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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"*.

Newsletter

Law no. 61/2023 "*On the Control of the Cultivation and Processing of the Cannabis Plant and the Production of its By-products for Medical and Industrial Purposes*".

On 21.08.2023, the Law no. 61/2023 "*On the Control of the Cultivation and Processing of the Cannabis Plant and the Production of its By-products for Medical and Industrial Purposes*" **(Law),** was published in the Official Gazette.

The Law aims to regulate/supervise the process of cultivation, production, circulation, and the export of cannabis plants, their by-products, and final products for medical and industrial purposes.

The Law provides for the establishment of the *National Cannabis Control Agency*, hereinafter referred as the Agency, responsible for the supervision, control, and inspection of the cultivation of cannabis plant and its by-products for medical and industrial purpose.

Additionally, the Law proposes the establishment of the *License Commission* as a part of the Agency which will review and evaluate license applications specifically for the cultivation of cannabis for medical purposes.

Further, the Law introduces the *National Register of Licensed Entities,* a state database administered by the Agency. The Register will contain all the information regarding license applications, decision-making for licensing, authorization requests, permit applications, tracking, monitoring and control, as well as administrative measures related to all stages of cannabis cultivation, in accordance with the provisions of this law.

Moreover, the provisions of the Law are focused on the following main points:

Medical Purpose

Under controlled conditions, different varieties and subspecies of *Cannabis Sativa*, *Cannabis Indica*, and *Cannabis Ruderalis* shall be cultivated for medical purposes and scientific research.

Industrial Purpose

Cannabis plants cultivated for industrial purposes, typically referred to as industrial hemp, are known for their low psychoactive component tetrahydrocannabinol (THC). According to the provisions of this Law, all fresh or dried parts of the *Cannabis Sativa* and *Cannabis Ruderalis* plant, as well as their seeds, containing not more than 0.8% THC, shall be used for industrial purposes.

Licensing and Permitting

The entities applying for a license for the production of cannabis for medical purposes must meet the following main criteria:

- The entity must have a 3-year experience in the main activities, such as production, cultivation, and circulation of cannabis plants for medical purposes.
- The entity or one of its shareholders, holding 51% of the company's shares, must be engaged in the production of cannabis plant derivatives in one of the countries of the Organization for Economic Cooperation and Development (OECD) for at least 5 years and possess good manufacturing practices (GMP) issued by the European Medicines Agency or the US Food and Drug Administration for at least 3 years.
- The entity must have a company capital of no less than ALL 100,000,000 (one hundred million).

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

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

The license is issued for a duration of 15 (fifteen) years and covers one or multiple of the above-mentioned activities, and the licensee has the right to request renewal for each activity upon the expiration of the initial license period. The renewal process is based on a selection procedure organized by the Agency.

Whereas the permit for the production of cannabis for industrial purposes is granted for a duration of 5 (five) years for the following activities:

a) Import of cannabis seeds/seedlings for industrial purposes.
b) Reproduction of cannabis seeds/seedlings for industrial purposes.
c) Cultivation of cannabis plants for industrial purposes.
d) Export of by-products and final products derived from cannabis for industrial purposes.

To apply for a permit to produce cannabis for industrial purposes, interested entities must submit their request to the responsible agricultural ministry. As part of the application, they must also provide a list of their employed personnel responsible for cultivating cannabis plants for industrial use. This list must include at least one agronomist having expertise in the field of agricultural science and specifically knowledgeable about cannabis cultivation.

Regulatory Compliance and Penalties

The emphasis on conducting activities related to the production of cannabis for medical/industrial purposes in accordance with the provisions of the Law indicates the importance of compliance with the regulations and guidelines set forth in the legislation.

In this context, cultivation, use, sale, distribution, advertising, or any other activity related to the production of cannabis for medical or industrial purposes beyond the limits specified in this Law is prohibited.

Failure to comply with the regulation outlined in the legislation may result in penalties as follow:

- Fines ranging from ALL 500,000 (five hundred thousand) up to 5,000,000 (five million). The specific amount of the fine depends on the nature and severity of the violation.
- Temporary suspension of activity exercise from 6 (six) months up to 3 (three) years.

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Boga & Associates

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The firm's particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment. The firm delivers services to leading 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.