LAW No. 61/2023

FOR THE CONTROL OF THE CULTIVATION AND PROCESSING OF THE CANNABIS PLANT AND PRODUCTION OF ITS BY-PRODUCTS FOR MEDICAL AND INDUSTRIAL PURPOSES

In support of Articles 78 and 83, point 1, of the Constitution, upon the proposal of the Council of Ministers, the

ASSEMBLY OF THE REPUBLIC OF ALBANIA
DECIDED:

CHAPTER I

GENERAL PROVISIONS

Article 1

Object

The object of this law is to establish the rules for the cultivation, production, and controlled circulation of the cannabis plant, its by-products, and final products for medical and industrial use.

Article 2

Purpose

The purpose of this law is to regulate and guarantee the process of control and supervision of cultivation, production and circulation, as well as the export of the cannabis plant, its by-products and final products for medical and industrial purposes.

Article 3

Definitions

For the purposes of this law, the following terms are defined as:

1. "Licensed activity" is any activity of a commercial, economic and professional nature that is carried out by licensed entities for the import of seeds or seedlings of the cannabis plant, cultivation, production, transportation, as well as the export of by-products and final products of cannabis for medical purposes.
2. "Permitted activity" is any activity of a commercial, economic and professional nature, which is carried out by the entities allowed for the importation of seeds or seedlings of the cannabis plant, cultivation, production, transport, as well as the export of by-products and final products of cannabis for industrial purposes.
3. "Cannabis plant for industrial purposes" is the cannabis plant, including all fresh or dried parts of the plant and seeds of the species cannabis sativa and cannabis ruderalis of varieties containing not more than 0.8% THC, and which is cultivated for industrial purposes.
4. "Cannabis plants for medical purposes" are plants of different varieties, variations and subspecies of cannabis sativa, cannabis indica and cannabis ruderalis, obtained by cultivation for medical purposes and scientific research under controlled conditions, according to the rules provided in this law.

5. "Cannabis" means the flowering and fruiting tops of plants of the genus cannabis, excluding seeds and leaves when these are not accompanied by tops from which the resin has not been removed, whatever name they may have.
6. "Traceability" is the process of tracking and tracing seeds, seedlings, substances, plants, materials and preparations, which are the subject of this law, in all stages of planting, cultivation, production of by-products and final product, marketing and supply until the end user.
7. "Cultivation" is the process starting from the planting of seeds or seedlings to the harvesting of the plant of cannabis.
8. "Cannabis plant residues" are parts of the cannabis plant cultivated for medicinal purposes or their waste after production and processing, which are treated as unnecessary.
9. "Industrial by-product" means materials obtained from the entire cannabis plant, including stem, flower and seed, which is produced for industrial purposes, which include but are not limited to uses for the construction, textile, cosmetics, energy production, paper production, etc.
10. "By-products for medicinal purposes" are substances and preparations extracted from the cannabis plant, which are used for the preparation of final products, which include drugs and cosmetic products.
11. "Production unit" is:
a) an area of land from 5 to 10 hectares, fenced, in which the cultivation of the cannabis plant for medicinal purposes is allowed, which also includes warehouses and other special premises, in function of the processes related to the cultivation of the cannabis plant cannabis and the production of by-products for medical purposes;
b) a land area of not less than 1 hectare on which the cultivation of the cannabis plant is allowed for industrial purposes, including warehouses and other special premises, in function of the processes related to the cultivation of the cannabis plant and the production of by-products of the cannabis plant for industrial purposes.
12. "Preparation" is the extract, mixture or crude plant material obtained from the cannabis plant, in a solid or liquid state, or in any other state, which contains a narcotic drug or psychotropic substance.
13. "Manufacturing" is the process involved in the preparation, processing, mixing, purification and any other activity intended to obtain the products and by-products of the cannabis plant for medicinal purposes and for industrial purposes.
14. "End product for medicinal purposes of the cannabis plant" is the narcotic drug, psychotropic substances and cosmetic products.
15. "Final product for industrial purposes of the cannabis plant" is any product that contains in its composition the plant of cannabis for industrial purposes.
16. "Circulation" is any manner of passing into civil circulation the cannabis plant, its by-products and final product for consideration, including import, export, transit, supply, purchase, sale, exchange and storage.
17. "Marking" is the process of placing a unique mark in the form of a code, stamp, label or any other unique form of marking on cannabis seeds, seedlings, substances, plants, by-products or final products thereof, proving that cultivation has been carried out according to the rules defined in this law, in order to identify and trace it.
18. "Employee Cleanliness Verification" is a process of verification, review and evaluation, which refers to the performance of a preliminary, careful and critical check on the suitability of the person who is employed by the National Agency for the Control of Cannabis or by the subject licensed under this law.

Article 4

Scope of Application

1. This law applies to any entity performing licensed activities for:

a) The import of seeds or seedlings or their reproduction;
b) The cultivation of the cannabis plant for medical and industrial purposes;
c) The production of by-products or final products;
d) The circulation of the cannabis plant, by-products, or final products.

2. This law also applies to any state structure involved in the supervision, control, and inspection of its implementation.

Article 5

General Prohibitions

1. In the Republic of Albania, it is prohibited:

a) To cultivate the medical cannabis plant and produce its by-products and final products in excess of this law's provisions;
b) To cultivate the cannabis plant and produce its by-products and final products for medicinal purposes if not marked and traceable according to this law;
c) To possess tools, equipment, and instruments for producing the medical cannabis plant and its by-products and final products, except as declared by a licensed entity under this law;
d) To use cannabis plant by-products and final products except as provided in this law and applicable legislation;
e) To engage in retail or wholesale sale, distribution, acquisition, or consumption of cannabis by-products or final products for medical purposes in the territory of the Republic of Albania;
f) To advertise, directly or indirectly, the importation of cannabis seeds or seedlings, and the cultivation, production, sale, possession, or use of the medical cannabis plant.

Article 6

Image Purity Verification Process

1. According to the provisions of this law, only persons who pass the process of verifying the purity of the image can be employed as employees of the Agency or in licensed or permitted entities.
2. To carry out the process of verifying the purity of the image of the Agency's employees, as well as persons employed by entities licensed or permitted according to the provisions of this law, the Agency cooperates with the State Police and the responsible authorities or institutions that hold or administer the data for this purpose.
3. The process of verifying the purity of the image includes the criterion of moral integrity, as well as specific ethical-professional criteria for certain work positions.
4. The procedures, deadlines, criteria, and necessary documentation for verifying the purity of the image are determined by a joint instruction of the Minister responsible for health, the Minister responsible for agriculture, and the Minister responsible for internal affairs and security, with the proposal of the General Director of the Agency.

CHAPTER II CREATION, ORGANIZATION, FUNCTIONING AND COMPETENCES OF THE AGENCY

Article 7

Establishment, Status, and Financing of the Agency

1. The National Agency for the Control of Cannabis, hereinafter referred to as the Agency, is a legal entity funded by the public budget and operates under the authority of the Minister responsible for health. Its mission is to supervise, control, and inspect the cultivation and processing of the cannabis plant, the production of its by-products for medical and industrial purposes, and to monitor the implementation of this law.
2. The Agency is organized and operates at the central level, with its headquarters in Tirana, and extends its activities throughout the territory of the Republic of Albania.
3. The funding sources of the Agency include income from the state budget and revenues generated from its activities based on and for the implementation of this law. The procedure and method of using the income are determined by a decision of the Council of Ministers.
4. The Agency has an official coat of arms, logo, and seal. The coat of arms includes the coat of arms of the Republic of Albania, with the inscription: "Republic of Albania, Ministry of Health and Social Protection, National Agency for the Control of Cannabis".
5. The seal of the Agency has a form and constituent elements determined according to the legislation in force for the production, administration, control, and storage of official seals.

Article 8

Direction and Organization

1. The Agency is headed by the General Director, who organizes and directs all activities of the institution and reports to the Minister responsible for health.
2. The Licenses Commission operates under the Agency, with the aim of supporting it in exercising its powers, in accordance with its role and duties as stipulated by this law.
3. The structure and organization of the Agency are approved by an order of the Prime Minister, upon the proposal of the Minister responsible for health.
4. The employment relations of the Agency's employees are regulated according to the Labor Code.
5. Employees of the Agency must have integrity and a clean moral image. They must not have been convicted by a final court decision for a criminal offense related to narcotics.
6. Persons employed by the National Agency for the Control of Cannabis must meet general requirements, criteria for a clean image, and specific professional criteria for certain job positions.
7. The verification of the criteria for the cleanliness of the image applies to the person seeking employment in the Agency, as well as to their connections with family members or others. Persons who do not meet the criterion of a clean image cannot establish or continue a working relationship with the Agency.
8. The professional criteria for the employees of the Agency, as well as the verification of the image of the employees of licensed entities, are determined by a joint instruction of the Minister responsible for internal affairs and security, the Minister responsible for agriculture, and the Minister responsible for health, upon the proposal of the General Director of the Agency.

Article 9

Competences of the Agency

1. The Agency exercises its powers based on the principles of legality, professionalism, responsibility, accountability, efficiency, and transparency, in accordance with the legislation in force.

2. The Agency, in exercising its administrative activities, has the following powers:

a) Organizes the procedures for granting licenses, according to the rules defined in this law and by the Minister responsible for health.

b) Supervises the activities of licensed and permitted entities, in accordance with the conditions and criteria defined in the license and permit for the cultivation of the cannabis plant for medical and industrial purposes.

c) Drafts the standards for areas and plots of land where the cultivation of the cannabis plant for medical and industrial purposes will be allowed, which are approved by a decision of the Council of Ministers, upon the proposal of the Ministry responsible for agriculture.

d) Prepares a report every three years regarding the fulfilment of the conditions for granting licenses and permits, and recommends, as appropriate, the fulfilment of the conditions or the suspension or cancellation of licenses and permits.

e) Cooperates with other competent bodies to achieve the objectives and obligations derived from international agreements to which the Republic of Albania is a party.

f) Presents reports to competent international organizations on the import and export of the cannabis plant and its by-products or final products, in accordance with obligations arising from international conventions for the control of narcotic and psychotropic substances.

g) Continuously cooperates with the European Centre for Monitoring Drugs and Addiction and the International Narcotics Control Board.

h) Verifies the purity of the image of every employee of the Agency and of licensed or permitted entities, according to the provisions of this law, in cooperation with responsible authorities or institutions that keep or administer the data for this purpose. The verification of the figure is carried out at the time of the person's engagement, as well as periodically, according to the provisions of the joint instruction mentioned in Article 8 of this law.

i) Cooperates with law enforcement agencies and state structures to maintain the purity of the image of employees of licensed or permitted entities, as well as to prevent criminal offenses.

j) Maintains and administers registers, databases, and statistics at the national level according to the provisions of this law.

k) Issues the export authorization for industrial cannabis and cannabis products for industrial purposes.

l) Drafts regulations, instructions, and methodologies for the unification of processes and work standards of the Agency's employees and proposes them for approval to the Minister responsible for health.

m) Proposes to the Minister responsible for agriculture and the Minister responsible for the environment the cadastral areas where cannabis will be cultivated for industrial purposes.

n) Issues administrative measures with fines and prohibition of activity against licensed and permitted entities, according to this law.

o) Evaluates requests for the sale of shares of partners of license or permit holding entities and proposes for approval, after the approval of the Licenses Commission, to the Minister responsible for health for licenses and the Minister responsible for agriculture for permits.

3. The Agency, in exercising its technical activities, has the following powers:

a) Supervises the use and planting by licensed entities of seeds and seedlings imported or produced in the Republic of Albania, in accordance with the legislation in force for planting and propagating plant material, as well as registered in the national catalog.

b) Drafts the standards for each stage of the process related to the cultivation of the cannabis plant, which are approved by the guidance of the Minister responsible for agriculture.

c) Coordinates the work with responsible state authorities for the registration and immediate inclusion in the national catalog of seeds and seedlings, which are accompanied by distinctiveness-uniformity-stability (DUS) testing.

d) Oversees and monitors the planting and cultivation of the cannabis plant and its by-products used for medical and industrial purposes, and, if it finds that the subject has planted or cultivated

quantities different from those provided for in the permit or license, decides on their destruction and proposes corresponding sanctions.
e) Controls and inspects all cultivation processes of the cannabis plant at every stage of planting, harvesting, drying, storage, and production of plant raw material.
f) Controls and inspects, based on the license, the premises and headquarters where the processing of by-products and final products for medical purposes takes place.
g) Takes measures for the seizure and disposal of cannabis plants or its by-products, according to the provisions of this law.
h) Cooperates with customs authorities to monitor the import of seeds and seedlings, as well as the export regime of by-products or final products of medical and industrial cannabis.
i) Performs any other activity provided by other laws or by-laws in implementation of this law.

Article 10

Functions of the Agency

1. The Agency supervises licensed and permitted activities at each stage and for each production cycle to ensure that the activities:
a) Are carried out in accordance with legal provisions and bylaws issued based on and for the implementation thereof, with the determinations made in the license or permit, as well as with the determinations in the approved production plan.
b) Are not carried out contrary to the purposes of the law and the international obligations of the Republic of Albania.
2. The Agency carries out supervision, controls, and inspections according to this law and, when necessary, coordinates the process in cooperation with other institutions.
3. In fulfilling its tasks of control, inspection, and monitoring according to the provisions of this law, the Agency exchanges information with the prosecution offices of general jurisdiction, the Special Prosecutor's Office/National Bureau of Investigation, the State Police, and other competent authorities in the implementation of this law. It may also sign bilateral or multilateral cooperation agreements with them.
4. The Agency, mainly or upon request, performs verifications in accordance with the provisions of this law. After carrying out the verification, if the Agency assesses the need for measures for the suspension or cancellation of the license, it will forward the matter to the License Commission for consideration.
5. The Agency cooperates and exchanges information with the State Police and other national or international institutions, with which Albania has agreements in the field of combating the use and trafficking of narcotics and psychotropic substances, and against the laundering of proceeds from illegal activities.
6. The Agency collects and administers data necessary for the exercise of its functions on licensed and permitted activities, as well as on the holders of licenses or permits. The primary and secondary data are determined by the decision of the Council of Ministers, according to the provisions in point 6 of Article 13 of this law.
7. The Agency submits a six-month work report to the ministry responsible for health, which is also reported to the ministry responsible for order and security.
8. The Agency exercises any other function defined in the law or in the regulation for its operation. The rules for the internal organization of the Agency are approved by the minister responsible for health.

9. The Agency approves the activity regulations of licensed entities

Article 11

Licensing Commission

1. The Licensing Commission is established under the Agency for the review and evaluation of requests submitted for obtaining licenses for the cultivation of cannabis for medical purposes, according to the provisions of this law.
2. The Commission consists of 7 members with the following composition:
   a) 3 representatives from the ministry responsible for health;
   b) 1 representative from the ministry responsible for public order and security;
   c) 2 representatives from the ministry responsible for agriculture;
   d) 1 representative from the ministry responsible for the economy.
3. The chairman of the Commission is one of the representatives of the ministry responsible for health. The members of the Licensing Commission are appointed by order of the relevant ministers.
4. According to the provisions of point 2, ministers may appoint as members individuals who exercise public functions related to the function and duties of this Commission and have no less than 5 years of work experience. The members of the Commission are appointed for a period of up to 4 years.
5. The members of the Commission are obligated to sign a declaration of confidentiality and a declaration of the absence of conflict of interest and must be equipped with a security certificate from the Directorate of Securing Classified Information.
6. The Licensing Commission has the following duties:
   a) Administers and verifies the documentation submitted by entities applying for a license, according to the provisions of Article 16 of this law, provided by the Agency;
   b) Evaluates the fulfilment of the conditions related to premises, equipment, and personnel for obtaining the license;
   c) Draws up the list and the relevant report regarding the requesting entities, and prepares the proposal for granting or refusing the license;
   d) In case of detecting violations, according to the provisions of this law, proposes to the minister responsible for health to take administrative measures for suspension or revocation of the license.
7. The functions of assistance and logistical support to the Licensing Commission are performed by the Agency through employees appointed by the general director, who serve as the technical secretariat for the Commission's meetings.
8. The organization of the work and activities of the Commission is determined by order of the minister responsible for health. The members of the Commission exercise their activity against remuneration. The amount of remuneration for the chairman and members of the Commission is determined according to the decision of the Council of Ministers regarding the remuneration for members of councils, boards, or permanent commissions of central government units.

Article 12

Monitoring Units for the Cultivation, Production, and Marketing of Cannabis for Medical and Industrial Purposes

1. The specialized unit for the supervision, control, and inspection of the cultivation, production, and circulation of cannabis for industrial purposes, and the unit for the supervision, control, and inspection of the cultivation, production, and circulation of cannabis for medical purposes, are established and operate within the Agency.

2. The units direct and coordinate supervisory, control, and inspection activities in cooperation with the structures of the ministry responsible for agriculture for cannabis for industrial purposes, and the ministries responsible for health and public order for cannabis for medical purposes.
3. The unit for monitoring cannabis for industrial purposes, together with the structures of the ministry responsible for agriculture, prepares the report on lands that meet the standards for the cultivation of cannabis for industrial purposes. The joint report is submitted to the minister responsible for agriculture. By November 30 of each calendar year, the Council of Ministers approves the cadastral areas where the cultivation of cannabis for industrial purposes will be allowed, starting from January 1 of the following year.
4. The medical cannabis monitoring unit proposes to the minister responsible for health the report on the lands requested by the licensed entities, which meet the standards for the cultivation of cannabis for medical purposes, for approval by the Council of Ministers.
5. The units monitor the process to ensure the cultivation of only seeds and seedlings registered with the institution responsible for the registration of seeds and seedlings, and the importation only by entities equipped with import licenses and authorizations.
6. The unit monitors the process of importing seeds and seedlings that are varieties of cannabis for medical and industrial purposes, included in the Common European Catalog of Plant Varieties in Agriculture, as well as the process of their reproduction.

Article 13

National Register of Licensed and Permitted Cannabis Plant Activity

1. All licensed and permitted entities under this law are registered in the National Register of Licensed and Permitted Entities.
2. The register is established in the form of a state database, administered by the Agency, and contains all information on applications for licensing, decision-making on licensing, applications for authorization, decision-making on authorization, applications for permission, decision-making on permission, tracking, supervision and control, and administrative measures related to all stages of cannabis cultivation, from the moment of granting the license, permit, and authorization until their revocation, and the seizure or disposal of plants or by-products, according to the provisions of this law.
3. The following are recorded in the register:
   a) Entities licensed and permitted for the cultivation of cannabis and authorized for the importation of seeds and seedlings;
   b) Data on licenses, permits for the cultivation of cannabis, and authorizations for the importation of seeds and seedlings, as well as their suspension or cancellation;
   c) Types of seeds and seedlings cultivated by entities according to the European list of cannabis seeds for medical and industrial purposes;
   d) The imported amount, the produced amount, the buyer of the raw material, the fertilizer products used;
   e) Data on the authorization of the export of by-products or final products of cannabis for industrial and medical purposes according to the provisions of this law;
   f) Type and amount of cannabis plant, by-products, or final products disposed of. In the case of industrial cannabis, these data are recorded according to the subject's self-declaration;
   g) Placement of unique marks and tracking of all stages of seed and seedling provision, cultivation, production, marketing, supply, and transport serving the identification of the cannabis plant, by-products, and final products. Unique marks in the case of industrial cannabis are not placed for marketing to the end user for export;
   h) Administrative measures taken against cultivation entities.

4. The register interacts with other databases that serve the process of granting licenses, permits, and authorizations, as well as the supervision of the process of cultivating cannabis for medical and industrial purposes.
5. The corresponding structures of the ministries responsible for health, finance, public order and security, and agriculture have access to this register.
6. The detailed definition of primary and secondary data, the determination of the specific databases with which this register interacts, the level of its access by interested parties or the public, the definition of the data that will be public, as well as the manner of recording and storing the data and documents contained in the register are determined by a decision of the Council of Ministers, with the joint proposal of the minister responsible for health, the minister responsible for agriculture, and the minister responsible for order and public safety.

Chapter III: Procedure for Obtaining a License to Engage in Activities Related to the Production of Cannabis for Medical Purposes

Article 14

License to Exercise Activity

1. The license for the production of cannabis for medical purposes may include the following activities:
   a) Cultivation and production of the cannabis plant for medical purposes.
   b) Transportation of seeds, plants, and cannabis products and by-products for medical purposes within the territory of the Republic of Albania.
   c) Export of cannabis plants, products, and by-products for medical purposes.

2. The license is granted for one or more activities, as specified in point 1 of this article, for a period of 15 years, with the right to renew upon request, for each activity and based on the selection procedure organized by the Agency. The format of the license for conducting activities related to the production of cannabis for medical purposes is approved by order of the minister responsible for health.
3. The license is granted only to entities that meet the conditions and criteria set out in this law, and only for the units and activities requested and specified in their development plan, by specifying the coordinates of the location of the units and the entity's relationship with the land.
4. The license is issued in the name of the entity and is non-transferable and non-assignable. The license includes as part of it the activities for which the entity is licensed, with the fulfillment of the requirements set out in this law.
5. If the license specifies that certain activities provided for in the license may be carried out wholly or partially by other entities, these entities will be verified in relation to the fulfillment of the condition of a clean record and expressly identified in the license. Changes related to the transfer of ownership of these entities require prior written approval from the Licensing Commission. The Commission gives or refuses prior approval within 3 months of the complete submission of the request, based on the documentation determined regarding the verification of the clean record.
6. The license specifies one or more units for which the entity has met the criteria. If the entity is licensed for more than one unit, they must be adjacent to each other and, in any case, not more than 4 units in the same license.
7. The license for the cultivation activity is granted only for open areas, covered areas, or greenhouses. The area of the licensed unit for the cultivation of cannabis for medical purposes cannot be smaller than 5 hectares and not larger than 10 hectares.
8. The total area allowed for the cultivation of the cannabis plant for medical purposes cannot exceed 200 hectares nationwide.
9. The applicant, to be issued a license, pays a fee of 100,000 (one hundred thousand) lekë at the time of submission of the request, which is non-refundable. The fee payment procedure and the method of using this fee are determined by a joint instruction of the minister responsible for finance and the minister responsible for health.
10. The conditions for issuing the license, as defined in point 2 of article 15, must be respected by the licensed entity throughout the validity period of the license. Every 3 years, the conditions of the

license are re-evaluated by the Agency, which, if it finds non-fulfillment of the conditions and criteria, proposes, as appropriate, the suspension or revocation of the license or requests the entity to fulfill the conditions within a 30-day period.

11. No later than 6 months before the expiration of the license validity period, the entity may request its renewal when it proves that it meets the conditions for obtaining a license according to the provisions of this law.

Article 15

Conditions for Licensing

1. Any legal entity seeking to be licensed must meet the following conditions for each activity required for licensing:

a) Have 3 years of experience in at least 3 of the main activities, such as: production, cultivation, and circulation of cannabis plants for medical purposes.

b) The entity or a shareholder owning 51% of the company's shares must:

i. Be engaged in the production of cannabis plant by-products in one of the countries of the Organisation for Economic Co-operation and Development for at least 5 years.

ii. Be in possession of good manufacturing practices issued by the European Medicines Agency or the U.S. Food and Drug Administration for at least 3 years.

iii. Have a company capital of not less than 100,000,000 (one hundred million) Albanian Lekë.

iv. Have demonstrated positive financial performance in the last fiscal year.

v. Have the necessary administrative, organizational, and reliability capacities to successfully engage in the main activities required for licensing.

vi. Not be listed as or declared financiers of terrorism.

2. A legal entity applying for a license for the production of medical cannabis must, among other things:

a) Specify in detail the activity or activities for which it seeks to be licensed.

b) Present the units where the activity will be carried out with coordinates, as well as the legal relationship with the land.

c) Present a business development plan, identifying the cultivation model and purpose, as well as the minimum and maximum area of the development unit.

d) Present the plan for the processing of environments for drying, cutting, and storage, equipped in accordance with the production capacity, previously provided for in the production development plan.

e) Present the security plan for the cultivation and processing area, specifying protection, enclosure, camera security, and 24-hour physical security elements, entry deterrents, and barbed wire fences, according to standards set by decision of the Council of Ministers.

f) Present a self-declaration of employment for at least 10 persons for each unit, 2 of whom must be qualified employees in the fields of pharmacy and agro-engineering, with work experience of not less than 3 years in the respective field.

g) Present a self-declaration of readiness to conclude agreements with the responsible structure in the ministry responsible for public order and security, to guarantee access for inspection to the private security company overseeing the cultivation environments of the cannabis plant and its by-products, as well as the movement of dedicated vehicles for the trade of raw materials and products, according to rules and tariffs set by the Council of Ministers.

h) Present a self-declaration for the commencement of the activities described in the license within 12 months from its approval.

i) Present a self-declaration that after the third year it will pay an annual fee equal to 1.5% of the annual turnover, but in any case, not less than 10,000,000 (ten million) Albanian Lekë.

j) Present a bank guarantee of 10% of the investment value.

k) Present a self-declaration that it will fulfill all requirements for traceability according to the provisions of this law.
l) Present a self-declaration for the processes carried out by third parties and their identification with accurate data for assessment and verification purposes.
m) Present a self-declaration for the availability of payments of the tracing system fees.

Article 16

Submission of Application and Required Documentation

The application for licensing shall be submitted to the Agency, along with the following documentation and information:
a) Certificate of registration with the National Business Center.
b) Historical extract of the legal entity and, where applicable, the deed of establishment and the company's statutes and list of beneficial owners, if any.
c) Data of the legal representative or authorized person to follow the licensing procedure.
d) Certifications issued by competent authorities, such as:

i. Certificate of the subject's security, issued by the Classified Information Security Directorate for Albanian citizens, and an equivalent certificate for foreign citizens issued by the competent authorities of the country where they are residents.

ii. Certification issued by the prosecutor's office proving that the subject, administrator, members of the management bodies, partners, or shareholders are not under criminal prosecution.

iii. Certification issued by the judiciary proving that the subject, administrator, members of the management bodies, partners, or shareholders are not under trial for any criminal offense.

iv. Certificate of judicial status proving that the subject, administrator, members of the management bodies, partners, or shareholders have not been criminally convicted by a final court decision.

v. Certification from the enforcement authority proving that the subject is not in compulsory execution process for unpaid pecuniary obligations.

vi. Certification proving that the applicant entity, partners, or shareholders of the applicant subject are not in bankruptcy proceedings.

vii. Financial statements of the applicant entity, as well as its shareholders for the last 3 years prior to the submission of the application.

viii. Documents verifying experience in the relevant activities according to the requirements specified in this law.

ix. Certification from the tax authorities for the settlement of tax obligations both by the subject and by any legal entity in case of company merger.

x. Certification of the availability of qualified personnel to carry out activities in accordance with the requirements of this law.

e) Relevant regulations for the rules and operation of the activity or activities for which licensing is sought.
f) Self-declaration regarding the conclusion of the preliminary agreement for physical protection and security in accordance with the provisions of this law.
g) Self-declaration regarding the payment of the bank guarantee according to the provisions of this law.

Article 17

Announcement of the Competition for Licensing

1. The Agency announces the competition notice for licensing, for medical purposes, for all its activities licensed according to the provisions of this law.
2. The notice contains:

a) The list of necessary documentation.

b) The place and deadline for the submission of the application and documentation.
c) The language and manner of presenting the documents.
d) The place, date, and time for the documentation review.

Article 18

Procedure for Selecting the Winning Subject

1. The selection of the subject is made through a competition procedure organized by the Agency, in accordance with the conditions specified in this law, after evaluation by the Licensing Commission.
2. The Members of the Licensing Commission self-declare under their responsibility that participation in this commission does not constitute grounds for the emergence of a conflict of interest with the participating subjects in the competition. In case of a non self-declaration, measures according to the provisions of the legislation in force for preventing conflicts of interest in the exercise of public functions, shall apply.
3. The Licensing Commission, after verifying the documentation, after evaluating the fulfillment of the conditions and criteria provided for by this law, prepares a final list by ranking the participants in the competition according to the points obtained in accordance with the scoring scheme approved by the Commission. The candidate ranked first on the list is considered the winner.
4. The Commission ranks the participants in the competition according to the evaluation of experience or expertise in carrying out the activity and professional experience, referring to:
a) first, the results of the evaluation of experience in the main activities for which the license is issued, according to the provisions of subparagraph "a" of paragraph 1 of Article 15;
b) secondly, in cases of equal results of experience evaluation, years of experience or professional experience, according to the provisions of subparagraph "b" of paragraph 1 of Article 15.
5. The Commission prepares, approves, and publishes more detailed rules, which determine:
a) the criteria for evaluating experience in carrying out the main activities for which the license is issued among participants in the competition with equal scoring;
b) the criteria for evaluating the required professional experience;
c) the procedure followed in case of equal points.
6. The entities listed under paragraph 3 have the right to lodge an appeal with the Minister responsible for health within 10 days from the publication of the notice. The Minister's order may be appealed in court according to the provisions of the legislation in force for the adjudication of administrative disputes.
7. Upon the expiration of the deadline for the submission of appeals and their review, and after the declared winning applicant has fulfilled, within 30 days, the criterion related to the guarantee fund, the Agency submits the proposal for the issuance of the license to the Minister responsible for health

Article 19

License Approval

1. The Minister responsible for health, upon receipt of the proposal for the winning subject according to the provisions of Article 18 of this law, approves the license within 3 months.
2. The order for the issuance of the license specifies the name of the subject, the conduct of the activity, the deadline, the area expressed in coordinates, a description of the licensed activity within this license, as well as the activities or processes allowed to be carried out by third parties on behalf of the license holder. The minister's order is published in the National Register of licensed entities.

3. If the minister remains silent within 90 days from the submission of the proposal by the Agency, then the request is considered rejected.
4. The subject is considered the holder of the license for the exercise of the activity or activities, within the meaning of this law, on the date of the minister's order for licensing.

Article 20

Amendment of License Data

1. During the exercise of the activity, the license holder is obliged to notify the Agency of all changes and deviations from the measures planned earlier in the business development plan, changes in the documentation submitted at the time of submitting the application for licensing, and changes in the data related to changes in third parties or the termination of the agreement regarding activities that will be partially or entirely exercised by third parties.
2. The licensed entity addresses the Agency with a written notification within 10 working days from the moment the change occurs, describing any facts and circumstances that have led to changes or deviations from the planning.
3. The Agency approves or rejects the approval for these changes within 1 month from the complete submission of information, based on the documentation specified by sub-legal act by the Agency, and proposes concrete measures to the Minister responsible for health.
4. The Minister responsible for health, upon receipt of the Agency's proposal, if it is found that the changes are related to the activities specified in the license, approves the changes to the license, which are published in the same manner as the publication of the license.

Article 21

Suspension and Revocation of License

1. The Minister responsible for health may suspend the license if the subject:
    a) fails to comply with current legislation and sub-legal acts issued for the exercise of the activities for which the license is granted;
    b) violates the conditions of the license;
    c) does not appear within the specified period for the amendment of license data.
2. The Minister responsible for health decides to revoke the license if the subject:
    a. repeatedly violates the conditions of the license;
    b. repeatedly violates the current legislation for the exercise of the activities for which the license is granted;
    c. requests the revocation of the license;
    d. does not start the development of the activity within a period of 12 months from the approval of the license;
    e. obtained the license through deception;
    f. is declared bankrupt and is unable to fulfill the obligations under the conditions of this license;
    g. with the termination of the legal entity, the license holder.
3. Verification and determination of the violations specified in paragraphs 1 and 2 of this article are conducted by the Licensing Commission, after hearing the explanations of the subject, the license holder.

4. The Minister responsible for health, upon the proposal of the Licensing Commission, decides on the suspension or revocation of the license.
5. The procedure for submission, deadlines, and consideration of the proposal for the suspension or revocation of the license is approved by the guidance of the Minister responsible for health.
6. The decision to suspend or revoke the license is made regardless of the administrative and criminal sanctions that may be applied and is published in the same manner as the publication of the license.

CHAPTER IV
ISSUANCE OF PERMITS FOR ACTIVITIES RELATED TO THE PRODUCTION OF INDUSTRIAL CANNABIS

Article 22

Permit for the Exercise of Activity

1. The permit for the exercise of the activity of producing cannabis for industrial purposes, hereinafter referred to as the "permit," allows the activity of importing seeds or seedlings, or reproducing them for use as seeds/seedlings, cultivating, producing and processing, transporting, as well as exporting by-products and final products of cannabis for industrial purposes.
2. The permit is issued for a period of 5 years, with the right of renewal, for areas not smaller than 1 hectare.
3. The format of the permit and the criteria for the activities included in it are approved by the instruction of the Minister responsible for agriculture.
4. The permit is approved by order of the Minister responsible for agriculture, based on the selection procedures organized by the responsible structure in the Ministry responsible for agriculture and is published in the relevant register.
5. The activities included in this permit cannot be transferred to third parties, except for those allowed in the description of the permit.
6. A copy of each approved permit and the documentation, based on which the review and approval procedure of the permit was followed, is submitted to the Agency, within 5 days from the issuance of the minister’s order for the approval of the permit.

Article 23

Conditions for Obtaining a Permit

1. The application for obtaining a production permit is submitted to the ministry responsible for agriculture and must be accompanied by the following documentation:
   a) the registration document of the farmer, legal or physical person;
   b) the list of employed or subcontracted personnel to manage the cultivation process, which must include at least one agronomist, accompanied by:
      i. a certificate issued by the prosecution body proving that the subject is not under criminal investigation;

ii. a certificate issued by the judicial body proving that the subject is not on trial for any criminal offense;

iii. a criminal record certificate proving that the subject has not been convicted by a final court decision;

iv. a declaration consenting to the conduct of background checks by the competent authorities on the cleanliness of the employees' records;

c) a self-declaration of the source of funding for expenses;

d) a self-declaration of no tax liabilities to the tax administration and local units;

e) a self-declaration of the preliminary agreement for physical security and safety, according to the rules and tariffs set by the Council of Ministers' decision;

f) a preliminary sales agreement with the licensed entity for processing the raw material, which will purchase it;

g) property documentation, a copy of the land register and a map indicating the registration of the land, or a lease contract if the land is not owned by the applicant, with the location in approved cadastral zones for cultivation. If the land does not have a final ownership document, the act of land acquisition and the cadastral plan must be submitted;

h) a self-declaration of payments of the tracking system fees.

2. After verifying the documentation by the responsible structure in the ministry responsible for agriculture, a copy of the documentation is sent to the ministry responsible for public order and safety, which within 10 days provides an evaluation for the approval or rejection of the application.
3. The responsible structure in the ministry responsible for agriculture, after receiving the evaluation from the ministry responsible for public order and safety, within 10 days, submits a report to the minister responsible for agriculture for granting the permit or rejecting the application.
4. The minister responsible for agriculture, upon receiving the report from the unit, as specified in point 3 of this article, approves the permit. If the minister remains silent within 30 days from the submission of the report, the application is considered rejected.
5. The subject is considered a permit holder, within the meaning of this law, on the date of the minister's order for granting the permit.
6. The production permit is revoked if during the exercise of the activity it is found that:
   a) the activity is conducted in violation of the law's criteria;
   b) the activity is conducted in violation of the permit's conditions;
   c) the fees for the tracking and marking system are not paid;
   d) other legal provisions related to the exercise of the activity of the permit holder are violated.
7. During the verification phase carried out, according to the provisions of point 6 of this article, the minister may decide to suspend the cultivation permit until a final decision is made.

HEAD V
DEVELOPMENT OF LICENSED OR PERMITTED ACTIVITIES

Article 24

Production Unit

1. The activities specified in the license or permit, as stipulated by this law, are carried out only within the premises of the production unit with restricted and monitored access.
2. The production unit is a limited area of land ranging from 5 to 10 hectares, which includes warehouses and other areas dedicated solely to processes related to the cultivation of the cannabis plant and the production of its by-products for medical purposes. It also includes an area no smaller than 1 hectare, which includes warehouses and other areas dedicated solely to processes related to

the cultivation of the cannabis plant and the production of cannabis by-products for industrial purposes.
3. The number, area, and location of production units are detailed in the license or permit.
4. The license allows for production in up to 4 contiguous production units. For non-contiguous units, a separate license is required.
5. The capacity of the unit for processing and storage must correspond to its cultivation capacity.

Article 25

Import of Cannabis Plant Seeds and Seedlings

The import of cannabis plant seeds and seedlings is carried out by the licensed or permitted entity following authorization granted by the State Agency of Seeds and Seedlings, in accordance with the provisions of Law No. 10 416, dated 7.4.2011, "On Planting Material and Plant Propagation."

Article 26

Planting of Cannabis

1. The entity licensed or permitted for the planting activity is allowed to plant only seeds and seedlings registered in the responsible institution for the registration of seeds and seedlings.
2. The entity licensed for the planting of cannabis for medical purposes or permitted for the cultivation of cannabis for industrial purposes, no later than 10 days before the commencement of planting cannabis seeds, is obliged to notify the Agency or the regional unit of the Ministry responsible for agriculture, requesting their presence during the planting process.
3. After monitoring the planting process, in the presence of the representative of the entity, a corresponding record is kept, a copy of which is deposited with the Agency.
4. Data on the planting process are recorded in the relevant register.

Article 27

Supervision of Plant Harvesting

1. The cultivator of cannabis plants, no later than 15 days before the commencement of cannabis plant harvesting, is required to notify the Agency, requesting the presence of a representative of this agency during the harvesting process. The Agency notifies the responsible ministries according to the purpose of cultivating cannabis plants.
2. After monitoring the harvesting process, in the presence of the entity's representative, a corresponding record is kept, a copy of which is deposited with the Agency.
3. Upon completion of the cannabis harvesting process for medical purposes, the Agency conducts check on the quantities harvested and the produced material, and records in the minutes the number of seedlings collected and the quantity in weight of the moist mass.
4. Data on the harvesting process are recorded in the relevant register.

Article 28

Processing and Primary Material

1. The material produced from cannabis plants is dried, cleaned, sorted, packaged, and labelled.
2. After the completion of harvesting, the above-ground portion of the harvested cannabis plant is dried in a specially arranged space.
3. The cannabis cultivator maintains a special record in 3 copies for the quantity produced, in the presence of Agency employees. One copy is sent to the ministry responsible for public order and security, one copy is retained by the cultivating entity, while one copy is kept by the Agency.

4. The cannabis cultivator submits a report to the responsible ministry structure for public order and security and the Agency for the completion of the production process, cultivation, and the quantity of dried material obtained, within 10 days from the completion date of the process.
5. Before the dried material is packaged, the Agency conducts quality control in certified and accredited laboratories, according to the provisions of the relevant legislation for the accreditation of conformity assessment bodies. The method for quality control, related to the content of cannabinoid and tetrahydrocannabinol components, as well as physicochemical and microbiological control for the packaging method, shape, and quantity, is determined by the guidelines of the minister responsible for agriculture.
6. The packaging of dried cannabis plants contains the following information:
   a) Name and headquarters of the cultivating entity;
   b) Day, month, and year of harvesting and production;
   c) Name of the primary material;
   d) Net and gross weight of the dried mass;
   e) Form of the plant, whether it is leaf, flower, plant, whole, or cut;
   f) Packaging date and expiry date; g) Unique identification mark.

Article 29

Products and By-Products Produced from Medical Cannabis Plant

1. Products and by-products intended for medicinal use, produced from the medicinal cannabis plant by the licensed manufacturer, are subject to all provisions specified in the current legislation for medicines and pharmaceutical services, legislation for narcotic drugs and psychotropic substances, and legislation for cosmetic products before their release into circulation.
2. All by-products and products produced in the country, according to point 1, are intended solely for export, according to the provisions of this law.

Article 30

Transportation

Possession, movement, escort, and transportation of seeds, seedlings, primary material of medicinal cannabis plant, and its by-products from one place to another are carried out by the licensed entity for this activity, after prior notification to the Agency. In any case, transportation is conducted through escort by a physical security and safety company contracted by the licensed entity.

Article 31

Security

The safety and security of the unit, transportation, and trade are undertaken by the entity that has concluded a safety and security unit contract with the licensed entity.

Article 32

Export of Cannabis Plant By-Products

1. The export of by-products or finished products of the cannabis plant is carried out by the licensed entity, according to the provisions of this law.
2. The export of by-products or finished products of cannabis for medicinal purposes is conducted according to the current legislation for medicines and legislation for narcotic drugs and psychotropic substances, and for cosmetic products.

3. The export of by-products or finished products of cannabis for industrial purposes is conducted by the Agency, according to the provisions of the joint instruction of the Minister responsible for agriculture and the Minister responsible for the economy.
4. The export of by-products or finished products of the cannabis plant must be accompanied by a special export authorization, which includes the following information:
   a) The name of the product, international name of the owner, if applicable, and the quantity to be exported;
   b) The name and address of the importer and exporter and should specify the period within which the import or export must be carried out;
   c) If the importing country requires the obligation to be equipped with an import certificate or another analogous document, the number and date of the import certificate and the authority that issued it.

5. Before issuing the export authorization, in countries that require the obligation to be equipped with an import certificate or another analogous document, the Agency must request the submission of an import certificate from the subject issued by the competent authorities of the importing country or territory.

CHAPTER VI

MARKING AND TRACKING

Article 33

Transmission

1. The agency administers the National Register of Permitted and Licensed Entities and oversees the placement of unique marks for identification and traceability at all stages of cultivation, production, marketing, supply, and transport of the cannabis plant, by-products, and final products to the end-user according to the provisions of this law.
2. Licensed and permitted entities, as defined by this law, are obligated to enter data into this register.
3. For the purposes of control and inspection of licensed and permitted activities in this register, access is granted to:
   a) the ministry responsible for health;
   b) the ministry responsible for agriculture;
   c) the ministry responsible for finance;
   d) the ministry responsible for order and security;
   e) National Agency of Medicines and Medical Devices;
   f) institutions or entities permitted by order of the minister responsible for health.

Article 34

Marking and Tracking

1. Marking is done through a unique sign in the form of a code, stamp, label, or any other type of marking and is mandatory at all stages, including importation, cultivation, production, processing, storage of medical and industrial cannabis plants, by-products, and their final products, as well as the export and use of by-products or final products of the medical and industrial cannabis plant to facilitate traceability.
2. Traceability is an identification method for determining the precise location of the medical and industrial cannabis plant, its by-products, and final products at all stages from planting to final use, as well as its ownership at all stages. Tracking does not apply to industrial cannabis intended for direct sale to end-users.

3. All holders of a license, according to the provisions of this law, are obliged to mark the plant, seed, substance, preparation, product, which is the object of their activity, and to comply with all legislation related to marking and tracking.
4. The cost of marking and tracking shall be borne by entities licensed and permitted under this law. Fees and payment procedures are determined by the decision of the Council of Ministers, based on proposals from the minister responsible for finance, the minister responsible for health, and the minister responsible for agriculture.
5. The requirements for traceability, as well as the rules for the unique marking elements, label, stamp, or other forms of marking, the procedure and method of marking and tracing, as well as the authority or party authorized to carry out the marking and traceability, are determined by the decision of the Council of Ministers, with proposals from the minister responsible for health and the minister responsible for agriculture.

CHAPTER VII

SUPERVISION

Article 35

Responsible Bodies

1. For the inspection of the implementation of the provisions of this law, the Agency, the structures responsible for the registration of seeds and seedlings and plant health, and the National Agency of Medicines and Medical Devices, according to the tasks provided for in this law and in accordance with their legal powers, are responsible.
2. The agency coordinates the supervision process with other institutions.

Article 36

Supervision and Control

1. The supervision of the implementation of the provisions of this law and the rules adopted on its basis, in relation to licensed activities, is carried out by the Agency through its employees.
2. The fulfillment of obligations under drug laws is supervised and monitored by the structure responsible for pharmaceutical inspection.
3. The fulfillment of obligations for the process of registration of seeds and seedlings and control of plant health is carried out by the responsible structures of the ministry responsible for agriculture.
4. Supervision during the process of disposal of the cannabis plant and its by-products or final products is done by the Agency in cooperation with the responsible structure of the ministry responsible for public order and safety.
5. More detailed rules for supervision are determined by decision of the Council of Ministers, based on the general rules of legislation in force for inspections.

Article 37

Taking Samples

1. Sampling is carried out by the Agency in cooperation with the institutions responsible for supervision, according to this law.
2. The minister responsible for health and the minister responsible for agriculture, through joint instructions, determine the method, quantity of sampling, and the laboratory for performing analyses with accredited methods for quality control, whether inside or outside the country.

CHAPTER VIII

SEIZURE AND CONFISCATION

Article 38

Confiscation of Medical Cannabis Plant, By-Products, and Final Products

1. The medical cannabis plant, its by-products, and final products are confiscated by order of the minister responsible for health, upon proposal of the Agency, if it is established that:
   a) they are cultivated, processed, circulated, or possessed by an unlicensed entity;
   b) they are not marked and traceable according to the provisions of this law.

2. The medical cannabis plant, its by-products, and final products confiscated under this law are subject, where applicable, to the regulations for the administration of confiscated drugs, according to the legislation in force on drugs and pharmaceutical services.
3. The Agency records the type and quantity of confiscated cannabis in the registry. In cases of confiscation of the cannabis plant, its by-products, and final products, the Agency and state supervisory institutions are obligated to notify the structures responsible for order and security and to apply relevant sanctions for all actions violating the provisions of this law.

Article 39

Destruction of Cultivated Plants

1. Medical cannabis plants, regardless of intended use, if they have germinated spontaneously, as well as remains of the medical cannabis plant on the earth's surface specified in the license or permit, are disposed of according to the manner and provisions of this law by the licensed or permitted entity, in the presence of an Agency representative. Relevant minutes are kept according to the legislation in force.
2. If the entity fails to fulfill the obligation of point 1, the destruction is carried out by the Agency at the expense of the entity, against which administrative measures are taken for non-fulfillment of this obligation.
3. The entity authorized for the cultivation of industrial cannabis carries out the disposal of plants not used for commercial purposes or of plant residues and reports to the Agency on the amount of plants disposed of.
4. The Agency maintains separate records of the type and quantity of cannabis plants disposed of.
5. The detailed method of disposing of spontaneously grown plants and harvested plant residues or destroyed, according to points 1, 2, and 3 of this article, is determined by joint instruction of the minister responsible for health, the minister responsible for agriculture, and the minister responsible for public order and security.

CHAPTER IX

SANCTIONS

Article 40

Administrative Sanctions

1. The following violations, when not constituting a criminal offense, constitute administrative misdemeanors and shall be punished as follows:

a) with a fine ranging from 500,000 (five hundred thousand) to 1,000,000 (one million) ALL if the licensed or permitted entity:

i. uses narcotic drugs and psychotropic substances contrary to the conditions established by this law;

ii. advertises directly or indirectly all activities related to the medical cannabis plant;

iii. sells in the territory of the Republic of Albania the medical cannabis plant, its by-products, or final products;

iv. fails to implement measures issued by the Agency regarding the exercise of licensed or permitted activities;

v. obstructs the sampling process as per Article 37 of this law;

vi. exceeds the deadline set for collecting the produced quantities of dried cannabis mass obtained for medical purposes;

vii. fails to fulfill obligations regarding notification to the ministry responsible for public order and security, the ministry responsible for agriculture, and the ministry responsible for health, regarding any circumstances indicating suspicion that cannabis or parts thereof have been used or may be used for the production of narcotic and psychotropic substances;

viii. fails to fulfill obligations related to maintaining registers of quantities of cannabis produced and purchased for medical and/or industrial purposes or fails to submit reports within legal deadlines to supervisory authorities;

b) with a fine ranging from 1,000,000 (one million) to 3,000,000 (three million) ALL if the licensed or permitted entity:

i. fails to comply with conditions related to transport of the medical cannabis plant during transportation or conditions for storage in original packaging;

ii. fails to comply with rules regarding processing and production development plans;

iii. fails to comply with rules related to security plans, including definition of protection elements, fencing, camera security, and physical security;

iv. fails to comply with rules regarding marking or tracking.

c) with a fine ranging from 3,000,000 (three million) to 5,000,000 (five million) ALL if the licensed or permitted entity:

i. hides or falsifies documents concerning planting and management of larger areas of medical or industrial cannabis, or fails to complete registration of areas within specified periods;

ii. fails to declare areas on which it cultivates medical cannabis and/or industrial cannabis;

iii. exports by-products or final products in quantities different from those declared, according to provisions of this law;

iv. falsifies data for the purpose of completing registers required by this law;

v. performs activities for which it is not licensed, permitted, or authorized;

vi. continues activity even after expiration of license or permit; vii. obstructs or evades monitoring or verification related to marking and tracking;

viii. cultivates, produces, processes, supplies, trades, stores, transports unmarked narcotic or psychotropic products, as stipulated in Article 34 for marking and tracking.

2. In addition to the fine provided in point 1 of this article, the legal person may also be sanctioned with a temporary ban on carrying out activities for a period of 6 months to 3 years.
3. Administrative offenses, as per the provisions of this law, are identified and sanctioned by the Agency.
4. In cases of identifying violations of the Criminal Code, the Agency reports, in accordance with provisions of the Criminal Code, to relevant authorities as per provisions of the Code of Criminal Procedure.
5. Revenues from fines are directed 100% to the state budget.

Article 41

Appeal

Regarding administrative measures taken by the Agency, as well as any other administrative actions carried out in violation of the Administrative Procedures Code and this law, subjects may appeal to the Administrative Court of First Instance of Tirana within 45 days of receiving notification.

CHAPTER X

TRANSITIONAL AND FINAL PROVISIONS

Article 42

Transitional Provisions

1. Entities that, at the time of entry into force of this law, are engaged in the activity of cultivating and producing cannabis for industrial purposes, according to the legislation in force for narcotic drugs and psychotropic substances, have the right to adapt their permitted activities to be licensed, in accordance with the provisions of this law, within 8 months from the entry into force of this law.
2. The exercise of the activity by the entities specified in point 1, without being licensed according to the provisions of this law, after this period is considered illegal.
3. The National Cannabis Control Agency is established within 3 months from the entry into force of this law.

Article 43

Sublegal Acts

1. The Council of Ministers is charged with approving the sublegal acts for the implementation of articles 7, point 3; 9, point 2; 13, point 6; 15, point 2; 23, point 1; 34, points 4 and 5; and 36, point 5 within 9 months from the entry into force of this law.
2. The Minister responsible for health is charged with issuing the sublegal acts for the implementation of articles 11, point 8; and 14, point 2 within 3 months from the entry into force of this law.
3. The Minister responsible for agriculture is charged with issuing the sublegal act for the implementation of article 9, point 3 within 3 months from the entry into force of this law.
4. The ministers according to their respective fields of responsibility are charged with issuing the sublegal acts for the implementation of articles 6, point 4; 8, point 8; 14, point 9; 32, point 3; 37, point 2; and 39, point 5 within 9 months from the entry into force of this law.

Article 44

Repeals

Upon the entry into force of this law, the provisions of law no. 7975, dated 26.7.1995, "On narcotic drugs and psychotropic substances", as amended, and other legal and sublegal acts that are contrary to the provisions of this law, are repealed.

Article 45

Entry into Force

This law enters into force 15 days after its publication in the Official Gazette.

CHAIRWOMAN

Lindita Nikolla

Approved on 21.7.2023.