LIFE SCIENCES

On November 12, 2020, the Argentine Government issued Decree 883/2020, which modifies the regulations of Law No. 27,350 on "Medical and Scientific Research for the Medicinal Use of the Cannabis Plant and its derivatives", and creates a new regulatory framework that allows timely, safe, inclusive and protective access for those who need to use Cannabis as a therapeutic tool.

Previous regulations (issued through Decree No. 738/17) were very restrictive, since only those who had joined research protocols in refractory epilepsy could access to Cannabis oil and its derivatives. Likewise, access was also economically exclusive considering the high cost that importation of said products implied.

In addition, although Section 8 of the aforementioned Law created a voluntary national registry in order to facilitate free access to Cannabis oil and its derivatives, it never became operational. This situation, in turn, prevented the adequate quality control of cannabis derivatives or alleged derivatives, which not only compromises the health of users but also generates unfounded expectations promoted by the simple desire for profit.

These regulatory restrictions set up barriers to the timely access of Cannabis by the population; in response, a significant nucleus of users decided to satisfy their own demand for Cannabis oil through self-cultivation practices, and over time they organized networks and created civil organizations that currently enjoy not only legal recognition but also social legitimacy.

By virtue of this circumstances, the Government issued Decree 883/2020 modifying the regulations of Law No. 27,350. The new regulations grant access to the controlled cultivation of the Cannabis plant, as well as its derivatives, for medicinal, therapeutic and / or palliative pain treatment, in order to guarantee and promote comprehensive health care, and free access to hemp oil and other derivatives of Cannabis to anyone who joins the "National Program for the study and research of medicinal use of the Cannabis plant, its derivatives and non-conventional treatments" (hereinafter "the Program").

So as to provide a balanced response between the right of access to health and health security, the new regulation establishes a specific registry for users who cultivate Cannabis for medicinal, therapeutic and / or palliative purposes, as well as promoting the creation of a network of associated public and private laboratories that guarantee the control of the derivatives produced.

The Ministry of Health, as the enforcement authority of Law No. 27,350, will create the necessary conditions to guarantee the provision of the required inputs and facilitate medical and / or scientific research on the Cannabis plant and its derivatives, as well as for treatment within the framework of the Program, through the issuance of operational and procedural norms that must take into account the value chain with respect to cultivation, production, and marketing for scientific, medicinal, and therapeutic purposes. The National Institute of Agricultural Technology (INTA for its acronym in Spanish) and the National Council for Scientific and Technical Research (CONICET for its acronym in Spanish) were authorized to cultivate Cannabis. The National Seed Institute (INASE for its acronym in Spanish) will regulate the conditions of production, dissemination, handling and conditioning of the organs of propagation of this species that allow the traceability of the plant products. The Ministry of Health will promote and prioritize regional production carried out through public laboratories grouped in the National Agency of Public Laboratories (ANLAP for its acronym in Spanish).

Patients who have a medical indication for the use of the Cannabis plant and its derivatives may: (i) purchase medicinal specialties produced in the country, (ii) import medicinal specialties duly registered before the health authority or (iii) acquire magisterial formulations prepared by authorized pharmacies. In addition, those who do not have health insurance, have the right to access it free of charge.

The Registry for users created within the scope of the Ministry of Health is called the "Cannabis Program Registry" (REPROCANN for its acronym in Spanish). In order to issue the corresponding authorization, the REPROCANN will register patients who access the Cannabis plant and its derivatives through controlled cultivation, as medicinal, therapeutic and / or palliative pain treatment. Patients may register to obtain the cultivation authorization for themselves, through a family member, a third person or a civil organization authorized by the Ministry of Health. Anyone who has a medical indication and has signed the corresponding informed consent may enroll in the REPROCANN. Data protection will be ensured in accordance with the provisions of Law No. 25,326.

The National State will provide technical collaboration to promote the public production of Cannabis in all its varieties and its eventual industrialization for its medicinal, therapeutic and research use in public laboratories. The products will be dispensed through the National Bank of Oncological Drugs and / or authorized pharmacies.