Presidencia de la República Oriental del Uruguay

D.246/021

MINISTRY OF THE INTERIOR
MINISTRY OF FOREIGN AFFAIRS
MINISTRY OF ECONOMY AND FINANCE
MINISTRY OF NATIONAL DEFENCE
MINISTRY OF EDUCATION AND CULTURE
MINISTRY OF TRANSPORT AND PUBLIC WORKS
MINISTRY OF INDUSTRY, ENERGY AND MINING
MINISTRY OF LABOUR AND SOCIAL SECURITY
MINISTRY OF PUBLIC HEALTH
MINISTRY OF LIVESTOCK, AGRICULTURE AND
FISHERIES MINISTRY OF TOURISM
MINISTRY OF HOUSING AND TERRITORIAL ORDER
MINISTRY OF SOCIAL DEVELOPMENT
MINISTRY OF ENVIRONMENT

Montevideo, July 28, 2021

IN VIEW OF: the need to update Decree No. 46/015 of February 4, 2015, which regulates Law No. 19,172 of December 20, 2013, which sets forth the legal framework applicable to the control and regulation of the import, export, planting, cultivation, harvesting, production, acquisition, storage, marketing, distribution and use of cannabis and its derivatives for scientific research and medicinal use;

WHEREAS: I) the Single Convention on Narcotic Drugs of 1961, as amended by the Protocol of 1972, approved by Executive Order No. 14,222 of July 11, 1974 and the Convention on Psychotropic Substances of 1971, approved by Executive Order No. 14,369 of May 8, 1975, do not inhibit the medicinal use of the substances referred to in the Section IN VIEW OF, such acknowledging that the medical use of narcotic drugs is indispensable for pain mitigation, both instruments admitting the use of such substances for medical and scientific purposes;

II) Executive Order No. 15,443 of August 5, 1983 sets forth standards on the import, representation, production, processing and marketing of medicinal products and other related products for human use;

III) Section 1 of Law No. 19,172 declared actions aimed at protecting, promoting and improving the population's public health through a policy aimed at minimizing risks and reducing harm from the use of cannabis as a matter of public interest;

IV) Section 3 subparagraph A) of Executive Order No. 14,294 of October 31, 1974, with the wording of Section 5 of Law No. 19,172, authorizes the planting, cultivation, harvesting and marketing of cannabis for scientific research and for the development of therapeutic products for medical use, in which case prior authorization must be obtained from the Cannabis Control and Regulation Institute;

V) Section 3 subparagraph D) of the aforementioned Executive Order No. 14,294, with the wording of Section 5 of Law No. 19,172, authorizes planting, cultivation, harvesting and industrialization of cannabis for pharmaceutical use, provided that it is carried out within the framework of the current legislation in force and according to the provisions of the relevant regulations;

VI) Law No. 19,847 of December 20, 2019, declared actions aimed at protecting, promoting and improving public health through quality-controlled and accessible, cannabis or cannabinoids-based products, as well as advice and information on benefits and risks of their use as a matter of public interest;

WHEREAS: I) the Executive Branch deems appropriate to strengthen and encourage the development of the exploitation of psychoactive and non-psychoactive cannabis for scientific research and medicinal use;

II) the advancement of scientific research related to the cultivation, production and use of cannabis and its derivatives is of fundamental importance in order to promote the output of knowledge in the field, which will result in the improvement of information, education and prevention related to the consumption of these substances, as well as in further development of the industry and its therapeutic use;

III) the use of medicinal cannabis has significant therapeutic potential, and the industry associated with its production is growing both nationally and internationally, and its characteristics can contribute to the creation of employment and industrial development for the country and advance its position in the region;

IV) notwithstanding the provisions of Executive Order No. 15,443, it is deemed necessary to establish certain specific provisions regarding the production, extraction and manufacture of raw materials, finished and semi-finished cannabis or cannabinoids-based products for medicinal use;

V) it is therefore necessary and appropriate to update the applicable regulations for the purpose of establishing an effective and agile regulatory framework, favoring the production growth of psychoactive and non-psychoactive cannabis for scientific research and medicinal use, also providing for mechanisms for the authorities with competence in this field to exercise adequate controls for the protection of the population's health and safety;

PURSUANT TO: the foregoing and to the provisions of Section 168, paragraph 4, of the Constitution, as well as the Single Convention on Narcotic Drugs of 1961, as amended by the Protocol of 1972, approved by Executive Order No. 14,222 of July 11, 1974, Executive Order No. 14,294 of October 31, 1974, the Convention on Psychotropic Substances of 1971, approved by Executive Order No. 14,369 of May 8, 1975, Executive Order No. 15,443 of August 5,

1983, Law No. 19,172 of December 20, 2013, Law No. 19,847 of December 20, 2019 and other concordant and complementary regulations;

THE PRESIDENT OF THE REPUBLIC,

acting under council of the Ministers,

D E C R E E S :

TITLE I

GENERAL CONSIDERATIONS

Section 1

Subject to the provisions set forth in Law No. 19,172 of December 20, 2013, this Decree and other standards in force, the planting, cultivation, harvesting, drying, conditioning, collection, production, manufacture and commercialization of psychoactive and non-psychoactive cannabis is permitted, to be used exclusively for scientific research or for the production, extraction and manufacture of raw materials, finished and semi-finished cannabis or cannabinoids-based products for medicinal use.

Section 2

The performance of the activities described in Section 1 of this Decree shall be subject to previously obtaining authorization from the Cannabis Control and Regulation Institute.

The licensees may in turn outsource the stages of drying, extraction, and manufacture with third parties licensed by the Cannabis Control and Regulation Institute and authorized by the Ministry of Public Health, as applicable.

Section 3

For the purposes of these regulations, it is defined as:

a) Psychoactive cannabis: the flowering or fruiting tops of the female cannabis plant, excluding the seeds and leaves when not accompanied by the tops, from which the resin has not been extracted, whose tetrahydrocannabinol content is equal to or greater than 1.0 % (one percent) in mass percentage on a dry basis.
b) Non-psychoactive cannabis: plants, flowering or fruiting tops of the cannabis plant or parts of the cannabis plant, whose tetrahydrocannabinol content is less than 1.0% (one percent) in mass percentage on a dry basis.
c) Scientific research: activities aimed at the development of research projects that contribute knowledge and to the elaboration of scientific evidence regarding the planting, cultivation, harvesting, use and other activities related to psychoactive and non-psychoactive cannabis and its derivatives, within current regulations.
d) Cannabinoids: for the purposes of this Decree, cannabinoids are understood to be those compounds derived from the cannabis plant, only of plant origin.
e) Raw material: whole female cannabis plant, its flowering parts or tops with or without fruit and/or extracts, including oils and resins, tinctures or preparations and/or mixtures thereof.
f) Semi-finished products: any medicinal cannabis-based product that is still in the process of being manufactured.
g) Finished products: any medicinal product made from cannabis that is in the final presentation in which it is to be dispensed, with the exception of those considered raw material or semi-finished products.

TITLE II

SCIENTIFIC RESEARCH

Section 4

The Government and the Cannabis Control and Regulation Institute shall encourage and facilitate activities aimed at the development of scientific research projects that contribute knowledge and to the elaboration of scientific evidence regarding the uses and processes associated with psychoactive and non-psychoactive cannabis and its derivatives, within the framework of current regulations in force.

Section 5

Parties interested in carrying out scientific research activities with cannabis and derived substances must submit the corresponding research project, complying with the conditions and requirements set forth by the Cannabis Control and Regulation Institute, and the following information must be included:

a) Identification of the natural or legal person who will be in charge of the investigation, including owners, partners and directors, as appropriate;
b) object and time limit of the investigation;
c) site where the activities will be carried out;
d) origin of the seeds or plants to be used in research;
e) varietal characteristics of the crops to be used;
f) percentage of tetrahydrocannabinol and cannabidiol, to be determined in laboratories authorized by the Cannabis Control and Regulation Institute for this purpose, using approved analytical techniques;
g) estimated production volumes;
h) applicable security procedures and measures;

i) appointment of a Technical Manager for the production process;
j) production surplus and by-products management;
k) purpose for which the product will be intended.

Scientific research projects on human subjects must have a Research Protocol approved by the Ethics Committee in Institutional Research, in the terms set forth by Decree No. 158/019 of June 3, 2019.

Section 6

Parties interested in obtaining an authorization to carry out scientific research tasks may request the Cannabis Control and Regulation Institute to authorize them to also carry out the corresponding production, or they may acquire psychoactive and non-psychoactive cannabis from producers authorized by the Cannabis Control and Regulation Institute.

Section 7

The authorization to carry out scientific research activities with cannabis and derived substances will be issued by the Cannabis Control and Regulation Institute through the granting of the corresponding license, which will set forth the terms and conditions to which the license will be subject.

The license shall indicate, *inter alia*, the following aspects:

a) natural or legal licensee;
b) research project;
c) term and conditions to which the license is subject;
d) site where the activities will be carried out;
e) origin of the seeds or plants to be used in the planting;
f) varietal characteristics of the crops to be used;
g) tetrahydrocannabinol and cannabidiol content;
h) authorized production volumes;

i) applicable security procedures and measures;
j) appointment of a Technical Manager of the production process;
k) production surplus and by-products management;
l) details of the purposes for which the product will be intended;
m) conditions required of owners, partners, directors and dependent personnel, if applicable.

Section 8

In accordance with the provisions of paragraph D) of Section 29 of Law No. 19,172 of December 20, 2013, the Board of Directors of the Cannabis Control and Regulation Institute shall set the cost of the license to be issued.

Section 9

The Cannabis Control and Regulation Institute will proceed to register *ex officio* those people who have obtained the corresponding license and paid the cost thereof in the Section of Cannabis Producers for Research of the Cannabis Registry.

Section 10

At the time of delivery of psychoactive and non-psychoactive cannabis to researchers, the quality and quantity of the product delivered must be recorded, informing the Cannabis Control and Regulation Institute within a maximum period of twenty-four hours.

Section 11

At the end of the research project, a report detailing the progress and results obtained must be submitted to the Cannabis Control and Regulation Institute and the Center for Advanced Studies in Cannabis created by Law No. 19,847 of December 19, 2019.

If the scientific research refers to the medicinal use of cannabis, the report must also be submitted to the General Directorate of Health of the Ministry of Public Health.

TITLE II

CANNABIS FOR MEDICINAL USE

Section 12

The activities for medicinal use described in Section 1 of this Decree, as appropriate, will be carried out by those who are authorized for this purpose by the Ministry of Public Health and authorized by the Cannabis Control and Regulation Institute, in accordance with the legal and regulatory provisions in force.

Section 13

The Cannabis Control and Regulation Institute shall authorize those natural or legal persons who request it to carry out the activities for medicinal use provided for in Section 1 of this Decree, subject to the provisions of the applicable legal standards, as well as in this Decree.

Section 14

Parties interested in carrying out the activities for medicinal use provided for in Section 1 of this Decree must comply with the conditions and requirements set forth by the Cannabis Control and Regulation Institute for these purposes, and the following information must be included:

a) Identification of the natural or legal person, including owners, partners and directors, as appropriate;
b) Object and term of the license applied for;
c) location where the activities will be carried out;
d) origin of the seeds or plants to be used;
e) varietal characteristics of the crops to be used;
f) percentage of tetrahydrocannabinol and cannabidiol, to be determined in laboratories authorized by the Department of Medicines of the Ministry of Public Health and authorized by the

Cannabis Control and Regulation Institute, through approved analytical techniques;

g) estimated production volumes;
h) procedures and security measures to be applied;
i) appointment of a Technical Manager of the production process;
j) production surplus and by-products management;
k) purpose for which the product will be intended.

Section 15

The authorization issued by the Cannabis Control and Regulation Institute, through the granting of the respective license, will set forth the terms and conditions to which the activities to be carried out by the interested parties will be subject, in accordance with the provisions of Section 9 of this Decree, as applicable.

Section 16

In accordance with the provisions of Section 29 subparagraph D) of Law No. 19,172 of December 20, 2013, the Board of Directors of the Cannabis Control and Regulation Institute shall set the cost of the license to be issued.

Section 17

The Cannabis Control and Regulation Institute shall proceed to register *ex officio* those persons who have obtained the corresponding license and have paid the cost thereof in the Medicinal Cannabis Section of the Cannabis Registry.

The foregoing notwithstanding, in the cases where the registration in other Registries by state or non-state entities corresponds, it must be done, in accordance with the requirements of the applicable regulations in force.

Section 18

Finished cannabis or cannabinoids-based products for medicinal use, as applicable, must be registered with the Department of

Medicines of the Ministry of Public Health, and must comply with legal and regulatory provisions in force, the Ministry of Public Health being the body in charge of its control.

Section 19

The raw material, finished and semi-finished cannabis or cannabinoids-based products for medicinal use must comply with the packaging and labeling conditions provided for in the current legal and regulatory regulations in force.

Section 20

The process of production and processing of raw materials, finished and semi-finished psychoactive and non-psychoactive cannabis or cannabinoids-based products for medicinal use shall be supervised by the Ministry of Public Health and the Cannabis Control and Regulation Institute within the framework of their respective scope.

Section 21

The distribution of the harvested psychoactive and non-psychoactive cannabis will be carried out under the responsibility of the producer, by himself or by third parties, from the production site directly to the place indicated for its exclusive use to produce or elaborate raw material, finished and semi-finished cannabis-based product for medicinal use.

At the time of delivery, whoever receives the end product from the psychoactive and non-psychoactive cannabis harvest must document the amount of cannabis received, detailing the tetrahydrocannabinol and cannabidiol content of the product received, and reporting to the Cannabis Control and Regulation Institute in a maximum period of twenty-four hours.

Section 22

The distribution of finished cannabis or cannabinoids-based products for medicinal use, for final consumption, will be carried out by the producer or

importer thereof or through drugstores or pharmacies of the fifth category which are duly authorized by the Ministry of Public Health, directly to the pharmacies of first and second category.

TITLE III

DISPENSING OF CANNABIS-BASED PRODUCTS FOR MEDICINAL USE

Section 23

The dispensing of psychoactive and non-psychoactive cannabis-based products for medicinal use may be carried out only by pharmacies of first and second categories authorized by the Ministry of Public Health, exclusively through medical prescription according to current regulations in force.

Section 24

Places where products for medicinal use authorized for sale to the public for dispensing are stored shall not be available to the public and must remain closed with adequate safety conditions and separated from other therapeutic products and medicines, as well as psychoactive cannabis for non-medical use, pursuant to the provisions of the Decree No. 120/014 of May 6, 2014). Likewise, pharmacies must comply with the applicable regulations on controlled medicines set forth in Executive Order No. 14.294 of October 31, 1974, Decree No. 454/976 of July 20, 1976, and other concordant rules.

Section 25

Pharmaceutical specialties based on psychoactive cannabis must be prescribed by university professionals, in official prescription, according to Executive Order No. 14,294 of October 31, 1974 and its regulations.

Pharmaceutical specialties based on psychoactive cannabis may be purchased by those legally capable and over 18 years of age, who have the corresponding official prescription issued by the attending physician.

The prescription should specify patient data, the name of the indicated product, pharmaceutical form, route of administration, dose and duration of treatment.

Section 26

The conditions of sale under which psychoactive and non-psychoactive cannabis-based products for medicinal use authorized for sale to the public will be dispensed shall be determined at the time of registration by the Department of Medicines of the Ministry of Public Health.

TITLE IV

COMMON PROVISIONS

CHAPTER ONE

MONEY LAUNDERING

Section 27

The applicant for a license to carry out the activities provided for in Section 1 of this Decree must include the request for information by the Cannabis Control and Regulation Institute regarding its corporate structure, if applicable, for the purposes of an adequate identification and knowledge of the final beneficiary, as well as the origin of the funds that are proposed to be allocated to the execution of the project, within the framework of current regulations in force on the prevention of money laundering and financing of terrorism. To this end, the Cannabis Control and Regulation Institute will request, prior to the granting of the license, a report to the National Secretariat against Money Laundering and

Financing of Terrorism, which, once the information has been received, may directly request from the interested parties the clarifications and extensions that it deems pertinent.

The prior report from the National Secretariat against Money Laundering and Financing of Terrorism will not be mandatory in research projects financed exclusively with national or international public funds.

The Cannabis Control and Regulation Institute may request, at any time, the updating of the information relating to the identity of the holders of the license granted, including holders of interests or final beneficiaries, in the case of legal persons, as well as other aspects detailed in the license.

CHAPTER TWO

SEEDS AND CUTTINGS

Section 28

The Cannabis Control and Regulation Institute, in the exercise of its tasks, shall authorize the import of seeds and other propagating material for the cultivation of psychoactive and non-psychoactive cannabis plants to be used exclusively for the purpose of scientific research or to produce or elaborate raw material, finished and semi-finished cannabis-based product for medicinal use.

Section 29

Persons authorized by the Cannabis Control and Regulation Institute to carry out the activities provided for in Section 1 of this Decree may produce seeds and other psychoactive and non-psychoactive cannabis propagation material,

in accordance with the license granted by the Cannabis Control and Regulation Institute.

All persons who produce and market material for the propagation of both psychoactive and non-psychoactive cannabis must register with the General Register of Seed Growers with the National Institute of Seed. The varieties that are marketed must be registered in the National Register of Cultivars of the National Institute of Seed.

CHAPTER THREE

POWERS OF CONTROL AND OVERSIGHT IN THE PLANTING, HARVESTING, DISTRIBUTION AND MARKETING OF CANNABIS

Section 30

The Cannabis Control and Regulation Institute shall control the activities provided for in Section 1 of this Decree, the powers of the Ministry of Public Health in this regard notwithstanding.

Section 31

The Cannabis Control and Regulation Institute shall have the broadest powers of investigation and oversight, in accordance with the provisions of Section 27 of Law No. 19,172 of December 20, 2013, as well as Section 90 of Decree No. 120/014 of May 6, 2014.

Section 32

The Board of Directors of the Cannabis Control and Regulation Institute will apply the corresponding sanctions to those who violate the current rules in force on licenses matters.

Section 33

Decisions issued by the Board of Directors or the Executive Director of the Cannabis Control and Regulation Institute may be challenged

in accordance with the provisions of Sections 35 and 36 of Law No. 19,172 of December 20, 2013.

CHAPTER FOUR

QUALITY CONTROL AND SAFETY IN PRODUCTION

Section 34

The quality control of the harvest of cannabis for medicinal use must be carried out by laboratories authorized by the Ministry of Public Health and authorized by the Cannabis Control and Regulation Institute in terms of the quantification of cannabinoids.

The Cannabis Control and Regulation Institute will determine the end purpose of the product in the event that it does not fall within the parameters set forth in the respective license.

Section 35

Any surpluses resulting from the production shall be available to the Cannabis Control and Regulation Institute, which will arrange its end purpose.

Section 36

The Cannabis Control and Regulation Institute will define the safety measures that can be required in the stages of planting, processing, distribution and marketing of psychoactive and non-psychoactive cannabis in agreement with the Ministry of the Interior.

CHAPTER FIVE

ADVERTISING

Section 37

Any form of advertising, direct or indirect, promotion, endorsement or sponsorship of products obtained from psychoactive cannabis by any of the various means of communication (written press, radio, television, film, magazines, filming in general, posters, billboards on public roads, brochures, banners, e-mail, internet technologies, as well as any other suitable means) is forbidden.

CHAPTER SIX

FOREIGN TRADE

Section 38

Parties interested in importing and exporting raw material, finished or semi-finished psychoactive and non-psychoactive cannabis or cannabinoids-based products for medicinal use or scientific research, must request the corresponding authorization from the Controlled Substances Division of the Ministry of Public Health, according to the provisions of the current regulations in force.

In the application for authorization of import or export of finished products, the certificate of Registration and Authorization of Sale of the Specialty or certificate of Registration for Export issued by the Department of Medicines of the Ministry of Public Health, in the corresponding cases, must be submitted.

Import and export authorizations will expire one hundred and twenty and ninety days after they are issued, respectively. They shall be used only once and may not cover the import or export of cannabis varieties or products of a different nature or in quantities other than those authorized.

The procedure corresponding to obtaining import and export authorizations will be carried out by the Other Government Agencies Electronic Single Window (VUCE [in its Spanish acronym]) for both psychotropic drugs and narcotics.

In the case of narcotics, in addition to the aforementioned procedure, the approval of the Minister of Public Health must be required, in compliance with current international regulations in force on the matter.

Section 39

Raw materials and semi-finished, psychoactive and non-psychoactive cannabis-based products for medicinal use or scientific research may be imported or exported after obtaining an authorization issued by the Ministry of Public Health through the Controlled Substances Division. In order to obtain this authorization, interested parties must comply with the following documentation:

a) Valid license for scientific research or authorizing cultivation, industrialization and commercialization issued by the Cannabis Control and Regulation Institute.
b) In case of export, the import authorization certificate issued by the health authority of the importing country, stating that the import of the cannabis product mentioned therein is authorized and where the destination of the product to be imported and the purpose of it is set forth.
c) Identification of the variety of psychoactive and non-psychoactive cannabis of each batch to be imported or exported.
d) Proforma invoice issued by the exporter.
e) Description of the raw material to be imported or exported, quantity, characteristics, tetrahydrocannabinol and cannabidiol content and condition. In case of such plant material, express the amount in its dry weight.

f) In case of export, the percentage of tetrahydrocannabinol and cannabidiol must be determined in laboratories authorized by the Department of Medicines of the Ministry of Public Health and authorized by the Cannabis Control and Regulation Institute, through the analytical techniques approved by this body.
g) Affidavit of movements expressed in the terms provided by the Controlled Substances Division of the Ministry of Public Health.
h) Copy of the Certificate of authorization of the importer or exporter in force, if applicable, issued by the Ministry of Public Health through the Department of Medicines.

Section 40

Finished psychoactive and non-psychoactive cannabis-based products for medicinal use or scientific research may be imported or exported after obtaining an authorization issued by the Ministry of Public Health through the Controlled Substances Division. In order to obtain such authorization, interested parties must submit the following documentation:

a) Valid license for research or authorizing cultivation, industrialization and commercialization issued by the Cannabis Control and Regulation Institute.
b) In case of export, import authorization certificate issued by the health authority of the importing country, stating that the import of the cannabis product mentioned therein has been authorized and establishing the destination of the product to be imported and the purpose thereof.
c) identification of the products to be imported or exported.
d) Proforma invoice issued by the exporter.

e) Affidavit of movements expressed in the terms provided by the Controlled Substances Division of the Ministry of Public Health.
f) Copy of the Certificate of authorization of the importer or exporter in force, issued by the Ministry of Public Health through the Department of Medicines.
g) Copy of the certificate of registration and authorization of sale of Pharmaceutical Specialties or certificate of registration for export issued by the Department of Medicines of the Ministry of Public Health.
h) In the case of zootherapeutics, the documentation corresponding to subparagraphs f) and g) issued by the Ministry of Livestock, Agriculture and Fisheries will be filed.

CHAPTER SEVEN

OTHER PROVISIONS

Section 41

The Cannabis Control and Regulation Institute will report Health information related to production, consumption, geographical location, cultivated area, crop projections and any other information that is required to the Ministry of Public Health.

The Ministry of Public Health will in turn send a copy of the certificates of authorization to those companies that work with cannabis for medicinal use, as well as the corresponding registration certificates to the Cannabis Control and Regulation Institute.

Section 42

The rate of the Tax on the Sale of Agricultural Goods for the generating events linked to psychoactive and non-psychoactive cannabis referred to in Section 1 is hereby set to 0% (zero percent).

Section 43

Decree No. 46/015 of February 10, 2015 and Sections 16 and 17 of Decree No. 454/976 of July 20, 1976 are hereby repealed.

Section 44

Let it be notified, etc.

LACALLE POU LUIS