REPUBLIKA E SHQIPËRISË

ASSEMBLY DRAFT LAW

No.__/2022

"FOR

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

In support of articles 78, 81, point 1, and 83, point 1, of the Constitution, with the proposal of the Council of Ministers,

ASSEMBLY

OF THE REPUBLIC OF ALBANIA DECIDED:

CHAPTER I GENERAL PROVISIONS

Article 1 Object of the Law

The object of this law is to determine the rules for the cultivation, production and controlled circulation of the cannabis plant and by-products, for medical and industrial use, through licensed entities and under the supervision of the National Agency for the Control and Monitoring of the Cultivation and Processing of the Cannabis Plant. Cannabis for medical and industrial purposes and the production of its by-products.

Article 2 Purpose of the Law

The purpose of this law is to regulate and guarantee the process of control, monitoring of the cultivation, processing of the cannabis plant and the production of its by-products, intended for medical and industrial purposes and their export according to the conditions and rules of this law and in implementation of the classification of the by-products of the cannabis plant, in accordance with the Single Convention on Narcotic Drugs of 1961, amended by the 1972 protocol and the Convention on Psychotropic Substances of 1971, ratified by laws No. 8722, dated 26.12.2000 "On the accession of the Republic of Albania to the "United Nations Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances" and No. 8723, dated 26.12.2000 "On the accession of the Republic of Albania to the "Single Convention on Narcotic Drugs, amended by the protocol of 1972 for the amendment of the Single Convention on Narcotic Drugs, 1961".

Article 3 Definitions

1. In this law, the following terms have the following meanings:

" **Licensed** activity" is any activity of a commercial, economic, professional nature that is carried out by licensed entities for the purpose of importing seeds and seedlings, cultivating the medical cannabis plant, producing plant by-products, transporting plant seeds and by-products of it, the export of plant raw material.

" **Permitted activity** " is any activity of a commercial, economic, professional nature that is carried out by licensed entities for the purpose of importing seeds and seedlings, cultivating industrial cannabis plants, transporting plant seeds and its by-products, exporting the material plant first.

"Narcotic drug" is considered a substance of natural or synthetic origin, which is classified as such according to the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971, acceded to by the Republic of Albania, the abusive use of which creates addiction of users from these subjects.

"**EMCDDA**" is the European Center for Monitoring Drugs and Drug Addiction.

"Cannabis" means the flowering and fruiting tops of plants of the genus Cannabis, excluding seeds and leaves when these are not associated with the tops from which the resin has not been removed, regardless of what name they may have.

"Traceability" is the process to trace and follow the seeds, seedlings, substances, plants, materials and preparations that are the subject of this law in all stages of planting, cultivation, production, circulation, supply to the end user.

"Cannabis plant for medical purposes" are the plants of different varieties, variations and subspecies of *Cannabis sativa, Cannabis indica* and *Cannabis ruderalis*, obtained from cultivation for medical purposes and scientific research under conditions controlled and regulated by this law.

"Cannabis plant for industrial purposes" is the *Cannabis* plant to be cultivated and produced for industrial purposes including all fresh or dried parts of the plant and seeds of the *Cannabis species (sativa, ruderalis)* of varieties containing no more than 0.2% THC.

"Cultivation" is the planting of seeds or seedlings until the cannabis plant is harvested.

"Medical cannabis plant residues" are parts of the medicinal cannabis plant or their residues after production and processing, which are treated as unnecessary.

"By-products for medical purposes" are substances and preparations that are extracted from the cannabis plant.

"By-products for industrial purposes " is the whole plant, including stem, flower and seed.

"**Unit"** is the area of land from 5 to 10 ha, limited, which also includes warehouses and other premises dedicated only to the processes related to the cultivation of the plant and the production of plant by-products for medicinal purposes and the area not smaller than 1 hectare, which also includes warehouses and other premises dedicated only to the processes related to the cultivation of the plant and the production of by-products of the cannabis plant

for industrial purposes **.**
"Preparation" is extract, mixture or crude plant material obtained from cannabis, in solid or liquid state or in any other state, which contains narcotic drug and/or psychotropic substance.
"**Production**" is any process starting from cultivation, preparation, processing, mixing, cleaning and any other activity, with which the narcotic drug or psychotropic substance is obtained or intended to be obtained according to the provisions of the legislation on drugs and pharmaceutical services.
"Circulation" is considered any way of passing into the civil circulation of the plant and its by-products, against payment or remuneration, including the processes of import, export, transit, supply, purchase, sale, exchange, storage, storage.
"Marking" is the process of placing a unique mark in the form of a code, stamp or label on seeds, seedlings, substances, plants, preparations, which is the object of this law for the purpose of identifying and tracking him/her.

Article 4
Scope and Prohibitions

1. This law applies to the activity of cultivation, production, trading according to the provisions of this law, import, export and control of the cannabis plant for medical and industrial purposes and its by-products, in accordance with the purpose and provisions of this law.

2. This law does not apply and prohibits:

a. The cultivation of the medical and industrial cannabis plant and the production of its by-products, contrary to the provisions of this law.

b. the cultivation of the cannabis plant and the production of its by-products, their circulation and possession if they are not marked and traceable, according to the provisions of this law.

c. the possession of means, equipment and instruments for the production of the cannabis plant and its by-products, except for the cases declared by the entity equipped with a license, provided for in this law.

ç. what the use of by-products of the cannabis plant, except for the cases provided for in this law and in the special legislation in force.

d. advertising made directly or indirectly or in any other form, in any other way regardless of the medium of publication, for production, circulation, keeping and using the cannabis plant and its by-products, except for scientific and professional medical publications.

dh. advertising in print and electronic media of products and by-products from plants containing concentrations higher than 0.2% of the THC component in the final product.

e. any activity that directly or indirectly contradicts or is not expressly provided for in this law.

Article 5
subjects

a. Subjects of this law are:

b. entities that are granted a license, according to the provisions of this law, who, in the case of cannabis for medical purposes, simultaneously possess another similar license in another country in the OECD area, as well as possessing GMP (Good Manufacturing Practice/ Good Manufacturing Practice), issued by EMA (European Medical Agency) or FDA (Food and Drug Administration);

c. Entities that are provided with a cultivation permit that exercise activity as legal entities, natural persons or as farmers.

CHAPTER II

CREATION, ORGANIZATION, FUNCTIONING AND COMPETENCES OF THE AGENCY

Article 6 Creation, status and financing

1. The National Agency for the Control and Monitoring of the Cultivation and Processing of the Cannabis Plant for medical and industrial purposes and the Production of its By-products (hereafter, the Agency) is established.

2. The Agency is the institution responsible for monitoring the implementation of the provisions of this law regarding the control and supervision of the cultivation and processing of the cannabis plant as well as the production of its by-products.

3. The agency is organized and functions at the central level, as a public legal entity with headquarters in Tirana, under the responsibility of the minister responsible for health.

4. The agency extends its activity throughout the territory of the Republic of Albania and cooperates with state administration institutions at the central and local level.

5. The funding sources of the Agency are from the state budget and its budgetary and financial activity is subject to the legislation in force for financial management and control.

6. The agency has the official coat of arms, logo and seal. The coat of arms consists of the Coat of Arms of the Republic of Albania with the notes "Republic of Albania, Ministry of Health and Social Protection, National Agency for Monitoring the Cultivation and Processing of the Cannabis Plant and the Production of its Byproducts".

7. The seal of the Agency has the form and constituent elements defined in the legislation in force for the production, administration, control and storage of official seals.

Section 1

ORGANIZATION AND FUNCTIONING OF THE AGENCY

Article 7 Direction and organization

1. The agency is headed by the General Director, who organizes and directs all the activities of the institution and answers to the minister responsible for health.

2. The Licenses Commission is established and functions under the Agency, which contributes to the exercise of the Agency's powers in accordance with their role and duties, according to the provisions of this law.

3. Its structure and organization are approved by order of the Prime Minister.

4. The working relations of the Agency's employees are regulated according to the Labor Code. The employment contract is only related to the fulfillment of the professional criteria and criteria of cleanliness of the image, of each employee, at all levels. The professional criteria of image purity and the procedures for evaluating their fulfillment are determined by the decision of the Council of Ministers.

Article 8 Powers of the Agency

1. The Agency exercises its powers on the basis of the principles of legality, professionalism, responsibility, accountability, efficiency and transparency and in accordance with the Single Convention on Narcotic Drugs of 1961, as amended by the 1972 protocol and the Convention on Psychotropic Substances of 1971, ratified by laws No. 8722, dated 26.12.2000 "On the accession of the Republic of Albania to the "United Nations Convention against Illicit Trafficking in Narcotic Drugs and Psychotropic Substances" and No. 8723, dated 26.12.2000 "On the accession of the Republic of Albania to the "Single Convention on Narcotic Drugs, amended by the protocol of 1972 for the amendment of the Single Convention on Narcotic Drugs, 1961".

2. The agency in the exercise of its activity has the following powers:

a. at the administrative level:

i. Draws up the evaluation criteria of applicants based on this law and the by-laws issued in its implementation;
ii. organizes the procedures for granting the license for the cultivation and processing of the cannabis plant as well as the production of its by-products for medical purposes;
iii. re-evaluates every 3 years, the fulfillment of the license granting conditions, according to the same evaluation criteria;
iv. guarantees the development of the activity of the licensed subjects in accordance

with the conditions and criteria defined in the license as well as of the subjects allowed for the cultivation of the cannabis plant for medical and industrial purposes;
v. cooperates with other competent bodies, in order to realize the objectives and obligations derived from the international agreements ratified by the Republic of Albania;
vi. presents reports to the competent international organizations, on the import and export of the cannabis plant and its by-products, in accordance with the obligations arising from the international conventions for the control of narcotic substances;
vii. is responsible for ongoing cooperation with the EMCDDA and the International Narcotics Control Board;
viii. coordinates the work with the authorities responsible for verifying the clean image of every employee of the Agency and the entities licensed for this purpose;
ix. maintains and administers registers, databases and statistics at the national level according to the provisions of this law;
x. issues import authorization for seeds that are cultivars of cannabis for industrial and medicinal purposes;
xi. drafts regulations, instructions and methodologies for the unification of the processes and work standards of the Agency's employees and proposes it to the minister responsible for health for approval;
xii. 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;
xiii. takes administrative measures against licensed subjects and subjects permitted under this law.

b. **at the technical level** :
i. It guarantees 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;
ii. Coordinates with the responsible state authorities for registration and inclusion in the national catalog of seeds and seedlings that are accompanied by DUS (distinctiveness, uniformity, stability) testing;
iii. oversees and monitors the planting and cultivation of the cannabis plant and its by-products used for medical and industrial purposes;
iv. inspects all the cultivation processes of the cannabis plant at every stage of planting, harvesting, drying, storage and storage, production of plant raw material;
v. Takes measures for seizure and destruction, according to the provisions of this law.

Article 9 Functions

1. The Agency supervises the licensed activity at each stage and for each production cycle, to ensure that the activity:
a. is carried out according to the law and by-laws issued pursuant to it, stipulations in the license and stipulations in the approved production plan;
b. it is not carried out contrary to the purposes of the law and the international obligations of the Republic of Albania.
2. The Agency carries out inspections according to this law and, when necessary,

coordinates inspections carried out in cooperation with other institutions.
3. The agency performs verifications according to the provisions of this law. Based on the verifications, the Agency evaluates the subject's request and forwards it to the Commission for approval.
4. The agency cooperates and exchanges information with the State Police and other institutions, national or international, with which Albania has agreements, in the field of the fight against the use and trafficking of narcotics and psychotropic substances and against the laundering of income from illegal activity.
5. The Agency collects and administers data on the licensed activity and the license holder, necessary for the exercise of its functions.
6. The agency submits a six-month work report to the Ministry responsible for health.
7. The Agency has any other powers or duties defined in the law or in the Regulation on its operation.

Article 10 License Commission

1. The License Commission is set up at the Agency for the review and evaluation of applications submitted for obtaining a license according to the provisions of this law.

2. The members of the Commission are elected for a period of 4 years, with the right to re-election only once.

3. The committee has the following composition:

a) three representatives from the ministry responsible for health;

b) a representative of the ministry responsible for public order and security;

c) two representatives of the ministry responsible for agriculture;

d) a representative from the ministry responsible for the economy.

4. The representative of the ministry responsible for health is elected as the chairman. The nominal names of the members of the License Commission are determined by order of the relevant ministers.

5. The members of the commission have an obligation and sign the declaration of confidentiality, the declaration of absence of conflict of interest and must be equipped with the security certificate from the Directorate of Security of Classified Information.

6. The License Commission has the following duties:

a) administers the lists and documentation made available by the Agency, of subjects that have applied to be licensed;

b) reviews and evaluates license applications;

c) assesses the fulfillment of the conditions regarding the premises, equipment and personnel for obtaining a license.

d) draws up the relationship for recommending candidates who meet the conditions and criteria to be licensed.

7. The functions of assistance and logistical support of the License Commission are performed by the Agency, through certain employees who serve as the technical secretariat for the meetings of the Commission.

8. The organization of the commission's work and activity is done by order of the minister responsible for health. The remuneration of the members of the License Commission is regulated according to the legislation in force for the determination of salaries and bonuses.

Article 11

Unit for monitoring the cultivation, production and circulation of cannabis for industrial purposes

1. In the Agency, the specialized monitoring and control unit for the cultivation, production and trade of cannabis for industrial purposes and the performance of the activity in accordance with this law and the cultivation permit is established and functions.

2. The unit directs and coordinates the monitoring and control activity in cooperation with the structures of the ministry responsible for agriculture.

3. The unit and structures of the ministry responsible for agriculture draw up the report on cultivated lands and present it to the minister responsible for agriculture. Every year, the Council of Ministers approves the cadastral areas where, starting from January 1 of the following year, the cultivation of cannabis for industrial purposes is allowed.

4. The unit monitors the process to guarantee the cultivation of only seeds and seedlings registered in the institution responsible for the registration of seeds and seedlings and importation only by entities equipped with import permits from the authorized institution.

5. The unit monitors the importation process of seeds and seedlings that are varieties of cultivation of cannabis for industrial purposes, valid only from the relevant European list of seeds for cannabis for industrial purposes.

CHAPTER III

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

SECTION 1

MEDICAL CANNABIS LICENSED DEVICE

Article 12

License to exercise activity

1. The license for exercising the activity of cultivation and processing of the cannabis plant as well as the production of its by-products for medical purposes, hereafter the license, is granted for a period of 15 years, with the right of renewal. The format of the

license and the activities included in it are approved by Decision of the Council of Ministers.

2. The license is approved by decision of the Council of Ministers, based on the selection procedure, organized by the Agency.

3. The decision of the Council of Ministers on the license is proposed by the minister responsible for health.

4. The license is granted only to the entity that fulfills the conditions and criteria defined in this law, as well as only for the area defined in its development plan, without specifying the location of these areas.

5. The license is a single one and is given to the applicant, who is selected first in the competition process, developed according to the procedures defined in the law. The activities included in this license may not be transferred to third parties, except as permitted in the license description.

6. The license defines one or more units for which the entity is licensed. If the subject is licensed for more than one unit, they must be adjacent to each other and in any case, no more than four units, in the same license. The total area allowed for the cultivation of the cannabis plant for medical purposes cannot be greater than 150 hectares at the national level.

7. The license is granted only on covered surfaces or greenhouses or open surfaces. The area of the activity license unit for medical purposes cannot be smaller than 5 hectares and not larger than 10 hectares.

8. The applicant for the license application pays, at the time of application, a fee which is non-refundable. Its value and use is determined by the instruction of the minister responsible for health and the minister responsible for finance, with the proposal of the Agency.

9. The license according to this article is revoked, if the subject does not start the development of the activity within a period of twelve months from the moment of entry into force of the decision of the Council of Ministers approving the license.

10. The conditions for granting the license are re-evaluated by the Agency every 3 years, which, if it finds that the conditions and criteria are not met, proposes to the relevant authorities, the cancellation of the license.

Article 13

Licensed Device Terms

1. Any legal entity that applies for a license must fulfill, in advance, the following conditions:

a) have experience in the cultivation, production, processing, circulation and administration of the cannabis plant for medicinal purposes;

b) himself or one of his shareholders who owns 51% of the company's shares must be:

i. exercising the activity of producing by-products of the cannabis plant in one of the OECD countries;

ii. holder of GMP (*Good Manufacturing Practice*), issued by EMA (*European Medical Agency*) or FDA (*Food and Drug Administration*).

c) to have company capital not less than 100,000,000 ALL.

2. The legal entity that competes for an activity license for medical purposes must:

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

b) to present the processing plan of drying, cutting and storage facilities, equipped in accordance with the production capacity, foreseen in advance in the production development plan.

c) to submit the security plan for the surface for cultivation and processing by defining the elements of protection, fencing, security with cameras and physical security for 24 hours, barrier elements before the entrance and barbed wire on the fence, according to the provisions of the standards of the relevant Decision of the Council of Ministers.

ç) Self-declaration for the employment of at least fifteen people, two of whom are qualified employees in the field of pharmacy and agro-engineering with work experience of no less than three years in the relevant field.

d) Self-declaration of the readiness to conclude an agreement with the responsible structure of the ministry responsible for public order and security to guarantee access for inspection to the private physical security company that supervises the cultivation environments of the cannabis plant and its by-products as well as the movement of dedicated vehicles of the circulation of raw materials and products, according to the rules and tariffs determined by the Council of Ministers.

dh) Self-declaration that it will start exercising the activities described in the license within 12 months from the entry into force of the decision of the Council of Ministers for the approval of the activity license.

e) 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 the equivalent in the national currency Lek of the amount not less than 10,000,000 (ten million) Lek.

Article 14 Documentation and submission of the request

1. The legal entity applying for a license submits to the Agency the request for application and the following documentation:

a) business registration document, original or notarized copy, issued within 3 months from the date of submission of the request;

b) documents to prove the partners/shareholders of the company and the last beneficial owners of the entity (if the application is submitted by a legal entity, the act of incorporation and the statute of the company are also presented);

c) data on the governing bodies of the applicant and legal representatives, persons authorized to follow the procedure;

ç) documents proving that the applicant entity has an active status;

d) the following certifications issued by the competent bodies, for the subject as:

i. The security certificate of the subject, issued by DSIK, for Albanian citizens and for foreign citizens, an analogous certificate issued by the authority of the country where they are resident;

i. the entity, the administrator, the members of the management bodies, the partners/shareholders, are not under criminal prosecution;

ii. that the entity, the administrator, the members of the management bodies, the partners/shareholders, are not on trial for any criminal offense;

iii. that the subject, the administrator, the members of the management bodies, the partners/shareholders, is not criminally convicted by a final court decision;

iv. that the entity is not in the process of mandatory execution for unpaid property obligations;

v. that the applicant entity or the partner entities/shareholders of the applicant entity are not in bankruptcy proceedings.

e) financial data on the business performance of the applicant's partners/shareholders for the last 3 years prior to the submission of the application;

ë) the document certifying that the capital of the company is not less than 100,000,000 (one hundred million) Lek;

f) the document, where it is noted that he has an experience in this activity of no less than 3 years, given by the relevant body of the country where the applicant has its headquarters;

g) the statement on the source of capital, which will be invested for the exercise of the activity;

gj) certification from the tax authorities for the payment of tax obligations, both from the applying company and from any legal entity, in case of a merger of companies;

h) the confirmation that there are qualified personnel in the exercise of the activity according to the requirements of this law, confirmed with the relevant documentation;

i) the relevant regulation for the rules and mode of operation of the activity that is seeking to be licensed;

j) the self-declaration for the conclusion of the preliminary agreement for storage and physical security according to the provisions of this law;

k) Self-declaration that it will pay the bank guarantee according to the provisions of this law.

2. The entity submits a notarized copy of this documentation accompanying the license application request.

Article 15

Procedure for granting the license

1. The agency publishes the notice of competition for granting the license for the cultivation and processing of the cannabis plant as well as the production of its by-products for medical purposes.

3. The notice contains:

a) list of documentation;

b) place, date and time of submission of documents;

c) the language of presentation of documents;

d) the way of submitting documents;

e) the place, time and date of document review.

Article 16

The procedure for the selection of the winning subject

1. The selection of the subject is made by the Agency, in accordance with the evaluation criteria, deadlines, the value of the guarantee fund and the competition procedure, determined by the decision of the Council of Ministers, after receiving the evaluation of the Commission of Licenses, which are set by order of the minister responsible for health, according to the criteria provided in this law.

2. The members of the Licensing Commission self-declare, under their responsibility, that participation in this commission does not constitute a cause for the emergence of a conflict of interest with the subjects participating in the competition. For non-declaration, the measures provided for in law no. 9367, dated 4.7.2005 "On the prevention of conflict of interests in the exercise of public functions", as amended, are applied.

3. The Licensing Commission announces the list of participants in the competition, ranking, according to the points received, the applicants who meet the conditions and criteria, according to this law. The candidate who has received the highest number of points is declared the winner.

4. The listed entities, according to point 3, have the right to submit the appeal to the body responsible for the proposal of the license for approval in the Council of Ministers,

within 10 days from the announcement of the announcement. The Minister's order is appealed to the court, according to the provisions of the legislation in force.

5. At the end of the deadline for filing complaints and their review, the Agency approves the granting of the license, after the applicant declared winner has submitted, within 30 days, the fulfillment of the criteria related to the guarantee fund.

Article 17

Approval of the license and its approval

1. The Minister responsible for health, upon receiving the notification for the winning entity, according to the provisions of Article 16, within no later than 20 days, submits the proposal for granting the license to the Council of Ministers for approval.

2. The decision of the Council of Ministers determines the name and the subject, the term, the area of the development of the activity. The license contains a description of the permitted activities that may be carried out with third parties on behalf of the license holder.

3. If the Council of Ministers does not express itself within 90 days, then the procedure will be considered cancelled.

4. With the publication of the Decision of the Council of Ministers in the Official Gazette, the subject is considered as the holder of the license for exercising the activity for medical purposes, in the sense of this law.

Article 18 Data changes

1. The cannabis grower is obliged to notify the Agency, within ten working days, of all changes and deviations from the previously planned measures in the business development plan for cannabis cultivation. The grower addresses the Agency with a written information, describing any facts and circumstances that have brought about changes or deviations from the planning. The agency supervises the grower's activity and informs the minister responsible for health by submitting a copy of the report kept on site by the inspection team.

2. Every measure that is taken regarding the continuation of the process, the Minister responsible for Health accompanies it with a reasoned order and in cases where he decides to suspend the process, along with other administrative actions, he informs the Council of Ministers at the first meeting.

SECTION 2

LICENSED INDUSTRIAL CANNABIS CULTIVATION DEVICE AND CULTIVATION

Article 19 Register of cultivators

1. Cultivation permit equipment is granted only to entities that are registered in the Register of Cultivators of industrial cannabis, which is created and administered in the ministry responsible for agriculture. Both the Agency and the ministry responsible for order and security have access to the register.

2. The subject requesting to be registered presents the following documentation:

a) Copy of the identifiable number of the farmer or copy of the number of the natural or legal person;

b) Description of plant cultivation methods;

c) The list of varieties that it intends to cultivate;

d) The land on which the plant will be cultivated, located within the cadastral areas approved by decision of the Council of Ministers.

3. The entity equipped with a cultivation permit updates the data in the register with:

a) The cultivation permit you have;

b) The authorization of the import of seeds and seedlings and the list of registered seeds and seedlings derived from the production;

c) Employed personnel, accompanied by proof of criminal record;

d) Departures and new hires.

4. The form and elements contained in the register are approved by order of the minister responsible for agriculture.

Article 20

Cultivation permit device and cancellation

1. The request for equipment with a cultivation permit is submitted to the ministry responsible for agriculture and is accompanied by the following documentation:

a) registration document of the farmer, natural or legal person;

b) self-declaration that the applicant is registered in the register of growers;

c) the list of personnel employed or subcontracted to manage the cultivation process, of which no less than 1 agronomist, accompanied by:

i) certification that they are not under criminal prosecution;

ii) certification that they are not on trial for any criminal offense;

iii) criminal record;

ç) self-declaration about the source of financing expenses;

d) self-declaration that there are no tax obligations to the tax administration and local units;

dh) the self-declaration for the conclusion of the preliminary agreement for storage and physical security according to the provisions of this law;

e) Self-declaration (or preliminary sales agreement) for the licensed raw material processing entity that will purchase the raw material.

f) Ownership documentation, copy of the land registration card and indicative map and lease contract if the land is not owned, located in cadastral areas approved for cultivation. If the land is not equipped with a final ownership document, the Land Acquisition Act and survey plan are presented.

g) *track and trace* system fee payments .

2. The responsible structure in the ministry verifies the documentation and submits a copy of the practice to the ministry responsible for public order and security, which within 10 days gives an assessment for approving or rejecting the request.

3. The responsible structure in the ministry, after receiving the assessment from the ministry responsible for order and security, within 10 days submits a report to the minister about the equipment with a cultivation permit or the rejection of the request.

4. The cultivation permit is revoked by the minister if, during the exercise of the activity, it is found that the activity is carried out in violation of the criteria of the law, the conditions of the cultivation permit, non-payment of *track and trace fees* and for other reasons provided by other laws. During the verification phase, the minister can decide to suspend the cultivation permit until the final decision is made.

5. A copy of each practice including the approved permit is submitted to the Agency.

6. The Minister, within 10 days from the presentation of the report, approves the cultivation permit. The permit is granted for a period of 5 years with the right of renewal, for an area not less than 1 hectare.

7. The format of the cultivation permit, the obligations, the permitted activities of the cultivation permit, are approved by order of the Minister of Agriculture.

Article 21 Cultivation

1. The entity equipped with a cultivation permit is allowed to plant only seeds and seedlings registered in the institution responsible for the registration of seeds and seedlings.

2. The subject will notify the local directorate of the state police, the ministry responsible for agriculture and the Agency for any circumstance or fact that occurred for the use of plants or parts of plants for the production of narcotics.

3. The entity notifies the Agency and the ministry responsible for agriculture no less than 10 days before harvesting the plant.

4. The farmer will keep a record of data according to the approved format.

5. The format of the register, and the data it contains on the seeds and seedlings that are planted, the quantity produced, the plants destroyed, the buyer of the raw material, the fertilizer products used, the annual analysis of the quality of the soil and other elements, is approved by order of the minister .

SECTION 3

PROCESS OF CULTIVATION, HARVESTING AND PROCESSING OF THE RAW MATERIAL

Article 22
Production unit

1. The activities defined in the license or permit according to this law take place only in the premises of the Production Unit, in special areas, with limited and monitored access.

2. The production unit is the surface of the land from 5 to 10 ha, which also includes the warehouse and other premises dedicated only to the processes related to the cultivation of the plant and the production of by-products of the cannabis plant for medical purposes and the surface no more smaller than 1 (one) hectare, which also includes warehouses and other premises dedicated only to the processes related to the cultivation of the plant and the production of by-products of the cannabis plant for industrial purposes.

3. The license allows the production of up to 4 marginal Production Units. For unlimited units, a new license or permit is required.

4. The capacity of the unit for processing and storage should correspond to its capacity for cultivation.

5. The license determines the number, area and location of production units.

Article 23

Registration of seeds and seedlings

1. The registration of seeds and seedlings is done according to the relevant legislation in the institution responsible for the registration of seeds and seedlings, valid from the relevant European list of seeds for cannabis for industrial purposes.

2. The agency has access to the register of cannabis seeds and seedlings.

Article 24

Import of cannabis plant seeds and seedlings

The import of seeds and seedlings of the cannabis plant is carried out by the entity equipped with the license or cultivation permit according to the authorization given by the

relevant authority.

Article 25

Procedure before starting the cultivation process

1. The licensed entity, no less than ten days before the start of planting, has the obligation to notify the Agency and the regional unit of the ministry responsible for agriculture to obtain approval for planting the cannabis plant for medicinal purposes.

2. In the request of the legal entity, the following is presented:

a) Notarized copy of the license for cultivation and processing of cannabis for medical purposes;
b) The development plan for the cultivation of cannabis, which contains data on how to cultivate cannabis, the amount of material to be planted (type of seed and seed material, seedlings, amount of wet and dry yield);
c) Complete georeferencing data of the surfaces where the cannabis plant will be cultivated.

3. The agency approves the planting of cannabis for medical purposes within 5 (five) working days from the day of receipt of the request, if it does not find legal reasons or reasons to prevent or delay the process. In such cases, the postponement of the deadline by the Agency is justified by a decision.

4. The entity equipped with the permit for the cultivation of cannabis for medical purposes, before starting the planting of cannabis seeds, is obliged to ask the Agency and the regional Unit of the ministry responsible for agriculture to assist the planting process with inspectors. The notice is also attached to the mandated payment as service commission.

5. After starting the inspection supervision of the planting process, the Agency sends a copy of the minutes kept for the supervision carried out and presents it to the ministry responsible for health.

Article 26 Plant harvesting inspection

1. The grower of the cannabis plant, not later than 15 days before the day of the beginning of harvesting the cannabis plant, is obliged to notify the Agency. The agency notifies the responsible ministries according to the purpose of cultivating the cannabis plant.

2. After the completion of the cannabis harvesting process, the Agency carries out checks on the quantities of the harvest carried out and the material produced and records in the minutes the number of seedlings collected and the quantity by weight of the wet mass.

3. The form, content and manner of keeping the register for all stages of cultivation of the cannabis plant is approved by the Minister responsible for Health and the Minister responsible for Agriculture.

Article 27 Processing and raw material

1. The material produced by the cannabis plant is dried, cleaned, separated, packaged and labeled.

2. After the harvest is completed, the collected above-ground part of the cannabis plant is dried in a specially arranged space.

3. The cannabis grower keeps a special record, in triplicate, of the quantity produced, before using it for drug production in the presence of Agency inspectors. One copy is sent to the ministry responsible for public order and security, while one copy is kept by the signatory parties.

4. The packaging with the dry plant/cannabis is marked with the following information:

i. name and headquarters of the legal entity (cultivators/producers);

ii. date (day, month and year) of harvest and production;

iii. the name of the raw material;

iv. net and gross amount of dry matter;

v. shape (leaves, flowers, plants, whole, cut);

vi. packaging date and expiration date.

vii. unique identification mark in the form of a code, stamp or label.

5. The cannabis grower/processor submits a report to the responsible structure of the ministry responsible for public order and security and to the Agency for the completion of the production process, cultivation and dry mass obtained, within ten days from the day of completion of the process.

6. Before the dry material is packed, the Agency carries out quality control in certified and accredited laboratories with the best methods for quality control, according to the Guidelines approved by the minister responsible for health, regarding the content of cannabinoid and tetrahydrocannabinol components, such as and physical-chemical and microbiological control, for the packaging method, form and quantity.

Article 28

Substances and preparations produced from the cannabis plant

1. Substances and preparations intended for medical use produced from the cannabis

plant, by the authorized manufacturer, are subject to all the provisions provided for in the legislation in force on drugs and pharmaceutical services and the legislation on narcotic drugs and psychotropic substances, before putting them into circulation. theirs.

2. Medicines produced from the cannabis plant must be labeled, according to the provisions of this law, before being placed on the market.

3. The manufacturer cannot make an agreement with any buyer or authorized distributor of drugs, before the completion of the procedures of the device with authorization for marketing, in the Republic of Albania.

4. The production of these drugs in the Republic of Albania is carried out in accordance with the provisions of the law on drugs and pharmaceutical services, the principles and guidelines of good manufacturing practice and the Albanian legislation on environmental protection.

5. The principles and guidelines of good manufacturing practice are mandatory to be followed by all domestic drug manufacturers.

6. The production of drugs in the country is carried out by legal entities licensed for this activity, after receiving the production authorization from the minister responsible for health, according to the proposal of the Commission for the Verification of the Conditions for the Production of Medicines and the Certificate of Good Medicine Production, with a deadline two years old.

7. The production authorization is issued for the complete production of the drug from the raw material to the final product.

8. Production authorization is also mandatory for drugs produced in the country, intended for export.

Article 29 Transport

The activity of carrying, moving, accompanying and transporting seeds, seedlings, raw material, the cannabis plant and its by-products, from one place to another, is done with prior notification to the Agency and with specialized accompaniment by the entity that has concluded the contract of storage and security of the unit.

Article 30 Security

The storage and security of the unit, transport and trading is done by the entity that has concluded the contract of storage and security of the unit.

Article 31

Export of by-products of the cannabis plant

1. The export of by-products of the cannabis plant is carried out by the entity equipped with the license according to this law.

2. The export of cannabis by-products for medical purposes is done according to the

legislation in force on drugs and the legislation on narcotic drugs and psychotropic substances.

3. The export of cannabis by-products for industrial purposes is done according to the legislation in force for plant protection.

CHAPTER IV

MARKING AND TRACKING SYSTEM

Article 32 Traceability

1. The Marking and Tracking System is a state database, through which information organized and stored in electronic form is collected for the placement of unique marks and tracking of all stages of seed and seedling provision, cultivation, production, circulation, supply , transportation that serves the identification of the cannabis plant and its by-products to the use of the narcotic drug.

2. Licensed entities, according to the meaning of this law, are obliged to use this system, including entities authorized for wholesale and retail trading of narcotic drugs and psychotropic substances.

3. The system consists of an electronic register.

4. For purposes of control and verification of licensed activities and the use of narcotic drugs and psychotropic substances, this system is used by:

a) Agency;

b) Ministry responsible for health;

c) Ministry responsible for agriculture;

d) Ministry responsible for finance;

e) Ministry responsible for order and security;

f) National Agency for Medicines and Medical Devices.

5. The marking and tracking system, installation, maintenance, the way data are recorded and stored, electronic data or other documents containing information are determined by decision of the Council of Ministers with the proposal of the minister responsible for health and the minister responsible for agriculture.

Article 33

Database

The licensed entity is obliged to enter the data in the marking and tracking system, for all seeds, seedlings, plants and by-products processed by it, for all phases of the licensed activity.

Article 34 Marking and Tracking

1. Marking and tracking defined in this law, through a unique mark in the form of a

code, stamp or label is mandatory at all stages, including import, cultivation, production, processing, storage, storage of the cannabis plant and its by-products, export and the use of by-products of the cannabis plant.

2. All holders of a permit or license, according to the provisions of this law and the legislation in force for drugs and pharmaceutical services, are obliged to mark the plant, seed, substance, preparation, product, which is the object of their activity and to implement all legislation related to marking and tracking.

3. Any by-product of the cannabis plant for medical purposes, before being placed on the market, must be marked and identified by means of a code, stamp or label and any other type of information to ensure traceability.

4. The cost of marking and tracking is borne by entities licensed under this law. Fees and payment procedures are determined by the decision of the Council of Ministers, with the proposal of 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, elements, label or unique identification stamp, the procedure and way of marking and tracking, as well as the authority or authorized party for the realization of marking and traceability are determined by the decision of the Council of Ministers, with the proposal of the responsible minister. for health and the minister responsible for agriculture.

CHAPTER VI SUPERVISION

Article 35

Responsible bodies and inspections

1. For the supervision of the implementation of the provisions of this law, the Agency, the structures responsible for the registration of seeds and seedlings and the health of plants and the National Agency of Medicines and Medical Devices, according to the duties provided for in this law and in accordance with their legal powers, are charged.

2. The agency coordinates the inspection process with other institutions.

Article 36 Inspection supervision

1. The inspection supervision of the implementation of the provisions of this law and the rules adopted on the basis of this law, in relation to the licensed activities, is carried out by the Agency.

2. Fulfillment of obligations under the drug law is inspected and monitored by the structure responsible for pharmaceutical inspection.

3. The fulfillment of obligations for the process of seed and seedling registration and plant health control is carried out by the responsible structures of the responsible ministry of agriculture.

4. The inspection supervision for the destruction of the cannabis plant and its by-products is carried out by the Agency in cooperation with the responsible structure of

the ministry responsible for public order and safety.

5. The detailed inspection rules are determined by the decision of the Council of Ministers, based on the general rules of the inspection legislation.

Article 37

Taking samples and samples

1. Sampling is carried out through the Agency in cooperation with the institutions responsible for the inspection, according to this law.

2. The minister responsible for health and the minister responsible for agriculture determine with a joint instruction the method, quantity of sampling and the laboratory for performing analyzes with accredited methods for quality control, inside or outside the country

CHAPTER VIII SEIZURE AND CONFISCATION

Article 38

Seizure of the cannabis plant and its by-products

1. The cannabis plant and its by-products are immediately seized if they are cultivated, produced, put into circulation or possessed by an unauthorized entity, according to the provisions of this law.

2. The cannabis plant and its by-products are immediately seized if it is not marked and traceable according to the provisions of this law.

3. Narcotic drugs and psychotropic substances, seized according to this article, are subject, as far as applicable, to the regulation of the administration of confiscated drugs, according to the legislation in force on drugs and the pharmaceutical service.

4. The agency keeps a separate record of the type and quantity of cannabis plant seized.

5. State supervisory and inspection agencies and institutions have the obligation to notify the structures responsible for order and security in such cases, as well as to apply the relevant sanctions for all those actions that are contrary to the provisions of this law.

Article 39

Destruction of cultivated plants

1. Cannabis plants, regardless of the purpose of use, if they have grown on their own, as well as the remains of the medical or industrial cannabis plant, on the surface of the land, specified in the license, are destroyed, according to the manner and provision of this law, by the licensed subject, in the presence of the representative of the Agency. For the performance of this process, the relevant minutes are kept according to the legislation in force.

2. If the entity does not fulfill the obligation of point 1, the disposal is carried out by the Agency, at the expense of the entity, which is also penalized for not fulfilling this obligation.

3. The agency keeps a separate record of the type and quantity of the cannabis plant disposed of;

4. The method of disposing of self-grown plants and the remains of harvested cannabis plants is determined by a joint instruction of the minister responsible for health, the minister responsible for agriculture and the minister responsible for public order and security.

CHAPTER VIII SANCTIONS

Article 4
Misdemeanors

1. When they do not constitute a criminal offense, violations of the provisions of this law constitute administrative misdemeanors and will be punished with a fine of up to 5,000,000 (five million) Lek, if:

a. Advertises the product, directly or indirectly, or makes direct sales; ~~retail~~;
b. Does not apply the measures expressed by the decision of the supervising inspector; what Impedes the sampling process;
c. Grows cannabis for industrial purposes, without a prior contract and in violation of the law;
d. When he planted and managed larger areas with industrial cannabis, or when he did not complete the registration of the areas within the stipulated period;
Mr. It does not declare the surfaces on which it cultivates cannabis for medicinal purposes and/or cannabis for industrial purposes;
e. Performs processes for which he is not authorized or does not submit the necessary reports to the supervisory and controlling institutions within the deadline provided by law;
f. Exceeds the deadline set for the collection of produced quantities of cannabis straw for medical purposes and/or cannabis for industrial purposes;
g. Does not notify the ministry responsible for public order and security, the ministry responsible for agriculture and the ministry responsible for health of any situation that indicates suspicion that cannabis or plant parts have been used or may be used for the production of psychoactive substances;
h. Grows cannabis for industrial purposes without the relevant authorization;
i. Does not keep a Register of the quantity produced and purchased of cannabis for medical and/or industrial purposes, does not submit the report within the legal deadlines to the supervisory authorities;
j. Works in conditions that are contrary to the authorization given;
k. Does not repeat the request for renewal of permits;
th. Advertises cannabis-based products directly or covertly;
x. Does not show care for the preservation of plants in special environments for storage, drying, etc., allowing the entry of unauthorized persons;
xh. The data of his registers do not correspond with the institutions' registers after verification by the National Agency of Medicines and Medical Devices and the Ministry

responsible for health;
y. There is no strict administration of the circulation of unauthorized persons in the internal environments and the keys to the environments or the safes where the seeds, registers, etc. are stored, are used without supervision and protocol;
z. Does not record in real time when each import, export, transport, purchase, sale takes place or does not retain documentation for a minimum period of five years;
Mr. Does not submit analysis reports and an assessment of needs for the next year;
ah. Does not submit annual reports on confiscated or destroyed quantities of plants and preparations;
bb. Removes, destroys, manipulates the devices, signs, labels or stamps provided for in Article 34 of this law.
cc. Obstructs, avoids inspection or verification on traceability or avoids the marking and tracking system;
dd. Cultivates, produces, processes, supplies, trades, keeps, transports, plants, seeds, products with psychoactive substances and psychotropic substances not marked according to the provisions in 34 on Marking and Tracking.

2. In addition to the fine provided for in paragraph 1 of this article, the legal entity may also be sanctioned for misdemeanors, a temporary ban on carrying out the activity. The duration of the suspension of activity is set from six months to three years.

3. In addition to the fine, for the activities that are carried out in violation or exceeding the law, the responsible person in the legal entity is also assigned a measure prohibiting the performance of the activity. The duration of the suspension cannot be longer than one year.

4. The responsible person in the legal entity is fined in the amount of 300,000 (three hundred thousand) to 700,000 (seven hundred thousand) lek for misdemeanor if:

a. it turns out that beyond the deadline of four months after the end of the harvest, he has not yet delivered the complete production, namely all the quantities of cannabis parts for the purpose, which can be used for the production of psychoactive substances;
b. does not make an accurate declaration of the areas for the production of plants, or declares them beyond the deadline of 15 days after planting;
c. cultivates industrial cannabis without approval and under conditions contrary to the provisions of this law;

what does not present the areas for the production of cannabis for the purpose in the deadline later than 15 days after planting;
d. submits the complete production beyond the deadline of four months after the end of the harvest, namely all quantities of its parts, which are used for the production of psychoactive substances;
dh. does not update the registers with the data provided by the law within the deadline and in real time, as well as when it does not submit the report within the stipulated deadlines;
e. does not prepare the immediate notification to the Ministries and the authorities responsible for the supervision of any situation that indicates suspicion that the hemp or the parts of the cannabis for the purpose have been used or may be used for the production of psychoactive substances;
e. does not take all measures to stop misuse of plants and/or their damage;
f. removes, damages, manipulates, devices, signs, labels or stamps as well as obstructs, avoids inspection or verification on traceability according to the provisions of this law.

Article 41

Administrative offenses committed by employees of the state administration

A fine in the amount of 3,000 (three thousand) to 10,000 (ten thousand) ALL is set for the employee of the state administration, when he does not respond within the time limits set by this law to the demands made by the subjects in implementation of the law.

Article 42 Appeal

Regarding certain fines, as well as any other administrative action contrary to the Code of Administrative Procedures and this law, the punished persons can appeal to the Administrative Court.

Article 43 Register of fines

1. The agency has the obligation to keep a separate register for fines and in the practice of each entity, to keep copies of certain fines and to mandate payments for their collection by the entities.

2. The form, content and manner of keeping the register for the fines assigned for misdemeanors and for the result of the initiated procedures are provided for in the joint instruction approved by the Minister responsible for Health in coordination with the Minister responsible for Agriculture.

3. The assessment of the amount of the fine for the legal entity is carried out in accordance with the legislation in force for misdemeanors.

CHAPTER X

TRANSITIONAL AND FINAL PROVISIONS

Article 44 Transitional Provisions

1. Entities interested in the cultivation of plants containing narcotic and psychotropic substances for medical purposes have the right to apply for a permit after 01.01.2023.

2. Legal entities that produce and cultivate cannabis for medical purposes and legal entities that export cannabis are obliged to take measures to organize their work in accordance with the provisions of this law and/or with the recommendations and decisions of the supervisory authorities. and controlling.

3. Entities interested in the cultivation and production of cannabis for industrial purposes have the right to apply for authorization after 01.01.2023.

4. Communication between subjects, as well as their communication with state institutions and authorities, is considered valid and legal only when it is done in writing.

5. All other by-laws related to the cultivation, production, circulation and use of psychoactive products from the cannabis plant in the implementation of this law, will be approved within a period of three years from the day this law enters into force.

6. In any case of review of complaints by the subjects of this law, any communication other than official letters will be considered invalid and illegal.

Article 45 Bylaws

1. The Council of Ministers, by November 30 of each year, approves with the Agency's proposal the cadastral areas (territories) where the cultivation of cannabis for industrial purposes will be allowed.

2. The Prime Minister is instructed to issue the act provided for in Article 7, point 3, within 9 months from the entry into force of this law.

3. The Council of Ministers is tasked to issue the acts provided by Article 7, Item 4, Article 12, Item 1, Article 13, Item 2/c and 2/d, Article 16, Item 1, within 9 months from the entry into force of this law. article 32, point 5, article 34, point 4 and point 5, article 36, point 5.

4. The ministries are charged, according to their area of responsibility, to issue the by-laws provided for by article 10, item 8, article 12, item 8, article 19, item 4, article 20, item 7, article 21, item 5, article 26, point 3, article 27, point 6, article 37, point 2, article 39, point 4, article 43, point 2.

5. With the entry into force of this law, all legal and by-law provisions, which are contrary to its provisions, are repealed.

Article 46 Repeals

After the entry into force of this law, the provisions of law No. 7975, dated 26.07.1995 "On psychoactive drugs and psychotropic substances", which conflict with the provisions of this law, are repealed.

Article 47 Entry into force

This law enters into force 15 days from the date of publication in the Official Gazette of the Republic of Albania".