Law No. 19847

DECLARATION OF ACTIONS AIMED AT PROTECTING, PROMOTING AND IMPROVING PUBLIC HEALTH THROUGH QUALITY-CONTROLLED AND ACCESSIBLE CANNABIS OR CANNABINOIDS-BASED PRODUCTS, AS WELL AS MEDICAL ADVICE AND INFORMATION ON BENEFITS AND RISKS OF THEIR USE AS A MATTER OF PUBLIC INTEREST

CHAPTER I - GENERAL AND GUIDING PRINCIPLES OF THE LAW

Section 1

Actions aimed at protecting, promoting and improving public health through quality-controlled and accessible cannabis or cannabinoids-based products, as well as medical advice and information on the benefits and risks of their use, are hereby declared to be of public interest.

(*) **Notes:**

See in this standard, Section: 12.

Section 2

The Ministry of Public Health shall:

A) Implement and monitor the National Medicinal and Therapeutic Cannabis

Program as defined in Section 10 of this standard.

B) Promote the development of the Active Pharmacovigilance System for

medicinal cannabis users as provided herein.

Section 3

Access to medicinal and therapeutic cannabis shall be carried out in compliance with the provisions of Section 1 of Law No. 18,211 of December 5, 2007. To this end, the Ministry of Public Health is hereby empowered to include it in comprehensive benefit programs, in compliance, when appropriate, with Section 5 subparagraph E) of Law No. 18,211 of December 5, 2007.

CHAPTER II – SYSTEM STRUCTURE

Section 4

Access to treatments based on medicinal and therapeutic cannabis will be made through quality-controlled products that guarantee safety for human use, and a medical prescription must be required for it.

The products through which the treatments referred to in this Section shall be accessible are:

I) Pharmaceutical specialties registered with the Ministry of Public

Health in accordance with current regulations.

II) Plant products in compliance the following classification: A) Plant

Specialty. B) New phytotherapeutic medical product. C) Traditional

phytotherapeutic medical product. D) Cannabis-based plant product.

III) Compounded medications prescribed by the attending physician and

prepared by Pharmaceutical Chemists in authorized pharmacies

specifically for this purpose, formulated from standardized

cannabis or cannabinoids extracts

whose production is

authorized by the health authority as a raw plant material with

pharmacological activity.

IV) In case that, by medical indication, it is necessary to import cannabis

and cannabinoids-based products for medicinal purposes,

this will be authorized by the Ministry of Public Health.

For the purposes of this law, the cannabis or cannabis extracts or cannabinoids-based Plant Product referred to in paragraphs II) and III) of this Section, are defined as a concentrate in a suitable carrier (fluid or dry), through extraction methods approved by the Ministry of Public Health regardless of: A) The technology used for the aforementioned extraction process. B) Whether it is an isolated component or the complete set of some variety. C) Whether it is psychoactive or non-psychoactive cannabis.

Patients will be able to access the products prescribed under the compounded medication by purchase exclusively in pharmacies authorized for this purpose, which will review the formulation set forth in the prescription and the effective putting into pharmaceutical form with steps that may include, among others: dilution, concentration, fractioning, mixing and packaging. The compounded medication must be released for sale by the Technical Director Pharmaceutical Chemist prior to marketing and delivery to the patient. Such medication must be registered in the pharmacy's books or under the registration system that the Health Authority deems appropriate.

Section 5

The Ministry of Public Health shall set:

I) Requirements to ensure quality and safety for human use of plant products or cannabis or cannabinoids extracts, which will be duly published.

II) A system of certification and quality control, with public and private bidders that have been authorized for this purpose.

Section 6

The Ministry of Public Health will develop recommendations addressed to all public and private institutions linked to the training of professionals in the disciplines that participate in this health program, so that their educational activities are adapted to the principles, policies and provisions established in this law.

Section 7

The Ministry of Public Health, in coordination with the Cannabis Control and Regulation Institute, the National Institute of Employment and Vocational Training, the University of the Republic, the Uruguayan Union of Medical Doctors, the Uruguayan Association of Chemistry and Pharmacy, the Union of Medical Industry and Related Affairs and the Uruguayan Society of Endocannabinology will develop, in accordance with the methods set forth by the regulations of this law, a line of training in cannabis for medicinal and therapeutic use with special emphasis on the training of human resources of public and private health providers within the National Integrated Health System.

Section 8

The value chain of cannabis and its derivatives will be included within the National System of Productive Transformation and Competitiveness, in accordance with the provisions of Law No. 19,472, of December 23, 2016, and its promotion plans and instruments.

Section 9

The Inter-institutional Commission for the Inclusion of Cannabis in the Financial System is hereby created, within the scope of the Ministry of Economy and Finance, consisting of the Prosecretariat of the Presidency of the Republic, in its capacity as President of the National Drug Board, the Ministry of Public Health, the Cannabis Control and Regulation Institute and the Central Bank of Uruguay.

CHAPTER III - NATIONAL PROGRAM FOR ACCESS TO MEDICINAL AND THERAPEUTIC CANNABIS

Section 10

The National Program for Access to Medicinal and Therapeutic Cannabis is hereby created. It will fall within the scope of the Ministry of Public Health and will operate in the General Directorate of Health with the aim of improving people's quality of life through the inclusion of medicinal and therapeutic cannabis in the National Integrated Health System.

Section 11

The National Program for Medicinal and Therapeutic Cannabis is responsible for:

I) Coordinating the Technical Advisory Committee defined in Section 13 of

this law.

II) Coordinating, with the Cannabis Control and Regulation Institute,

all matters pertaining to the evaluation, approval and oversight process

of medical and therapeutic cannabis licenses.

III) Putting out information regarding the uses and risks of cannabis with

medicinal and therapeutic purposes, as well as interaction with other

drugs.

IV) Encouraging training spaces for health personnel,

along with the competent institutions on the subject.

V) Proposing protocols and actions regarding the oversight of the

cannabis-based products, ensuring compliance with the

quality controls and their correct distribution and marketing.

Section 12

The National Program for Medicinal and Therapeutic Cannabis must be evaluated by the State Evaluation Agency or another independent academic institution in order to be reformulated and adjusted according to proven scientific advances and compliance with the provisions of Section 1 of this law.

CHAPTER IV - TEMPORARY PROVISIONS

Section 13

Within the scope of the Ministry of Public Health, a Technical Advisory Committee for the implementation of this law is hereby created, and will act as an advisory body to the Executive Branch for a two-year period.

Section 14

The tasks of the Technical Advisory Committee are:

I) Require information regarding impairments and difficulties for the incorporation

of cannabis-based products and treatments from public and

private entities of the National Integrated Health System.

II) Propose training activities for health personnel

on uses and applications of cannabis for medicinal and therapeutic use.

III) Make recommendations to the Ministry of Public Health on the

implementation of the regulations for effective access to treatment

indicated by the attending physician.

IV) Inform the Executive Branch, with the periodicity determined by the

regulation, on the evaluations carried out.

V) Prepare a document with all the recommendations issued,

submitting said document to the Executive Branch and the Legislative Branch in a

term not exceeding one year.

Section 15

The Technical Advisory Committee shall be of an honorary nature. Its members shall be appointed by the Executive Branch and shall include representatives of the Executive Branch, researchers, the medical corps, chemists and civil society; who must prove suitability in the subject of this law and research.

Section 16

The Commission for the Social and Productive Inclusion of Small and Medium Producers of Medicinal Cannabis and its Derivatives is hereby created. The Commission will operate within the framework of

the National System of Productive Transformation and Competitiveness, created by Law No. 19,472, of December 23, 2016, and will be made up of the Cannabis Control and Regulation Institute, the Ministry of Industry, Energy and Mining; the National Institute for Employment and Vocational Training, the National Institute of Cooperativism, the National Development Agency, the University of the Republic, the Ministry of Public Health, the Uruguayan Union of Medical Doctors, the Uruguayan Society of Endocannabinology, the Uruguayan Association of Chemistry and Pharmacy, the Union of Medical Industry and Related Affairs, a representative of the United Cannabis Oils and Creams Producers, a representative for Medicinal Cannabis Patients, and will operate for a term not exceeding one year from the promulgation of this law.

(*) **Notes:**

See in this standard, Section: 17.

Section 17

The Commission referred to in the previous Section shall be coordinated by the Planning and Budget Bureau within the framework of the National System of Productive Transformation and Competitiveness and shall have the following objectives:

I) Make recommendations to the Executive Branch for the integration of the

growers and producers to the different segments of the chain of

value of medical cannabis.

II) Promote the inclusion of those small and medium-sized producers of

cannabis and its derivatives that appear before the Cannabis Control and Regulation

Institute and state their will to be regularized through a sustainable productive project to

aspire to the corresponding license or related activities after sixty days of this law's entry into force.

III) Advise producers who require it regarding

entrepreneurship, quality requirements and other technical provisions

that were established in a timely manner by the competent

authority.

IV) Articulate the resources and instruments available within the National

System of Productive Transformation and Competitiveness for the

development and furthering of small and medium-sized production,

projects, marketing and export of cannabis and its derivatives.

Section 18

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(*) **Notes:**

This Section added to: Executive Order No. 14,294 of 31/OCT/1974 Section 3

subparagraph H).

Section 19

The Cannabis Control and Regulation Institute and the National Institute of Seeds will draft a proposal that must be submitted to the Executive Branch, within a period not exceeding one year from this law's entry into force, to establish a strategy for the promotion and access to seeds and cuttings for scientific research and the production of cannabis, guaranteeing national sovereignty in accordance with current regulations.

Section 20

The Executive Branch shall establish the regulation of this law within a period not exceeding one hundred and eighty days after its promulgation.