Understanding Peru's New Regulation on the medicinal and therapeutic use of cannabis and its derivatives

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About the report

Peru's Supreme Decree No. 004-2023-SA modifies Law No. 30681, regulating the medicinal and therapeutic use of cannabis and its derivatives. The decree (the New Regulation) was published on February 28, 2023 in *El Peruano*, the Peruvian Official Gazette, and will become effective on September 1, 2023. When the New Regulation enters into force, Law No. 30681 (the Regulation), will be repealed.

The New Regulation:

- Strengthens the regulation, scope and coverage of the use of cannabis and its derivatives for medical and therapeutic purposes.
- Regulates, in a more specific manner, the parameters and/or requirements so that those who are administered may carry out research, production, importation, and commercialization of cannabis and its derivatives and artisanal production of cannabis derivatives with associative cultivation.
- Establishes detailed control and supervision mechanisms to ensure that cannabis and its derivatives are used exclusively for medicinal and therapeutic purposes, thus granting other public entities control and supervision faculties.

In this report, we summarize the top points of the New Regulation and the changes it will bring to Peruvian law.

A quick look at Peru's regulation of cannabis for medicinal and therapeutic use

- **May 13, 2000**: publication of Law No. 27262, the General Seed Law.
- **June 1, 2012**: publication of Supreme Decree No. 006-2012-AG, "Regulation of the General Seed Law".
- **November 17, 2017**: publication of Law No. 30681, regulating the medicinal and therapeutic use of cannabis and its derivatives.
- **December 23, 2019**: publication of Supreme Decree No. 005-2019-SA, "Regulation of Law No. 30681, Law that governs the medicinal and therapeutic use of Cannabis and its derivatives, which regulates the medicinal and therapeutic use of cannabis and its derivatives.
- **July 25, 2021**: publication of Law No. 31312, which incorporates and modifies articles of Law No. 30681.
- **February 28, 2023**: publication of Supreme Decree No. 004-2023-SA, which approves the regulation that governs the medicinal and therapeutic use of cannabis and its derivatives, with an effective date of September 1, 2023.

Key definitions in the New Regulation

- **Cannabis**: The flowering or fruiting tops of the cannabis plant (except for the seeds and leaves not attached to the tops) from which resin has not been extracted
- **Psychoactive cannabis**: Has a tetrahydrocannabinol (THC) content equal to or greater than 1 percent in dry weight and is used for medicinal and therapeutic purposes
- **Non-psychoactive cannabis**: Has a THC content of less than 1 percent in dry weight and is used for medicinal and therapeutic purposes

Main modifications and general scope of the New Regulation

Administered: Associations of patients who are cannabis users are now included in the New Regulation under the definition of "administered." Therefore, with said amendment, the following will be considered as "administered":

1. Pharmaceutical establishments that are authorized and certified in good pharmaceutical practices
2. Cannabis patient associations – **NEW**
3. Universities
4. Agricultural research institutions
5. Public entities
6. Patients who make informed use of cannabis and its derivatives, or their relatives, guardians, curators or supporters when they must act on their behalf.

Associations of cannabis users: The New Regulation incorporates the regulation which addresses associations that artisanally produce cannabis for medicinal and therapeutic purposes:

- Associations that have been created to provide patients with access to improve their quality of life are made up of two or more patients or legal representatives or their designated supporters, registered in the National Registry of Patients Users of Cannabis and its derivatives for medicinal and therapeutic use (RENPUC, for its Spanish acronym), for the exclusive benefit of the qualified patients that comprise them.
- A license for the artisanal production of cannabis derivatives with associative cultivation of the plant of the cannabis genus entitles the holder to: plant, handle, harvest and post-harvest, process, transport and store cannabis for medicinal and therapeutic purposes. License holders may acquire seeds from those are licensed for the production of cannabis derivatives with cultivation.
- Note that cannabis and its derivatives from artisanal production generated by the associations **are for the exclusive benefit of qualified patients who are members of such associations**; therefore, such derived products may not be commercialized or transferred to third parties.
- The associations operate vis-à-vis the public administration through their legal representatives.
- Each license for the artisanal production of cannabis derivatives with associative cultivation of the cannabis plant for medicinal and therapeutic purposes **is granted, in Metropolitan Lima, by the General Directorate of Medicines, Supplies and Drugs (DIGEMID) and outside that region, by the Regional Directorates of Medicines, Supplies and Drugs, or those acting in their stead**.

Other provisions

- The definition of "special prescription" specifies that it is issued for the prescription of narcotic and psychotropic drugs **when the THC content in the formulation is equal to or higher than 1 percent**.
- The former name of the National Registry of Patients who Use Cannabis (Registro Nacional de Pacientes usuarios de Cannabis) has been changed to **National Registry of Patients who Use Cannabis and its derivatives for medicinal and therapeutic use (Registro Nacional de Pacientes Usuarios del Cannabis y sus derivados para uso medicinal y terapéutico - RENPUC)**.
- The requirement to have **a no-objection document issued by DIGEMID (required for customs clearance)** to import non-psychoactive cannabis is incorporated. In addition, SENASA's authorization is required for compliance with phytosanitary provisions.
- Home marketing is only allowed for cannabis-derived **products that contain less than 1 percent THC in their formulation or when they only contain cannabidiol (CBD)**, for patients who have completed the registration process in the RENPUC.

Licenses for activities related to cannabis and its derivatives for medicinal and therapeutic purposes

1. Investigation
2. Production
3. Import
4. Commercialization

These licenses are granted in an administrative procedure of prior evaluation in a maximum period of 30 working days, subject to negative silence.[1]

The licenses are non-transferable and have an indefinite term.

LICENSE ADEQUACY

- Licenses obtained under the Regulation must be adapted to the New Regulation within one year of its entry into force.
- Licenses that do not comply will be canceled.
- The New Regulation, like the former Regulation, regulates licenses for scientific research activities, importation, commercialization and production of cannabis and its derivatives; however, the denomination referring to such licenses is different and implies the fulfillment of additional requirements.
- The New Regulation incorporates the license for the artisanal production of cannabis derivatives with associative cultivation of the cannabis plant for medicinal and therapeutic purposes.

Previous regulation	New regulation
License for the production of cannabis and its derivatives for medicinal and therapeutic purposes including cultivation License for the production of cannabis and its derivatives for medicinal and therapeutic purposes including seeds	License for the production of cannabis derivatives, with cultivation of the cannabis plant
License for the production of cannabis and its derivatives for medicinal and therapeutic purposes, not including cultivation	License for the production of cannabis derivatives, without cultivation of the cannabis plant
Import and/or commercialization license to laboratories and drugstores	License for the importation of cannabis and its derivatives and commercialization of cannabis derivatives to pharmaceutical laboratories and drugstores
Marketing license to pharmacies, apothecaries and pharmacies of health establishments	License for the commercialization of cannabis derivatives to pharmacies, apothecaries and pharmacies of health establishments
License for scientific research on human subjects other than clinical trials License for scientific research on cannabis for medicinal use and its derivatives and finished products that do not involve human studies	License for scientific research on cannabis derivatives for preclinical study without cultivation
License for universities and agricultural research institutions	License for scientific research, with cultivation of the cannabis plant
	License for the artisanal production of cannabis derivatives with associative cultivation of the cannabis plant

[1] Negative administrative silence is a facultative right in favor of the administrated party and has the effect of enabling him/her to file pertinent administrative appeals and judicial actions after the expiration of the administration's resolution period.

Control authorities

HEALTH MINISTRY (MINSA)

Control authority	Competencies
General Directorate of Medicines, Inputs and Drugs (DIGEMID)	Issues the license for scientific research of cannabis derivatives for preclinical study without cultivation and controls the research product
Integrated Health Network Directorates (DIRIS)	Issues the license for the production, importation, commercialization and artisanal production of cannabis derivatives with associative cultivation of the plant of the cannabis genus, as appropriate Controls and supervises pharmaceutical establishments, universities or research institutions and associations, as well as cannabis products. *This is also the responsibility of DIGEMID*

MINISTRY OF INTERIOR (MININTER)

Control authority	Competencies
The Anti-Drug Directorate of the Peruvian National Police (DIRANDRO de la PNP)	Certifies compliance with security measures to ensure the safety and physical intangibility of cannabis and its derivatives, as well as the finished product, for medicinal and therapeutic use

MINISTRY OF AGRARIAN DEVELOPMENT AND IRRIGATION (MIDAGRI)

Control authority	Competencies
General Directorate of Agricultural Development and Agroecology (DGDAA)	Issues authorization of agricultural production plans for cannabis Issues reports on agricultural production plans for the granting of licenses for production of cannabis for medicinal and therapeutic purposes, including cultivation Supervises approved agricultural production plans according to the guidelines for the formulation of the agricultural production plan of cannabis for medicinal and therapeutic purposes for the granting of the production license that includes cultivation
National Institute for Agrarian Innovation (INIA)	Issues the license for scientific research with cultivation of plants of the cannabis genus

REGIONAL GOVERNMENTS

Control authority	Competencies
Regional Health Directorates or those acting as such at the regional level (DIRESA)	Issue licenses for importation, commercialization and artisanal production of cannabis derivatives with associative cultivation of the plant of the cannabis genus, as appropriate Control and supervises pharmaceutical establishments and associations of cannabis patients in its jurisdiction and cannabis products

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This report was prepared by the Life Sciences team of DLA Piper Peru. To find out more about the developments covered in this report and our life sciences work, please contact any of the authors:

Ana Teresa Barreto
Of Counsel
abarreto@dlapiper.pe

Jorge Córdova
Partner
jcordova@dlapiper.pe

Nicole Allemant
Associate
nallemant@dlapiper.pe

Nathalie Málaga
Associate
nmalaga@dlapiper.pe

Hiroshi Sugashima
Associate
hsugashima@dlapiper.pe

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