



Muja Law brings you the latest issue of *Food for Thought*.

Recently the Council of Ministers of the Republic of Albania has proposed a draft law "On the control of the cultivation and processing of the Cannabis Plant and the production of its by-products, for medical and industrial purposes" (hereinafter referred to as the "*Draft Law*").

Such proposal comes after the Albanian government undertook a national consultation with Albanian citizens. With a questionnaire addressed to every Albanian, in Albania or elsewhere in the world, a popular discussion was held during which the opinion of the citizens was taken in relation to matters of strategic importance for the country. One of the questions addressed to Albanian citizens was whether Albania should allow state-controlled cultivation, processing and export of cannabis for medicinal purposes (*Question no. 6*).

In this context, after the positive evaluation of this questionnaire, an initiative was taken to approve the Draft Law.

Some of the most important aspects of such Draft Law are as follows:

➤ **Draft Law "On the control of the cultivation and processing of the Cannabis Plant and the production of its by-products, for medical and industrial purposes"**

The Draft Law determines the rules for the cultivation, production and controlled circulation of the cannabis plant, its by-products and final products *for medical and industrial use*.

Also, the purpose of this Draft 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.

In virtue of the Draft Law the term "**Cannabis plant for industrial purposes**" refers to the cannabis plant, including all fresh or dried parts of the plant and seeds of the species *Cannabis sativa* and *Cannabis ruderalis*. These varieties contain no more than 0.8%

THC and are cultivated specifically for industrial purposes.

Additionally, the term "Cannabis plants for medical purposes" encompasses plants of various varieties, variations, and subspecies of Cannabis sativa, Cannabis indica, and Cannabis ruderalis. These plants are obtained through cultivation for medical purposes and scientific research under controlled conditions, in accordance with the regulations stipulated in this draft.

➤ Scope of application

The Draft Law provides that it applies to every subject that performs licensed activities for:

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

Also, the law shall apply to any state structure that performs supervision, control and inspection of the implementation of this law in the future.



➤ The National Cannabis Control Agency

The National Cannabis Control Agency (hereinafter "*the Agency*"), is a public budget legal entity, subordinate to the minister responsible for health, whose mission shall be that of supervision, control and inspection of the cultivation and processing of the cannabis plant and the production of its by-products for medical and industrial purposes and monitoring the implementation of this law.

As part of the Agency, the Licensing Commission is established to evaluate and assess applications for obtaining licenses for the cultivation of cannabis for medical purposes.

The license for the production of cannabis for medical purposes may include the following activities:

- a) Cultivation, production and processing 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.

The license can be granted for one or multiple activities specified above. The license is valid for a period of 15 years and can be renewed upon request for each activity. The Draft Law provides that the selection procedure for license renewal is organized by the Agency.

➤ Conditions for obtaining a license for the production of cannabis for medical purposes

In virtue of the Draft Law any legal subject seeking a license must meet the following conditions for each activity required for licensing:

- a) Possesses a minimum of *3 years of experience in at least 3 main activities*, such as the production, cultivation, and distribution of cannabis plants for medical purposes;
- b) The subject or one of its shareholders, owning 51% of the company's shares, must:
 - i. Have engaged in the production of cannabis plant by-products in one of the countries within the Organization for Economic Cooperation and Development (OECD) for a *minimum of 5 years*.
 - ii. Hold good manufacturing practices certification issued by either the European Medicines Agency or the US Food and Drug Administration for a *minimum of 3 years*.
 - iii. Maintain a company capital of no less than 100,000,000 (one hundred million) ALL.



The legal subject submitting an application for a medical cannabis production license must, among other requirements:

- a) Clearly *specify the activity or activities* for which it seeks to be licensed;
- b) Provide detailed information about the *units where the activities will take place*,

including their coordinates and legal relationship with the land;

c) Present a comprehensive business development plan that outlines the cultivation model, purpose of cultivation, and the *minimum and maximum surface area* of the development unit;

d) Submit a *processing plan* for drying, cutting and storage facilities, equipped according to the anticipated production capacity specified in the production development plan;

e) Present a security plan for the cultivation and processing area, which includes elements of protection, fencing, 24-hour physical security with cameras, entrance barriers and barbed wire on the fence, following the standards determined by the decision of the Council of Ministers;

f) Provide a self-declaration of *employing a minimum of 10 individuals* for each unit, including at least 2 qualified employees with a *minimum of 3 years of work experience* in the fields of pharmacy and agro-engineering;

g) Submit a self-declaration expressing the willingness to enter into an agreement with the responsible structure of the ministry responsible for public order and security. This agreement guarantees access for inspection to the private physical security company overseeing the cultivation environments of the cannabis plant and its by-products, as well as the movement of vehicles dedicated to trading raw materials and products, in accordance with the regulations and fees established by the Council of Ministers;

h) Provide a self-declaration stating the intention to commence the activities described in the license within 12 months of its approval;

i) Submit a self-declaration stating the commitment to 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, starting from the third year;

j) Submit a bank guarantee equivalent to 10% of the investment value;

k) Provide a self-declaration confirming compliance with all traceability requirements as stipulated in the law;

l) Submit a self-declaration disclosing the processes carried out by third parties, along with accurate identification data for evaluation and verification purposes;

m) Present a self-declaration confirming the availability of payment for tracking system fees.



➤ **Conditions for obtaining a license for the production of industrial cannabis**

The permit for the exercise of the activity (hereinafter referred to as the "*Permit*"), grants permission for the production of cannabis for industrial purposes. It allows the import of seeds or seedlings, or their reproduction for use as seeds/seedlings, as well as cultivation, production and processing, transportation, and export of by-products and final products of cannabis for industrial purposes.

In virtue of the Draft Law, in order to obtain a production permit, a request shall be submitted to the ministry responsible for agriculture. The request must be accompanied by the following documentation:

a) Registration document of the farmer, whether a natural person or a legal subject;

b) A list of personnel employed or subcontracted to manage the cultivation process, including at least one agronomist. This should be accompanied by:

i. A certificate issued by the prosecution body proving that the subject is not undergoing criminal prosecution;

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

iii. A certificate of judicial status proving that the subject has not been criminally convicted by a final court decision;

iv. A statement granting approval for the competent authorities to conduct checks on the employees' integrity.

c) A self-declaration regarding the source of financing for the expenses;

d) A self-declaration stating that there are no outstanding tax obligations towards the tax administration and local units;

e) A self-declaration confirming the conclusion of a preliminary agreement for storage and physical security, in accordance with the rules and fees determined by the decision of the Council of Ministers;

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

g) Ownership documentation, including a copy of the land registration card and an indicative map, or a lease contract if the land is not owned by the requesting subject. The land should be located in cadastral areas approved for cultivation. If the land does not have a final ownership document, the deed of taking ownership and the survey plan must be provided;

h) A self-declaration regarding the payment of tracking system fees.

➤ **Administrative offenses**

The Draft Law provides fines ranging from 500,000 (*five hundred thousand*) to 5,000,000 (*five million*) ALL for violations of its provisions.



➤ **Summary**

If the Draft Law will be approved, significant regulations will be put in place to govern the cultivation, production and circulation of cannabis for both medical and industrial purposes. The Draft Law aims to ensure transparency, control, and supervision throughout the entire cannabis supply chain.

One of the key provisions of the Draft Law is the establishment of the National Cannabis

Control Agency, a dedicated entity responsible for overseeing and monitoring the cultivation and processing of cannabis plants, as well as the production of its by-products for medical and industrial use.

To engage in cannabis-related activities, such as cultivation, production, and circulation, subjects must obtain the necessary licenses. In virtue of the Draft Law the licensing process involves a thorough evaluation by the Licensing Commission, which reviews and assesses applications in accordance with the law's provisions. Strict criteria will be put in place, including requirements for experience, compliance with manufacturing standards, financial stability and security measures. These measures aim to ensure that only qualified and responsible subjects will be involved in the cannabis industry.

Moreover, the Draft Law proposes administrative sanctions for non-compliance, reinforcing the importance of adhering to the regulations. Violations such as unauthorized drug use, improper advertising and non-compliance with transportation, security, and tracking requirements will result in fines.

The introduction of this new Draft Law aims at developing a transparent and responsible cannabis industry, balancing the economic opportunities and health benefits associated with cannabis production while safeguarding against potential risks. It sets a framework for the growth and development of the cannabis sector, providing a legal structure that ensures compliance, quality control and traceability.

It remains to be seen if this Draft Law will be approved by the Albanian Parliament and how it will contribute to the emergence of a regulated cannabis industry in Albania.



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Muja Law is a family-run law office where we work hard for the success of our clients and to provide excellence in legal service. Our roots go back to 2001 when our Managing Partner, Krenare Muja (Sheqeraku), opened her law practice office in Tirana, Albania. Krenare’s son Eno joined her in 2014, and the other son Adi entered the practice in 2019. What started in Tirana as a small, family-run law office has grown and flourished in the community for the last 20 years. The office consists of various respected and talented lawyers who possess outstanding educational and community service backgrounds and have a wealth of experience in representing a diverse client base in various areas of the law.

The office is full-service and advises clients on all areas of civil, commercial and administrative law. With significant industry expertise, we strive to provide our clients with practical business driven advice that is clear and straight to the point, constantly up to date, not only with the frequent legislative changes in Albania, but also the developments of international legal practice and domestic case law. The office delivers services to clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods. In our law office, we also like to help our clients with mediation services, as an alternative dispute resolution method to their problems.

While we have grown over the past 20 years and become recognized as one of Albania’s leading law offices, we are grounded in the essence of “who” we are and “where” we started. We understand the importance of family, hard-work, and dedication.

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