

LAW No. 61/2023

For the control of the cultivation and processing of the cannabis plant and the production of its by-products for medical and industrial purposes



The object of the law - determining the rules for the cultivation, production and controlled circulation of the cannabis plant, its by-products and final products for medical and industrial use

The purpose of the law - regulating and guaranteeing 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

Definitions under the law:

"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.

"End product for industrial purposes of the cannabis plant" is any product that contains cannabis plants for industrial purposes.

"End product for medical purposes of the cannabis plant" is the narcotic drug, psychotropic substances and cosmetic products.

"Industrial by-products" are 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.

"Cannabis plants for medicinal purposes" are plants of different varieties, variations and subspecies of *cannabis sativa*, *cannabis indica* and *cannabis ruderalis*, obtained by cultivation for medicinal purposes and scientific research under controlled conditions.



"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.

"Medical by-products" are substances and preparations extracted from the cannabis plant, used for the preparation of final products, which include drugs and cosmetic products.

License for the exercise of activities related to the production of cannabis for medical purposes



Activities:

- a) cultivation, production of the cannabis plant for medical purposes;
- b) transportation of seeds, plants and cannabis by-products for medical purposes in the territory of the Republic of Albania;
- c) export of cannabis plants, products and by-products for medical purposes.

Criteria:

- a) have 3 years of experience in at least 3 of the main activities, such as: production, cultivation and circulation of the cannabis plant for medical purposes;
- b) the entity or one of its shareholders, who owns 51% of the company's shares, must:
 - i. be engaged in the production of cannabis by-products in one of the countries of the Organization for Economic Cooperation and Development for at least 5 years;
 - ii. be a holder of good manufacturing practices issued by the European Medicines Agency or the US Food and Drug Administration for at least 3 years;
 - iii. to have company capital of not less than 100,000,000 (one hundred million) ALL;
 - iv. to have shown positive financial performance in the last financial year
- c. to have administrative, organizational capacities and the appropriate reliability to engage successfully in the main activities required for licensing;
- vi. not be included in the lists of persons registered or announced as financiers of terrorism

- The license is granted for one or several activities, for a period of 15 years, with the right of renewal upon request, for each of the activities and based on the selection procedure organized by the Agency
- The area of the activity license unit for cultivation of cannabis for medical purposes cannot be less than 5 hectares and not more than 10 hectares. It cannot be larger than 200 hectares at the national level
- It is given only on behalf of the subject and is non-transferable and inalienable
- At the time of submitting the request, a fee of 100,000 (one hundred thousand) ALL is paid, which is non-refundable.



The legal entity that submits a request for licensing has a number of documents that must be submitted to the institution. In summary, some of them are: business development plan; security plan for the area for cultivation and processing; bank guarantee in the amount of 10% of the investment value; 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) ALL; self-declaration for the employment of at least 10 people for each unit, 2 of whom must be qualified employees in the field of pharmacy and agro-engineering, with work experience of not less than 3 years in the relevant field and other documents specified in the law or required by the responsible institution.

Procedure for obtaining a license



The National Cannabis Control Agency announces the license competition notice.

The Licensing Commission verifies the documentation, evaluates the fulfillment of the conditions and criteria, draws up a final list ranking the participants in the competition according to the points obtained in accordance with a scoring scheme approved by this Commission.

Subjects can complain to the Minister responsible for health within 10 days from the announcement of the winner. The minister's order can be appealed to the court according to the deadlines specified in the law.

At the end of the deadline for filing complaints and their review, the Agency submits the proposal for granting the license to the Minister.

The minister approves the license within 3 months. If not expressed within 90 days from the proposal, the request is considered rejected.

Permit for the exercise of activities related to the production of industrial cannabis

- The permit obtained allows the activity of importing seeds or seedlings, or their reproduction for the purposes of use as seeds/seedlings, cultivation, production and processing, transport, as well as the export of by-products and final products of cannabis for industrial purposes
- granted for a 5-year term, with the right of renewal, for areas not smaller than 1 hectare
- 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 published in the relevant register
- And in this case, the subject must present the necessary documentation in his request to be provided with a permit. Some of these documents are: registration document as a farmer, a natural or legal person; the list of personnel employed or subcontracted for managing the cultivation process, having no less than 1 agronomist; self-declaration about the source of financing expenses; self-declaration for storage and physical security, etc.



The procedure for obtaining a permit

After submitting the request, and after verifying the documentation by the responsible structure in the ministry responsible for agriculture, a copy of the practice is forwarded to the ministry responsible for order and public security, which within 10 days gives an assessment for approving or rejecting the request. The responsible structure in the ministry responsible for agriculture, after receiving the assessment from the ministry responsible for order and security, within 10 days, submits a report to the minister responsible for agriculture for the equipment with permission or the rejection of the request. The minister responsible for agriculture, upon receiving the unit's report, approves the permit. If the minister does not express himself within 30 days from the presentation of the report, the request is considered rejected.

Prohibitions

The law also defines some of the general prohibitions, which include the prohibition of the cultivation of the cannabis plant and the production of products and by-products in excess of the legal provisions, without marking and tracking; the prohibition of possession of means for the production of the plant without being licensed; prohibition of the use of products and by-products, except in cases provided by law; prohibition of retail or wholesale sale and distribution as well as prohibition of acquisition and consumption of products in Albania; prohibition of direct or indirect advertising of cannabis-related activity.



In cases where the violations do not constitute criminal offenses, the law defines them as administrative misdemeanors punishable by a fine ranging from ALL 500,000 to ALL 5,000,000.

For a clearer and more detailed overview of the processes of production, processing, cultivation of cannabis in Albania and the activity of the National Cannabis Control Agency, it is necessary to consult the law. Meanwhile, in the future we will be waiting for by-laws which will regulate necessary aspects of the implementation of the law in practice.

This law is expected to enter into force at the beginning of September 2023, however, its effective implementation will require more time due to the establishment of the relevant responsible structures and the adoption of the by-laws necessary to further concretize the procedures.

For any further questions and clarifications, you are welcome to contact us!



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