

# CANNABIS LEGISLATION IN ARGENTINA

March, 2023



BERETTA GODOY

## A. INTRODUCTION

The cannabis industry is experiencing unprecedented global growth, mainly driven by legislative changes that decriminalize consumption and regulate the production of cannabis derivatives for different purposes.

This evolution essentially responds to the growing social demand for regulation of the medicinal use of cannabis, which is partly supported by scientific advances that demonstrate the potential therapeutic usefulness of some cannabis derivatives in an increasing number of diseases.

In Argentina, everything related to cannabis in general terms was exclusively regulated by criminal law.

As of 2017, Argentina joined the group of countries that have authorized the use of cannabis for research, therapeutic, and medicinal purposes through the enactment of "*Law on Medical and Scientific Research of the Medicinal Use of the Cannabis Plant and its Derivatives*".

Furthermore, in May 2022, Congress passed Law 27,669 on the "*Regulatory Framework for the Development of the Medical Cannabis and Industrial Hemp Industry*". Through it, the aim is to complement the regulatory framework by promoting the development of a local cannabis and hemp production chain, regulated and controlled by the State, for medicinal and industrial purposes. The Executive Power shall adopt the necessary regulations.

The cultivation of cannabis for adult-recreational use is not currently permitted, nor is the registration or commercialization of seeds for this purpose, both of which are still subject to criminal law.

This memo analyzes the main characteristics of the existing regulation to date.

## B. MEDICAL USE OF THE CANNABIS PLANT AND ITS DERIVATIVES

Law 27.350 on Medical and Scientific Research of the Medicinal Use of the Cannabis Plant and its Derivatives sets forth the regulatory framework for medical and scientific research on the medicinal, therapeutic and/or pain palliative use of the cannabis plant and its derivatives<sup>1</sup>.

---

<sup>1</sup> In accordance with estimates from the Argentine Cannabis Chamber, there would be 5,000,000 potential users (projections of users with different health conditions in which the use of cannabis is scientifically supported in terms of its effectiveness and feasibility: Post-chemotherapy nausea in cancer, Spasticity and Pain in Multiple Sclerosis, Refractory Epilepsy, Generalized Anxiety Disorder, Chronic Pain, Tremor in Parkinson's Disease. (Cannabis and Argentina - State of the Situation. Projection of Industry and Commerce - ARGENCANN 2021)

This same law created, within the scope of the Ministry of Health, the National Program for the Study and Research of the Medicinal Use of the Cannabis Plant, its derivatives, and non-conventional treatments. Its main (and limited) objectives are as follows:

- i. Research of therapeutic purposes and verification of the effectiveness of treatments, as well as development of different therapeutic alternatives.
- ii. Provision of free access to hemp oil and other cannabis derivatives to any person who joins the program, under the conditions stipulated in the regulations.<sup>2</sup>;
- iii. Provision of counseling, adequate coverage, and complete monitoring of the treatment to the affected population that participates in the program.

To this end, actions may be taken to ensure the supply of the necessary inputs to carry out scientific and medical studies of the cannabis plant for medicinal purposes, either through importation or production by the national government.

The cultivation of cannabis by CONICET<sup>3</sup> and INTA<sup>4</sup> is authorized for medical and/or scientific research purposes, as well as to produce the substance for the treatment to be provided by the program<sup>5</sup>.

Production, release, handling, conditioning and importation of Cannabis.

These activities must be carried out inexorably with the authorization of the National Institute of Seeds (INASE) and for the uses permitted by the law on medicinal use, that is, for projects approved by the Ministry of Health of the Nation and for users registered with the REPROCANN.

Most of the provinces have endorsed Law 27.350, with discrepancies as to the degree of development and implementation. Others, such as Jujuy, have produced their own regulatory framework<sup>6</sup>.

## C. LAW ON THE REGULATORY FRAMEWORK FOR THE DEVELOPMENT OF THE MEDICINAL CANNABIS INDUSTRY AND INDUSTRIAL HEMP

Law 27.669 was enacted in May 2022:

- a) Seeks to promote public, private, or mixed investment projects, establishing the regulatory framework for the national production and commercialization chain

---

<sup>2</sup> Free access, in contrast to what is prescribed by law, is only valid for patients with exclusive public coverage; otherwise, coverage for treatment must be provided by social security organizations and prepaid medical services.

<sup>3</sup> National Council of Scientific and Technical Research.

<sup>4</sup> National Institute of Agricultural Technology.

<sup>5</sup> Home cultivation is not provided for by the law, although it is included in the regulations, which raises compatibility issues with the criminal law and the law on medicinal use, which states that production shall be prioritized and encouraged through public laboratories grouped under the National Agency of Public Laboratories.

<sup>6</sup> Some provinces have created their own research programs, while others distribute cannabis oil through provincial public laboratories, such as the Pharmaceutical Industrial Laboratory (LIF) of the province of Santa Fe, which produced medicinal oil by the end of 2021. There are also municipal initiatives.

and/or for the purpose of exporting the cannabis plant, its seeds and derivatives for medicinal use, including scientific research and industrial use.

- b) Authorizes the registration and filing, before the regulatory authority, of seeds, cultivation, harvest, production, storage, fractionation, transportation, distribution, processing, commercialization, import, export of cannabis seeds, cannabis plant, and its derivatives intended for medicinal and industrial uses.
- c) Does not regulate neither the recreational use of the cannabis plant nor modifies the current home cultivation regime.
- d) Seeks to legalize and develop the use of hemp and its derivatives as an input in several industries. A differential and more lenient regime will be applied with regard to authorizations for the aforementioned purposes, expressly excluded from criminal law.

As of today, this law is not regulated, a fundamental aspect for the provisions of the law to become operative.

## D. PERMITTED ACTIVITIES

The activities permitted by the existing regulation are as follows:

***i. Import, export, "controlled" seed production, seed processing or commercialization.***

National and foreign germplasm varieties can be registered in the National Register of Cultivated Varieties (RNC)<sup>7</sup> and/or in the National Property Register of Cultivated Varieties (RNPC)<sup>8</sup>, in order to obtain national germplasm.

Any person carrying out such activities must be registered with the National Registry of Seed Trade and Control (RNCyFS).

Transfers of seeds for commercial purposes, planting or propagation by third parties may only be made by a person registered in the RNCyFS who, when transferring a seed, is responsible for its correct labeling.

---

<sup>7</sup> All cultivated varieties identified for the first time are registered in the RNC. Registration with the RNC enables the commercialization of plant varieties, although it does not grant ownership rights.

<sup>8</sup> The National Property Register of Cultivated Varieties protects the property rights of those who create new plant varieties. The registration of a cultivated variety with this Register does not represent an authorization commercialize it.

Authorizations for the production of cannabis seeds are due to the fact that they are considered as controlled class seeds<sup>9</sup>.

Those interested in producing it must be registered in Category A of the Breeding Registry. Once registered, they are authorized to market the production of registered varieties, but always within the framework of Law No. 27.350. Buyers shall be: (a) Registered users in the "A - Breeding" and "F - Distributor Seller" Categories, (b) those who have approved research and/or productive projects for medicinal use by the Ministry of Health, and (c) users registered with the REPROCANN.

On the other hand, in order to carry out research projects with medical cannabis, it is necessary to be registered in Category H of Producer Under Controlled Conditions, which includes any person who applies production techniques under special laboratory conditions that allow an accelerated propagation and/or ensure maximum sanitary quality levels and/or incorporation of germplasm of agronomic value. Those registered in this category may sell or purchase propagation material identified in categories A and F and are authorized to produce and trade cannabis derivatives.

Finally, businesses that resell the material produced by the nurseries to users registered in REPROCANN or to research projects may be registered in Category F - "Distributor Seller". They are only authorized to buy and sell material already identified by Categories A and H. They may not identify or fractionate the purchased material.

Only Categories A and H of the RNCyFS are authorized to identify or label propagation material for commercialization.

Propagating materials may be commercialized in the form of seeds, rooted cuttings and seedlings, provided that the varieties are registered in the catalog of the National Register of Cultivated Varieties.

For the import of cannabis sativa L varieties, it must be previously registered in the National Register of Cultivated Varieties or in the process of registration.<sup>10</sup>

The first two domestic medical cannabis strains were officially added to the National Cultivated Varieties Registry in April 2022.<sup>11</sup>

The cultivation of cannabis for adult-recreational use is not currently permitted, nor is the registration or commercialization of seeds for this purpose.

---

<sup>9</sup> Controlled seed "is one that, in addition to meeting the requirements demanded for the 'Identified' seed and demonstrating good performance in officially approved trials, is subject to official control during the stages of its production cycle. Within this class, the following "Categories" are recognized: "Original" (Basic or Foundation) and "Certified" in different grades.

<sup>10</sup> As for all plant products that present phytosanitary risk, they must obtain, from SENASA (National Service of Health and Agrifood Quality), the Phytosanitary Import Authorization and, if applicable, comply with the Post Entry Quarantine procedures.

<sup>11</sup> These are CAT3 and EVA species. There are currently 13 species registered in the National Cultivated Varieties Registry.

**ii. Access to the controlled cultivation of the cannabis plant, for medicinal, therapeutic and/or pain relief purposes.**

Persons wishing to have such access must register with the Registry of the Cannabis Program (REPROCANN). In order to access the necessary authorization, a National Registry of Authorized Persons for controlled cultivation for medicinal and/or therapeutic purposes has been set up.

Authorized persons will be able to acquire magistral formulations, medical specialties or import them.<sup>12</sup>

Registered growers are not covered by the traceability carried out by the INASE.

**iii. Production and commercialization for medicinal and industrial purposes.**

When the regulation of the Law to develop the production of medical cannabis and industrial hemp is finally enacted, the newly created Regulatory Agency of the Hemp and Medical Cannabis Industry (ARICCAME) shall regulate and issue the administrative authorizations with respect to the use of cannabis plant seeds, cannabis and its derivative products.

In particular, it shall:

- i. Issue authorizations for the import, export, cultivation, industrial production, manufacture, commercialization and acquisition, by any title of seeds of the cannabis plant, cannabis and its derivative products for medicinal or industrial purposes.
- ii. Regulate the storage, fractionation, transportation, distribution, traceability and use of cannabis seeds, cannabis plants, critical inputs of the production process and its derivative products, for industrial and medicinal use.
- iii. Regulate, manage and control the production chain, its commercialization and distribution (registration, control and traceability).

No activity may be started without prior authorization from ARICCAME.

The holder of an authorization must comply with the information system duly established with respect to the control and traceability of production processes and inputs.

A system for monitoring, control and respective sanctions is foreseen in order to guarantee good practices and quality, and also to avoid the diversion of authorized producers to illegal activities.

---

<sup>12</sup> The law on medicinal use does not refer to different forms of acquisition, but only provides for imports;

## E. THE ARGENTINE CANNABIS MARKET TODAY

It is difficult to determine the potential of the local cannabis market, but it has been estimated that it could reach US\$ 450,000,000<sup>13</sup>.

Regulations in force until the enactment of the law on the Regulatory Framework for the Development of the Medical Cannabis and Industrial Hemp Industry, oriented exclusively to medicinal and therapeutic cannabis, did not allow, with some exceptions, the immediate emergence of productive or industrial ventures. Among the exceptions we can mention:

### **i. Program for the local production of medicinal cannabis derivatives**

The province of Jujuy, with its company CANNAVA SE, was a pioneer and is the first state-owned company engaged in the production of medicinal cannabis derivatives. It is the only company authorized to legally produce cannabis in Argentina.<sup>14</sup> Through cooperation agreements with the private sector<sup>15</sup> the company plans to develop and cultivate 30 hectares. Cannava will provide the land and permits to import seeds, cultivate, harvest cannabis and process, produce and export cannabis products, while the private investor will provide the necessary financing and industry know-how. The result of the manufacturing and distribution activities, as well as cultivation, will be distributed between the parties.

### **ii. Manufacture, import, export, commercialization, monitoring and inspection of industrialized products intended for use and application in human medicine**

To this end, public or private laboratories domiciled in the country must obtain authorization from ANMAT after complying with the required procedures.<sup>16</sup>

---

<sup>13</sup> López, A. The cannabis value chain: international situation and trends, and opportunities for Argentina. CCE Working Papers No. 1, March 2021, Council for Structural Change - National Ministry of Productive Development.

<sup>14</sup> It is currently producing and commercializing a pharmaceutical grade medical cannabis derivative, rich in CBD (10%), for the treatment of refractory epilepsy and related neurological diseases. It is authorized to market throughout the national territory.

<sup>15</sup> Agreement with Blueberries Medical Corp, a Colombian company publicly traded in Germany, Canada and the United States.

<sup>16</sup> "Guide for the Sanitary Authorization of Cannabis-Based Plant Products and their Derivatives Intended for Use and Application in Human Medicine".

The Sanitary Authorization may authorize to elaborate, commercialize, import or export raw material, bulk products, in primary packaging and/or finished product over a 4-year period.

Those Active Pharmaceutical Ingredients that have percentages of Tetrahydrocannabinol (THC) higher than 0.3% w/w on a dry basis, considering the tetrahydrocannabinol acid (ATHC) that may be present, the corresponding regime for "Substances Subject to Special Control" shall apply.

### **iii. Commercialization of medicinal specialties and herbal products based on cannabis**

Within the medicinal field, ANMAT has authorized the registration at the Registry of Medicinal Specialties and the commercialization of medicinal cannabidiol-based specialties.<sup>17</sup>

It has also authorized cosmetic products containing the cannabinoid called pure Cannabidiol (CBD) of natural origin or CBD present in extracts and natural oils from certain parts of the Cannabis sativa L. plant with no more than 0.2% w/w of THC.<sup>18</sup>

Recently, the category "*Cannabis-based herbal products and their derivatives intended for use and application in human medicine*" was created<sup>19</sup> introducing a distinction between these products and those regulated as "medicines" (medicinal or herbal specialties).

### **iv. Registrations at the National Seed Institute (INASE)**

The already mentioned approval by INASE of the first cannabis varieties in the country that allows legal access to seeds (without the need to import them). The companies that have registered the varieties are León Verde (EVA) and Vivero del Oeste Riojano SAPEM (CAT3).

Although its scope is currently limited to marketing for medicinal and research purposes, this market should expand considerably with the enactment of the law to develop the production of medical cannabis and industrial hemp.

### **v. Research projects**

The company "Pampa Hemp" launched the first public-private agreement for the research and production of medical cannabis (with INTA) in the Province of Buenos Aires, Pergamino Experimental Station. Authorized by the National Ministry of Health, it is the first

---

<sup>17</sup> Registration under the trade name CONVUPIDIOL of Laboratorio Alef Medical Argentina S.A. Laboratorios ELEA markets, also with ANMAT authorization, Kanbis, an antiepileptic drug.

<sup>18</sup> For example, ELEA's Rati Salil CBD cream, a pain reliever.

<sup>19</sup> When the Active Pharmaceutical Ingredients of cannabinoids have percentages of Tetrahydrocannabinol (THC) higher than 0.3% w/w on a dry basis considering the tetrahydrocannabinol acid (ATHC) that could be present, the corresponding regime for psychotropic substances shall be applied to them.



private venture in Argentina to start a cannabis crop for productive purposes and for scientific and medical research.

Other private companies<sup>20</sup> have joined CONICET / INTA in order to develop research programs approved by the Ministry of Health, among them: (a) CANNSLA, (ii) Cálce Biosciences, (iii) León Verde, and (iv) Botanicanns. These partnerships include, among other conditions, provisions on the ownership of the research results (which will belong to the public entities or will be shared with the private company) and on the eventual commercial exploitation (generally priority to negotiate an exclusive license for a certain period of time).

These projects will enjoy a simplified regime for obtaining authorizations and/or licenses from ARICCAME.

#### *vi. New medicinal and industrial uses*

The enactment of the Law on the Regulatory Framework for the Development of the Medical Cannabis and Industrial Hemp Industry should significantly boost the creation of an industrial and medical cannabis market, although economic operators are currently waiting for the definitions and specifications to be set forth in the final regulation.

## F. CONCLUSIONS

In a major step towards the creation of a cannabis market in Argentina, two of the three main uses of cannabis have been regulated: medicinal and industrial, while strict prohibitions on adult-recreational use remain in force.

The law on narcotic drugs and its punitive approach to a number of behaviors, raising the possibility of a criminal sanction, was the main obstacle to the development of the cannabis sector, the approval of the law on the Regulatory Framework for the Development of the Medical Cannabis Industry and Industrial Hemp attempts to overcome this obstacle.

There are already a large number of ventures. It remains now to wait for the regulation of the recent law to give a boost to this sector.

\* \* \*

Should you have any questions or comments, please contact us at [sonoda@berettagodoy.com](mailto:sonoda@berettagodoy.com) or [sbarra@berettagodoy.com](mailto:sbarra@berettagodoy.com)

---

<sup>20</sup> There are multiple research projects organized by provinces, municipalities and universities.