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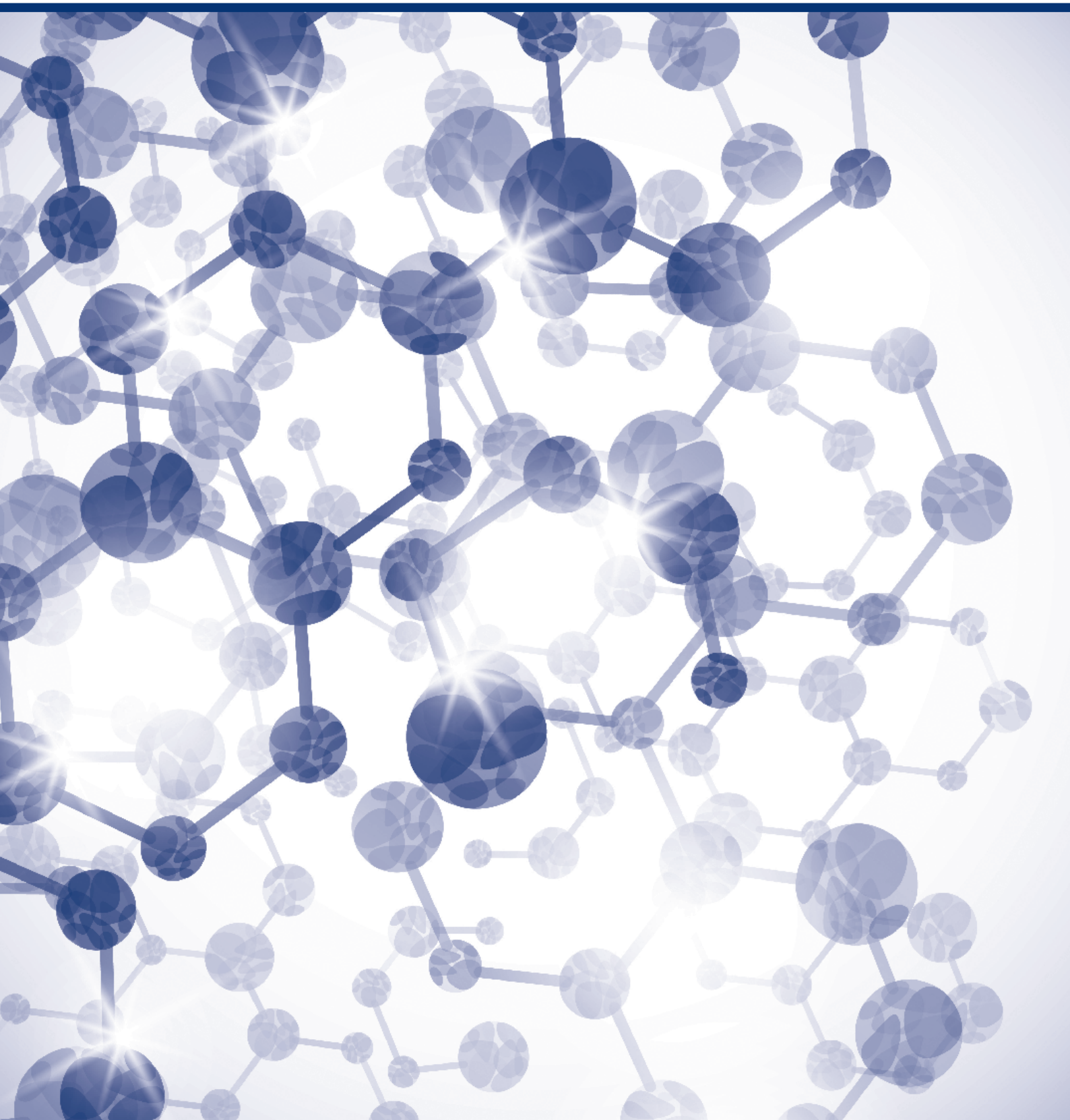

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The legalisation of cannabis for medicinal use in Peru

Introduction

The medicinal use of cannabis was legalised in Peru in October 2017 by Act Number 30681, which regulates medical and therapeutic cannabis and by-products. In accordance with this Law, a regulated research, import, trade and production system was established for cannabis and by-products solely for medical and therapeutic purposes.

The rules for the application of the new law were given by Supreme Executive Order Number 005-2019-SA on 23 February 2019. It represents significant changes to patients' access to treatment and consequently, regulations viability and enforcement.

Authorities and functions involved

The government ministries which enforce the regulation of medical and therapeutic cannabis as shown in Table 1:[1]

Table 1

Ministry	Responsibility
Ministry of Agriculture and Irrigation (MINAGRI)	Be committed to the food safety of the country to reach a better quality of live.
Ministry of Health (MINSA)	Protect people's dignity by promoting health, preventing diseases, and ensure comprehensive healthcare for all inhabitants of the country. People are the center of its mission.
Ministry of Internal Affairs (MININTER)	Exercise authority of internal government as well as internal and public order to protect people's free exercise of rights and fundamental freedoms.

Table 2 shows the ministries, core divisions and functions in relation to the regulation of the Act Number 30681.

Licences for cannabis

Licence is the official document that the appropriate authority grants to the parties concerned. It authorises them to conduct activities consisting of research, production, import, and marketing of cannabis for medicinal use and its derivatives, intended exclusively for medicinal and therapeutic purposes.

The following licences will be granted:

- licence for scientific research to universities and investigative institutions on agricultural and health matters;
- licence for import and/or trading, which is granted to laboratories and pharmaceutical wholesalers duly registered and certified;
- licence for production, which is granted to laboratories that have been duly registered and certified.

Specially convened authorisation for patients

Patients can import cannabis products directly through a special prescription and authorisation issued by the General Medicine, Supplies and Drug Administration (DIGEMID).[2]

The regulations do establish the possibility of the specially convened import of products containing cannabis, resins and essential oils for medical purposes only upon approval of the National Patient Registry for Medical and Therapeutic Cannabis and By-products, as well as the special prescription that will correspond to a six-month-treatment term.

The step-by-step procedure from prescription to obtaining the exceptional cannabis pharmaceutical product import authorisation is detailed in Table 3 below.

Table 2

CANNABIS PERU Suppression of Illicit Drug Trafficking Act, Executive Order No. 22095 Medical and Therapeutic Cannabis Act, Act No. 30681 Regulation of Narcotics, Psychotropic and Other Substances Subject to Health Control, Supreme Executive Order No. 023-2001-SA Regulations of the Act No. 30681, Supreme Executive Order No. 005-2019-SA				
MINISTRY OF AGRICULTURE AND IRRIGATION (MINAGRI)		**MINISTRY OF HEALTH (MINSA)**		**MINISTRY OF INTERNAL AFFAIRS (MININTER)**
Peruvian Service for Agricultural Health (SENASA)	**Peruvian Institute of Agricultural Innovation (INIA)**	**General Medicine, Supplies and Drug Administration (DIGEMID)**	**Peruvian Health Institute (INS)**	**Peruvian Police Force Anti-Drug Division (DIRANDRO)**
• Control seeds import procedures and post-entry quarantine of Cannabis	• Comply with assessments and registrations of Cannabis genetic material. • Issue agricultural research permit.	• Conduct health control and monitoring of pharmacies/drug stores and authorized institutions. • Issue manufacturer license, import license, and drug sales permit. • Issue health registration of pharmaceutical products.	• Conduct quality control and develop technology related to medical Cannabis. • Issue health scientific research permit. • Authorize clinical trials.	• Guarantee control, safety and monitoring of all operations regarding production and commercialization of Cannabis plant for medical and therapeutic purposes. • Approve safety protocols.

Rules regarding compounded drugs

Compounded drugs are pharmaceutical preparations tailored for an individual patient by a licensed pharmacist or under their supervision, in strict compliance with a detailed medical prescription, or the active ingredients as per technical and scientific standards in terms of pharmacy. They are dispensed by pharmacies and public or private hospitals.

Compounded drugs should be prepared upon presentation of the relevant prescription and are exclusively dispensed by the pharmacy receiving this prescription. They must not be kept in stock and their mass production is forbidden.

Pharmacy dispensing compounded drugs may prepare them directly or request their preparation to a specialised pharmacy. In this case, compounded drug preparation responsibility is assumed by the dispensing pharmacy and the specialised pharmacy to which preparation was requested.

For compounded drugs, wholesale or end products must not be used as supplies. Compounded drugs containing substances subject to health control shall comply with the Regulations on Narcotic Drugs, Psychotropic Substances and Other Substances.

Therefore, it shall be established that compounded drugs of cannabis by-products will be created from standardised cannabis by-products supplies. It is understood that such supplies, not being end products, do not required export and trade health registry.

International exports

Act Number 30681 provided that the Regulations shall establish requirements for the registry enforcement and licence issuance which, in compliance with the legal system and the law, may not restrict provisions thereof.

In this respect, Regulations of Act Number 30681 include ones relating to international trade: export as an activity fostering economies of scale, use of resources and materials, and a consequent production cost reduction deriving benefits to patients in the end. As set out in the Regulations, the Official Export Certificate shall comply with the provisions of the Regulations on Narcotic Drugs, Psychotropic Substances and Other Substances subject to health control.

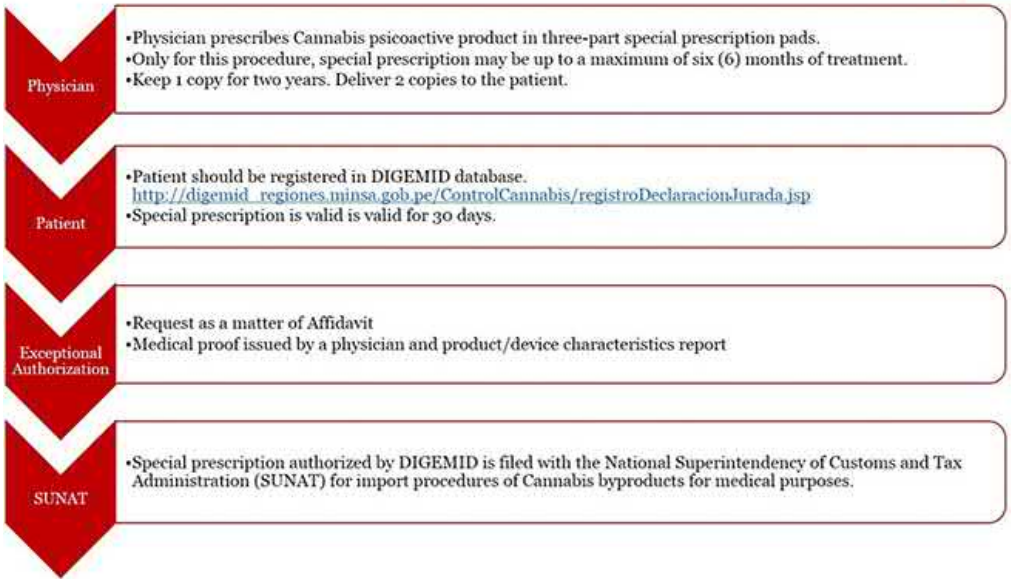
Marketing authorisation for products containing cannabis

Marketing authorisation for such products as medicines, herbal medicines and natural products is allowed. Each category difference shall be referred to in the presentation of safety and efficacy clinical trials. Natural products require the presentation of a clarification about traditional use only.

Psychoactive and non-psychoactive cannabis differentiated

A cannabis rating in respect to the variety of cannabinoids is provided by the Regulations, identifying psychoactive and non-psychoactive substances.

Table 3



In fact, non-psychoactive cannabis refers to cannabis of less than one per cent tetrahydrocannabinol (THC) dry weight as set out in the Regulations. Non-psychoactive cannabis is called hemp. As a non-controlled substance it is excluded from Narcotic Drugs and Psychotropic Substances Regulations enforcement.

Activities consisting of the research, agricultural production, industrialisation, import, and marketing of hemp, its parts and its derivatives, do not require licences issued by Ministry of Health. The Ministry of Agriculture and Irrigation shall establish the criteria and conditions that must be met for the cultivation and processing of hemp.

Finally, it should be mentioned that regulations viability and its immediate enforcement for patients will depend on authorities working together and the prompt issuing of licences and marketing authorisation.

Notes

1 Life Sciences Alert, May 2019 www.estudiorodrigo.com/en/life-sciences-alert-may-2019-2, accessed 18 July 2019.
2 Life Sciences Alert, June 2019 www.estudiorodrigo.com/en/life-sciences-alert-june-2019-2, accessed 18 July 2019.