs in special cases can be run by a veterinarian. For these purposes it is considered regent professional in accordance with the law and respective regulations, assumes the technical and scientific direction of any pharmaceutical establishment. Such a ruling is responsible for everything that affects the identity, purity and good drugs to be developed, prepared, handled, maintained and provided, as well as the violation of the laws and regulations arising from the operation of the establishments.

He is joined in this responsibility the owner of the establishment. "

" ARTICLE 97.- The installation and operation of pharmaceutical establishments require registration in the Ministry, prior authorization and registration at the College of Pharmacists. In the case of pharmaceutical establishments of veterinary drugs you will require further authorization and registration in the College of Veterinary Surgeons.

Natural and legal persons who wish to install a pharmaceutical establishment must accompany your request background information on facilities, equipment and professional who will assume the reGENCY, as appropriate regulations.

The installation and operation of the dispensaries require registration and meet the requirements for the acquisition of the appropriate license from the Institute of Research, Regulation and Control of Cannabis and Hemp (IICBA) in accordance with its law creating and regulation."

" ARTICLE 100.- The operating license which pharmaceutical establishments granted shall be valid **for two and in the case of the clinics will be for four years** , unless the lack of regent or violations committed by the warrant their closure Pharmacists association or the Ministry. The audit of these establishments will be made by the College of Pharmacists without prejudice to the powers of control and supervision of the Ministry.

The operating permit dispensaries granted shall be valid for four years unless the lack of regent or offenses committed warranting its closure by the **Institute of Research, Regulation and Control of Cannabis and Hemp (IICBA) in accordance Act with its creation and its regulations.**
"

" ARTICLE 101.- The processing, handling, sale, sale, supply and storage of medicines can only be made in duly authorized and registered by the competent institutions pharmaceutical establishments.

"ARTICLE 102.- The import of medicines and their distribution will only be permitted to legal or natural persons registered with the Ministry, prior authorization and registration at the College of Pharmacists, in accordance with the laws and regulations relevant provisions.

The distribution of drugs produced in the country with the cannabis plant by legal or natural persons may only be made after obtaining the respective license granted by the **Institute of Research, Regulation and Control of Cannabis and Hemp (IICBA) in accordance with established in the Act and its regulations creation.** "

" ARTICLE 103.- In any case, the central government and public institutions with health functions may, directly import, process, manipulate, store, sell or supply medicines, raw materials or medical-surgical materials, where compliance with their programs or emergency situations require it , with the sole approval of the Ministry or the **Institute of Research, Regulation and Control of Cannabis and Hemp (IICBA)** , as appropriate and in accordance with the respective regulations. "

"ARTICLE 106. It is considered that a drug can legally be destined to trade, use and public consumption, it meets the regulatory requirements, or official pharmacopoeia declared by the Executive **or any legally authorized institution**, in terms of identity and quality, safety and efficacy for the purposes in use, consume or prescribe and as for that natural or legal persons

responsible dealing with import, trade, handling, distribution and prescription, have met the requirements legal and regulatory relevant to each of these actions. "

" ARTICLE 120.- are counter drugs that the Ministry declare as such in the corresponding decree, after hearing the opinion of the College of Pharmacists. In the case of veterinary medicinal products it will also consulted the College of Veterinarians.

Medicines produced with cannabis and hemp plants may not be declared as counter. "

" ARTICLE 124.- The label or labeling of every packaging of medicinal products or drugs can only be made in stores and by authorized persons and must include the regulatory content and special mentions that the Ministry **or the institution authorized to order** to safeguard safety and health of people. Both labeling indicated as attached literature must be written in Spanish language. "

" ARTICLE 127.- prohibited and subject to destruction, cultivation, opium poppy (*Papaver somniferum*) of coca (*Erythroxylon coca*) remains the competent authority **and cannabis indica, cannabis sativa and cannabis and hemp rudelaris unauthorized by law and by the competent authority** and any other plant similar effects so declared by the Ministry.

Import, export, trafficking and use of the aforementioned plants and their seeds is also prohibited whenever this germinating capacity **and estuvieren not authorized by law and competent authority. "**

" ARTICLE 128.- any person to import any narcotic drugs and medicines, which by its use may produce physical or psychological dependence on individuals, included in the corresponding restrictive decree issued by the Executive is prohibited.

Such imports will exclusive attribution of the Ministry and will exercise direct free from all taxes, charges and encumbrances, limiting the amount of imports to medical needs and scientific research in the country and, in any case, according to international conventions that the Government has signed or ratified.

In relation to cannabis plants indicates, cannabis sativa and rudelaris cannabis and hemp not above shall apply and instead should be the provisions of the Law Research, Regulation and Control of Cannabis and hemp grown for medicinal use , food and industrial. "

" ARTICLE 130.- sale or supply to the public of narcotic drugs or psychotropic substances and products capable of producing physical or psychological dependence on people is prohibited.

In relation to cannabis indica plant, cannabis sativa and rudelaris cannabis and hemp not above shall apply and instead should be the provisions of the Law for Research,

Regulation and Control of Cannabis and hemp grown for medicinal use , food and industrial. "

" ARTICLE 131.- Only doctors, dentists and veterinarians, in lawful exercise of their professions may prescribe and administer subject to the relevant regulatory requirements, narcotic drugs and psychotropic substances or products, anesthetics and similar prescription declared restricted by the Ministry. "

Personal administration of such drugs can only be made by the aforementioned professionals or by personnel authorized under the responsibility of the practitioner prescribes. "

" ARTICLE 132.- Only duly regentados pharmaceutical establishments may obtain narcotic drugs and psychotropic substances or products declared restricted use by the Ministry or regulated by the **Institute of Research, Regulation and Control of Cannabis and hemp**, in accordance with the provisions **legal and** relevant and must keep a strict control of the movement of such medicines regulation. "

" ARTICLE 133.- The storage and handling of narcotic drugs and psychotropic substances or products declared restricted use by the Ministry **or regulated by the Institute of Research, Regulation and Control of Cannabis and hemp** and the office of the recipes in which prescribed, shall personally and exclusively to pharmacists. "

" ARTICLE 134.- are prohibited processing, transit through the Republic, traffic or commerce, trade or possession for distribution and supply and management, to any title, of narcotics and psychotropic substances or use products declared restricted by the Ministry, in violation of the terms of this law and its regulations, or special orders issued by the Ministry for better control of these. "

In relation to cannabis indica plant, cannabis sativa and rudelaris cannabis and hemp not above shall apply and instead should be the provisions of the Law for Research, Regulation and Control of Cannabis and hemp grown for medicinal use , food and industrial. "

"ARTICLE 135.- The pharmaceutical regents are especially required to display the relevant documentation to the competent health authority needed to better control the trade, supply and use of the substances mentioned in the previous article and personal product and severally liable the owner of the establishment for offenses that were committed there. "

" ARTICLE 136.- Everyone is obliged to allow immediate entry of officials of the Ministry **and the Institute for Research, Regulation and Control of Cannabis and Cannabis within the scope of their competence and at authorized places** , properly identified, to its establishment **agroindustry, laboratory, greenhouse, industrial, commercial** or warehousing and property of their care in order to take samples there is a need, **measurements of ranges approved, quality, biosafety, food safety** and to monitor the condition **of the crop** , production, trafficking, possession, storage or supply of drugs and especially **seeds, roots, plants, flowers and** narcotics and psychotropic substances or products declared restricted **or regulated, as appropriate.** "

" ARTICLE 137.- will be subject to forfeiture:

- a) The narcotic drugs, psychotropic substances and products declared restricted use by the Ministry, when developed, traded, are held or are providing illegal or offside form.
- b) Damaged, adulterated and counterfeit drugs.
- c) The drugs are developed, traded, stored, distributed or supplied on illegal or offside form.
- d) Crops and Article 127 plants and seeds mean when germinating capacity to possess, in addition will be subject to destruction by the competent authority, **unless they are regulated by a law.** "

"PARAGRAPH VI

Restrictions on promotion and advertising

drug and similar

ARTICLE 140.- sale and trade of medical or free samples and tenure in pharmacies is prohibited, **clinics**, or local retail trade.

In any case the delivery of samples, **and promotion** of drugs can only be made to professionals in medical sciences by doctors or pharmacists duly accredited visitors and members who shall be incorporated into the College of Physicians and Surgeons or Pharmaceutical. Similarly, with regard to medicinal products for veterinary use shall be carried out by members incorporated into the College of Veterinary Medical or Pharmaceutical. Information about your supply shall contain at least the list of active ingredients, their way of proper administration and contraindications.

Despite this, the delivery of medical samples as promotion or advertising of medicinal cannabis or hemp "is prohibited.

" ARTICLE 141.- prohibited promotion **or advertising** of drugs and cosmetics to the public, when misleading; when made in violation of the regulations, authorizations obtained if it is drugs or restrictions that the Executive impose, in view of the nature of the drug and the type of disease, physical mess and symptoms for which it is used. "

" ARTICLE 371.- will suffer imprisonment of six to twelve years, who, in any capacity, cultivate poppy plants (Papaver somniferum), coca (Erythroxilon coca) or marijuana hemp (cannabis indica and cannabis sativa), and any other plants or seeds of similar effects, the cultivation, possession or trafficking banned or have been declared restricted by the Ministry of Health **or which are not regulated and permitted by law.**

The same penalty will suffer the owner or beneficial owner or lessee or holder to any title of the property where the plantation is located, if aware of the fate that is given to the grounds, no immediately the complaint before the ordinary courts or before the authorities' police corresponding or not defile the aforementioned plants and which export are, we import, traffics or owns for these purposes, the plants mentioned in this article and germinating seeds whenever this property.

When the owner or beneficial owner or lessee is a legal person, the person will respond administrator of that person, knowing the fate that was given to the land fails to make the corresponding complaint or orders the destruction of that plant.

It shall be punished as an accomplice which labor are growing plants than those provided in the first paragraph of this article, when you shall know the nature of them.

Above, shall not apply to those natural or legal persons who are within the cases covered in special legislation respective referring to the medical, food and industrial use of cannabis and cannabis plants and have a concession, license or permit duly issued by the Institute of Research, Regulation and Control of Cannabis and Hemp. "

" Article 376. Anyone who imports, exports, sells, elaborate, provides any or traffics in any form, or owns for those purposes, medicines containing narcotic drugs or selling OTC restricted by health authorities, **without proper concession license or prior permission stipulated by the law or the respective regulations** , suffer penalty of **ninety to one hundred** days fine if the act constitutes an offense. "

" Article 382. shall be punished by **sixty to one hundred twenty** days fine he who misleading or ambiguous advertising or propaganda that may be harmful to the health of people or may mislead the public on matters relating to the preservation or restoration of health, unless the fact constitutes a crime. "

Article 66. Amendments to the Law on narcotics, psychotropic substances, drugs of unauthorized use, related activities, money laundering and terrorist financing, N°8204 Act.

Reformense Articles 1, 2, 3, 5 and 58 of the Act N°8204 to hereinafter read as follows:

"Article 1. This Act regulates the prevention, supply, prescribing, administration, handling, use, possession, trafficking and sale of narcotics, psychotropic substances, inhalants and other drugs and drugs capable of producing physical or mental agencies, including the Single Convention on Narcotic Drugs of the United Nations, May 30, 1961, approved by Costa Rica by Act No. 4544 of March 18, 1970, amended both by the Protocol Amending the Single Convention on Narcotic Drugs, Law No. 5168, of January 25, 1973, as well as the Vienna Convention on Psychotropic Substances of February 21, 1971, approved by Costa Rica by Act No. 4990, of 10 June 1972; also in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988 (1988 Convention), adopted by Costa Rica by Act No. 7198 of 25 September 1990.

In addition, lists of narcotics, psychotropic substances and similar lawful, which developed and published in La Gaceta, the Ministry of Health and the Ministry of Agriculture and Livestock (MAG), are regulated **except as provided for regulation of cannabis plants and hemp authorized for medicinal, food and industrial use will be regulated by a special law.** in addition, these ministries will have regulations on the subject are ordered.

control, inspection and control of activities related to inhalants, drugs or drugs and products, materials and chemicals involved in the development or production of such substances are also regulated; all without prejudice to the orderly on this matter in the General Health Act, No. 5395, of October 30, 1973, as amended; the General Law of the National Animal Health Service, No. 8495, of April 6, 2006 and its amendments; the Law on Ratification of the Loan Agreement signed between the Government of Costa Rica and the Inter-American Development Bank for a Program of Animal Health and Livestock Development (PROGASA), No. 7060, dated March 31, 1987.

In addition, regulate and penalize financial activities, in order to prevent money laundering and any measures that may be used to finance terrorist activities, as provided in this Act. It is the role of the state, and declared of public interest, the adoption of the necessary measures to prevent, control, investigate, avoid or suppress any illegal activity on the subject of this Act. "

" Article 2. The trade, the sale, industrialization, manufacturing, refining, processing, extraction, analysis, preparation, cultivation, production, import, export, transport, prescription, supply, storage, distribution and sale of drugs, substances or products referred to in this Act and its derivatives and specialties, **will be regulated activities** strictly to the **qualities and** quantities needed for medical treatment, toxicological and chemical analysis , training animals detectors used by police and the pharmacokinetic analysis in medical or sports field; to develop and produce legally medicines and other products from unauthorized use, or for research. **The Institute of Research, Regulation and Control of Cannabis and Hemp will be responsible**

for setting the parameters and regulations related to the cannabis plant and cannabis plant for use medicinal, food and industrial accordance with the provisions of its founding law.

Only legally authorized persons may intervene in everything related to these substances.

It is the duty of those authorized to prescribe narcotics and psychotropic substances used in medical or veterinary practice professionals, using the official forms provided by the Ministry of Health and the Agriculture and Livestock, as appropriate, or selling and control professional corporations authorized. The information included in these recipes have an affidavit. "

" Article 3. It is the duty of the State to **regulate and** prevent the abuse of narcotic drugs, psychotropic substances and any other product capable of producing physical or psychological dependence; also for the early identification, treatment, education, aftercare, rehabilitation and social rehabilitation of those affected, and ensure the financial resources necessary to recover the drug -dependent persons and affected directly or indirectly by consumption drug, to educate them, provide them treatment of physical and mental rehabilitation and readapt to society.

The treatments will be provided by the Ministry of Health, the Costa Rican Social Security Fund (CCSS) and the Institute on Alcoholism and Drug Dependence (IAFA), and any other entity or person legally authorized by the State institution. If it comes to minors, to achieve such treatment the National Children's Trust (PANI) shall issue the necessary protective measures provided in the Code of Children and Adolescents.

In any case, it is the IAFA exercise technical leadership and oversight on prevention and treatment, and to propose, design and evaluate prevention programs of drug use.

Research, regulation and control of cannabis and cannabis for medicinal, food and industrial use will be in charge of the Institute of Research, Regulation and Control of Cannabis and Hemp. "

"Section 5. Preventative measures aimed at preventing the cultivation, production, possession, trafficking and consumption of drugs and other products referred to in this Act, **except in the case of cannabis and cannabis plants authorized for medical use, food and industrial regulated by special law**, shall be coordinated by the Costa Rican Drug Institute. Prevention and care in the field, is required to consult technically IAFA. "

"Article 58.- imprisonment of eight to fifteen years shall be imposed on who, without legal authority, distributes, trades, supply, manufacture, develop, refine, transform, extract, prepare, grow, produce, transport, store or sell the drugs, substances or products referred to in this Act, or cultivate the plants from which such substances or products are obtained.

The same penalty shall be imposed on anyone who, without proper authorization, possesses such drugs, substances or products for any of the stated purposes, and who, **without due**

authorization certificate (concession, license, authorization or permit), possesses or trades seeds germinating capacity or other natural products to produce the said drugs. "

CHAPTER II

FINAL PROVISIONS

Article 67. Special procedure for commencement of activities of licensees, licensors and licensees and funding IICBA.

The Ministry of Health must open an account in the name of IICBA where deposits to fulfill the purposes set out in this Act will be made.

Prior and parallel to the approval of the respective regulations by the IICBA, the Ministry of Health is authorized to make a general invitation interested in participating and obtain a concession or license those established in this Act. In this first call, one will conform **Business Council Support Board** to assess, among others, the visions of potential bidders, available resources for the operation of IICBA and other aspects relating to the importation of the first seeds, establishment of greenhouses, laboratories and clinics in the country and can contribute their knowledge and experience for the preparation of the respective regulations. Of each meeting and a record shall be recorded in a file that will guard the IICBA.

As a result of the meetings that keep the Business Council together with the Board will be:

- a) Selection of the first seeds of the hemp plant cannabis and whose import will be authorized by the Board of IICBA.
- b) Inputs for the preparation of regulations.

CHAPTER III

TRANSITORY DISPOSITIONS

TRANSIENT I.

The Board of IICBA shall comply within two months from the entry into force of this Act. To achieve this goal each of the responsible institutions will manage appropriate action to appoint representatives. The Ministry of Health will be responsible for coordinating the integration of the Board. In the case of representative dealers growers of cannabis and hemp class A, the Ministry of Health will appoint a representative **pro tempore for two years**, the group of companies interested in obtaining a concession of this kind and make a refundable deposit of ten percent of the amount of the grant.

TRANSIENT II.

The Board of IICBA will have three months to issue all regulations set forth in this Law.

TRANSIENT III.

The Executive Branch shall regulate this law within three months from the entry into force.

TRANSIENT IV.

The Board of IICBA will start the tender process for granting concessions from six months after the entry into force of this Law. The Ministry of Health will provide technical support to IICBA to prepare the respective cartel and the provision of administrative services.

Governed from its publication. -

San Jose, August 11, 2014.-

MARVIN ATENCIO DELGADO

DEPUTY

[1] O'Shaugnessy WB. On the preparations of the Indian hemp, or Gunjah. Transactions of the Medical and Physical Society of Bengal (1838-1840) , p. 421-461 quoted by Manfred Fankhauser in History of Cannabis in Western Medicine.

[2] Single Convention on Narcotic Drugs of the United Nations, May 30, 1961, approved by Costa Rica by Act No. 4544 of March 18, 1970, amended both by the Protocol Amending the Convention only on Narcotics, Law No. 5168 of 25 January 1973. See also the Vienna Convention on Psychotropic Substances of February 21, 1971, approved by Costa Rica by Act No. 4990 of June 10 1972; Also, the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 19 December 1988 (1988 Convention), adopted by Costa Rica by Act No. 7198 of 25 September 1990.