# Regulations on cannabis production, research and medical use

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## Introduction

On 12 January 2021 the General Health Law Regulations for the Control of Production, Investigation and Medicinal Use of Cannabis and its Pharmacological Derivatives were published in the *Federal Official Gazette*. The regulations entered into force on 13 January 2021.

The regulations regulate raw materials, pharmacological derivatives and medicines derived from cannabis and the production, research and manufacture thereof.

The authorities responsible for interpreting and implementing the regulations are:

- the Ministry of Health (through the Commission for the Protection Against Health Risks);
- the Ministry of Agriculture and Rural Development (through the National Service for Agrifood Safety and Quality and the National Service for the Inspection and Certification of Seeds);
- the Ministry of Economy; and
- the Treasury (thorough the Tax Administration Service).

Regulated activities include:

- primary production for manufacturing supply;
- the use of raw material for research and seed production;
- health and pharmacological research;
- the manufacturing of pharmacological derivatives and medicines and the performance of medical activities relating to diagnoses, therapy, rehabilitation and palliative care; and
- import, export and marketing.

These regulations establish the processes and requirements that must be met by individuals and legal entities in order to carry out the above activities.

## Requirements

### *Quality control laboratories*

Holders of marketing authorisations for cannabis derivatives must have an independent quality control laboratory which must meet the requirements set out in the regulations.

### *Research*

Research is subject to authorisation. Research protocols must be duly authorised by the competent authorities.

### *Planting*

Planting permits and authorisations for research and manufacturing must be obtained from the National Agro-Alimentary Health, Safety and Quality Service (SENASICA). To obtain these permits and authorisations, applicants must submit their investigation protocol and carry out these activities in confined, authorised premises.

SENASICA will issue the corresponding resolutions regarding cannabis planting for health research and the manufacture of pharmacological derivatives and medicines and establish monitoring, control, prevention and phytosanitary measures, in addition to those submitted, or deny such permits when the requesting party fails to meet the requirements set out in the regulations.

SENASICA will also oversee the integration of the National Registry for Cannabis planting permits for research and manufacturing purposes.

***Medical use***
Health professionals are responsible for prescribing cannabis medicines and must obtain a barcode prescription registration to do so. To obtain such a barcode, health professionals must file the necessary authorisation requests with the Federal Commission for the Protection against Sanitary Risk (COFEPRIS).

Only recognised health professionals may prescribe these medicines through the issuance of special prescriptions. These prescriptions must meet the specific characteristics and requirements set out in the regulations.

Drug stores require express authorisation to sell these medicines and must obtain a registry of the patients who require them. These registries must meet the applicable personal data protection provisions.

Legal possession of these medicines must be evidenced with the corresponding prescription or the invoice issued by the seller, as the case may be.

International passengers (whether residents of Mexico or elsewhere) who require cannabis medicines and carry such with them must also carry the corresponding prescription or permit issued by the competent foreign authorities at all times.

***Manufacturing***
Possessors are liable for the manufacture and possession of raw materials, pharmacological derivatives or medicines derived from cannabis. They must keep documents that evidence the legality of such possession for three years from their date of issuance and have these available at all times.

Premises which are used to manufacture, import or export these goods must, at all times, have control books which have been duly authorised by COFEPRIS, as well as the necessary control systems for their safekeeping.

Factories and laboratories that process, warehouse or market raw materials, pharmacological derivatives or medicines derived from cannabis may market these only to premises that also have a licence to operate as a warehouse, centre of distribution of medicines, biologics and blood derivatives for human use or authorised drugstore.

No herbal remedies may be manufactured with cannabis (natural or synthetic) as a raw material.

***Import***
The regulations also establish the possibility of importing and exporting raw materials, pharmacological derivatives or medicine derived from cannabis. For such purposes, a health permit for import or export is required and the country of origin or destination of such goods must not forbid their import or export.

COFEPRIS, together with SENASICA, will issue import permits for raw material, seeds for planting, plants for planting and vegetable origin matter for dissemination. In such cases, the category and phytosanitary certificate for import must be provided.

The import of genetically modified seeds must also meet the applicable provisions set out by the Law for Genetically Modified Organism Safety.

Raw materials for planting are also subject to the issuance of a phytosanitary certificate for import, as well as a requirement to provide considerable information regarding the final product's use.

The health and agricultural authorities may grant seed import permits only for medical and research uses and provided that the corresponding research protocol has been duly filed or the products have obtained a marketing authorisation.

In the case of import permits for seeds whose purpose is manufacturing, it is necessary to include a statement of equivalence under the Federal Law for the Production, Certification and Marketing of the Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food, as well as a phytosanitary certification.

For pharmacological derivatives and medicines derived from cannabis, it is necessary to file, among other things:

- a health licence;
- a sanitary responsible notice;
- authorised control books;

- a research protocol authorisation; and
- a copy of the marketing authorisation issued by COFEPRIS.

Prior to the customs clearance of cannabis pharmacological derivatives or medicines derived from cannabis, and after their export, a notice which meets the diverse requirements set out in the regulations must be filed with COFEPRIS.

After customs clearance, in order to have such products secured, a copy of the import permit must be filed, together with:

- a digital tax certificate or invoice certified by the Mexican consul in the country of origin;
- a certificate of analysis of the manufacturer;
- an airway bill or similar; and
- a copy of the import manifest.

After such securement, it is necessary to request the products' liberation by a health officer, who must state the corresponding information in the minute and control book, including the number and date of the import permit.

For personal use cannabis medicines and medical use cannabis, an import permit may be granted on the filing of the corresponding prescription. This must include the professional licence number of the doctor, as well as the product and its amount, and be filed together with the import manifest before the customs house.

***Export***
It is possible to obtain a permit for the export of cannabis pharmacological derivatives and medicines. This requires the presence of a health officer who must state in the corresponding minute the goods exported and that these correspond with those expressly authorised. The health officer is responsible for verifying the export permit data, product, lot number, expiration date and amounts.

***Premises***
Premises where these products are used to provide medical attention or which supply cannabis medicines must meet the general provisions set out in the General Health Law Regulations Regarding Health Control of Activities, Premises, Products and Services, as well as the General Health Law for Rendering Health Services.

***Prescriptions***
In order to prescribe these products on the above premises, the applicable provisions in the General Health Law and the Regulations for Health Services must be met.

***Publicity***
The publicity of these products is permitted only when it is required of health professionals and is prohibited in any case where it may be considered promotional or where it will be included in media bound for the public at large. The publicity of such products is also subject to the restrictions relating to or included in the relevant marketing authorisations.

***Marketing***
To market these products, the corresponding premises must have a health licence, a health officer, control books and acquisition permits and be registered with the Federal Taxpayer Registry.

**Comment**

The General Health Law Regulations for the Control of Production, Investigation and Medicinal Use of Cannabis and its Pharmacological Derivatives make it possible for individuals and legal entities to engage in activities regarding the manufacture, development, research and investigation, marketing, import and export of raw materials, pharmacological derivatives and medicines derived from cannabis. This represents an important development for these products in Mexico – not to mention new business opportunities.

*For further information on this topic please contact José Alberto Campos Vargas at Sanchez-DeVanny Eseverri SC by telephone (+52 55 5029 8500) or email (jacampos@sanchezdevanny.com). The Sanchez-DeVanny Eseverri SC website can be accessed at www.sanchezdevanny.com.*