# Commercialisation of Healthcare in Mexico: Overview

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A Q&A guide to the commercialisation of healthcare in Mexico.

This Q&A provides a high-level overview of the regulatory framework for the commercialisation of medical products in Mexico. It covers the key requirements for manufacturing, advertising and selling drugs, medical devices, biological products and natural health products.

## Medicines

1. What is the definition of medicine (or equivalent) in your jurisdiction?

Under the General Health Law, a medicine is defined as any substance or mixture of substances of natural or synthetic origin that meets all the following conditions:

- Has a therapeutic, preventive or rehabilitative effect.
- Is presented in pharmaceutical form.
- Is identified as a medicine by its pharmacological activity, and physical, chemical and biological characteristics.

A product that contains nutrients is considered a medicine if all the following apply:

- It is a preparation that contains vitamins, minerals, electrolytes, amino acids or fatty acids in concentrations higher than those found in natural foods.
- It is presented in a defined pharmaceutical form.
- The indication for use includes therapeutic, preventive or rehabilitative effects.

The General Health Law defines a drug as any natural, synthetic or biotechnological substance that meets the following conditions:

- Has some pharmacological activity.

 

- Is identified by its physical, chemical or biological actions.
- Is not presented in a pharmaceutical form.
- Meets the conditions to be used as a medicine or ingredient of a medicine.

2. What authorities are responsible for regulating the manufacture, marketing and advertising of medicines?

The Mexican authority responsible for enforcing the regulatory framework relating to medical products is the Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS), which is part of the Ministry of Health (*Secretaria de Salud*) (*see Question 30, COFEPRIS*).

Regarding advertising, the Federal Consumer Protection Bureau (PROFECO) can verify that information provided on medical products is true and communicated in a way that does not mislead consumers.

3. What notifications, registrations, approvals and licences are required to manufacture and market medicines and their active pharmaceutical ingredients?

## Manufacturing

Companies manufacturing medicinal products must obtain a manufacturing licence/approval (*licencia sanitaria*) from COFEPRIS.

The requirements for manufacturing approval are mainly set out in the General Health Law and its regulations, as well as Official Mexican Standards (NOMs) setting good manufacturing practices for medicinal products (NOM-059-SSA1-2015) and health requirements for manufacturing (NOM-164-SSA1-2015). These regulate and provide guidelines and standards relating to:

- Workforce conditions in manufacturing facilities (for example, responsibilities, uniforms, and medical examinations).
- Legal and technical documentation.
- Facility requirements.
- Manufacturing, validity and quality controls and protocols.

 

- Standard operation procedure.
- Biosafety measures.
- Packaging.
- Equipment.
- Destruction and elimination of waste.

The time frame for reviewing an application for a manufacturing approval is 60 working days (*General Health Law Regulations*). This is reduced by up to ten working days if the application has been previously reviewed by an authorised third health institution (that is, a private or public company authorised by COFEPRIS to review regulatory submissions).

COFEPRIS ensures that applicable NOMs are followed, from when a facility starts production and at least every two years after then.

## Marketing

To sell a drug, manufacturers must obtain a marketing authorisation from COFEPRIS. To obtain a marketing authorisation, a manufacturer must:

- Have an authorised manufacturing facility, either in Mexico or abroad.
- Provide a certificate of good manufacturing practices.
- Provide a certificate of free sale, for products manufactured abroad.
- Appoint a legal representative.
- Have a pharmacovigilance unit.
- Have a storage facility.
- Provide information on patent rights.
- Provide scientific information on safety and efficacy (for new drugs) or interchangeability tests (for generic drugs).
- Provide information on stability, identity and purity.
- Provide information on prescription.
- File a draft label.
- Pay government fees.

The requirements may vary depending on the manufacturer and the type of drug. For drugs that are developed to treat rare medical conditions (orphan drugs), the standards to prove safety and efficacy (and therefore suitability for sale) depend on the specific orphan drug.

The applicable regulations establish a system of co-operation between COFEPRIS and the Mexican Institute of Industrial Property (IMPI) to prevent the granting of marketing authorisations in violation of exclusive rights.

 

COFEPRIS recently published new guidelines in the *Official Gazette* on the temporary authorisation of health supplies that contribute to the eradication and mitigation of the 2019 novel coronavirus disease (COVID-19) in Mexico. COFEPRIS will apply extraordinary measures in the processes of submission, evaluation and authorisation of health supplies and healthcare establishments, including temporary certification of good manufacturing practices for establishments that contribute to the eradication and mitigation of COVID-19.

4. What are the differences between the regulation of new innovative medicines and generic or biosimilar versions of those medicines?

## Generic Medicines

There are different requirements for patented and generic drugs.

Applicants must prove the safety and efficacy of new products through standard clinical trials. New products include:

- Medicines to be approved for the first time in Mexico.
- Medicines with a new combination of two compounds that do not exist in Mexico.
- Drugs or medications that are on the market but with a different therapeutic indication.

For generic drugs, applicants must only provide information concerning dissolution profiles or bioavailability studies regarding the innovator product, instead of their own clinical trials.

COFEPRIS and the IMPI co-operate to prevent the granting of marketing authorisations in violation of exclusive rights.

Under the IP Regulations, the IMPI must publish every six months a gazette that includes compound patents (*Linkage Gazette*). Formulation patents have been included since 2010, in accordance with a ruling of the Mexican Supreme Court.

When filing an application, a generic applicant must either:

- Prove ownership of, or the holding of a licence for, the corresponding patent registered with the IMPI.
- State under oath that the application does not violate any of the products included in the *Linkage Gazette* and complies with patent law.

## Biocomparables

For biocomparables (biosimilars), applicants must submit clinical tests and, when appropriate, in vitro tests, to prove that the safety, efficacy and quality of the product are comparable (similar) to those of the reference biologic.

 

COFEPRIS has published guidelines on biocomparability tests for Etanercept, Filgrastim, Infliximab, Insulin and its analogous Rituximab and Somatropin. These guidelines are recommendations only, as evaluations are conducted on a case-by-case basis.

The pre-clinical and clinical tests relied on by an applicant for a biocomparable must use the corresponding reference biologic to perform comparative and physico-chemical studies. For this, the applicant must submit:

- In vitro studies.
- A report of comparative test of pharmacokinetic, if required by the Ministry of Health, to show pharmacokinetic comparability on key parameters between the follow-on and the reference biologic.
- Pharmacodynamics test reports.
- Comparative efficacy and safety clinical test to show similarity between the follow-on and the reference biologic.

On 31 May 2021, the Ministry of Health published a decree in the *Official Gazette* amending several provisions of the Health Law Regulations on the approval of biocomparables. The key changes are as follows:

- The approval of biocomparables does no longer involve the Subcommittee for the Evaluation of Biotechnological Products; the opinion of the New Molecules Committee is now sufficient.
- Clinical studies carried out in the country of origin of biocomparables can be submitted as part of the marketing authorisation application. When applying for renewal of the marketing authorization, results of clinical studies carried out in Mexico must be submitted.

Although industry participants welcomed amendments on the approval of biologics, specific rules on the approval of follow-ons have caused debate. There is currently no indication of a data protection period for biologics. The recognition of data package exclusivity rights for biologics can only currently be achieved through litigation. Accordingly, there are concerns on the accurate application by COFEPRIS of the linkage provisions.

## 5. What are the differences between the regulation of prescription and over-the-counter medicines?

The same regulations generally apply to prescription and over-the-counter medicines. However, over-the-counter medicines can be advertised to the general public, subject to prior approval from COFEPRIS. Media channels must request certified copies of the corresponding marketing authorisations before releasing advertisements. Any visual or audio advertisement for over-the-counter medicines must:

- Include the message "consult your physician."
- Mention any required precautions when the use of the medicine represents a danger for persons with an existing pathology.

 

(*Article 43, General Health Law Regulation regarding Advertising (Reglamento de la Ley General de Salud en Materia de Publicidad)* (RLGSMP).)

6. Are there fewer or different requirements for the approval of medicines that have already been licensed or approved in another jurisdiction?

There is a special procedure for medicines to be approved for the first time in Mexico which have previously been approved by one of the following foreign agencies:

- European Medicines Agency.
- US Food and Drug Administration.
- Health Canada.
- Swiss Agency for Therapeutic Products.
- Australian Therapeutic Goods Administration.

These specific rules were issued by COFEPRIS. The approval procedure is based on the dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 60 working days.

In January 2020, the Ministry of Health published a decree in the *Official Gazette* that allows the importation of medicinal products already authorised in certain jurisdictions (that is, Canada, the EU, Switzerland and the US) without a domestic marketing authorisation. Certain requirements must be met before importation.

7. Is it possible to sell medicines to or buy medicines from other jurisdictions?

A marketing authorisation issued by COFEPRIS is required to sell medicines manufactured in other jurisdictions. In Mexico, selling medicines that require a specific marketing authorisation without authorisation can be prosecuted as a criminal offence.

Salvador, Ecuador and Colombia have announced that drugs with a marketing authorisation issued by COFEPRIS can be sold in these countries, as COFEPRIS has been recognised as a continental regulatory agency by the Pan American Health Organization.

To export medicines from Mexico, an export must:

 

- Obtain an export permit from COFEPRIS.
- Pay the corresponding government fees.
- Submit the import permit of the country where the goods are to be exported.

8. How is medicine promotion and advertising activity regulated, and what are the general requirements to advertise medicines?

The advertising of medicinal products in Mexico is governed by the:

- RLGSMP.
- Opinions issued by the Advertising Council.

COFEPRIS is responsible for enforcing the rules on advertising.

The Industrial Property Law and the Federal Law for Protection of Consumers also contain provisions on advertising.

Additionally, the National Chamber of the Pharmaceutical Industry issued a Code of Ethics that includes provisions on advertising. While those provisions are not mandatory, failure to comply may result in exclusion or suspension of rights for members of the Chamber.

Only over-the-counter drugs can be advertised to the general public, subject to prior approval from COFEPRIS (*see Question 5*).

Prescription medicines cannot be advertised to the general public (*Article 310, General Health Law*). Prescription drugs can be advertised to health professionals. However, advertisements directed to healthcare professionals can only be published in specialised media and must be based on the approved prescription information (*Article 42, RLGSMP*).

9. Are there additional or alternative regulations for special types of medicines or medicines intended for particular types of patients or diseases?

For drugs that are developed to treat rare medical conditions (orphan drugs), the standards to show safety and efficacy (and therefore suitability for sale) depend on the specific orphan drug.

 

There is a NOM on the prevention and control of diseases (NOM-036-SSA2-2012) that applies to vaccines, toxoids, fabotherapics (serums) and immunoglobulins. This NOM standardises the criteria and procedures for the:

- Application, management, and conservation of biologicals.
- Provision of vaccination services.
- Development of activities relating to the control, elimination and eradication of diseases through vaccination.

10. What controls apply to medicines or components of medicines that derive from humans or animals or incorporate modified genetic material?

The Biosafety, Genetically Modified Organism Law defines genetically modified organisms (GMOs) as living organisms that have acquired a novel genetic combination, generated through the specific use of modern biotechnology techniques. The purpose of this law is to regulate the activities of confined use, experimental release, release in a pilot programme, commercial release, commercialisation, and import/export of GMOs, to prevent, avoid or reduce the possible risks that these activities could cause to human health, the environment and biological diversity, and animal, plant and aquaculture health.

The Intersecretarial Commission for Biosafety and Genetically Modified Organisms (CIBIOGEM) of the National Council of Science and Technology (CONACYT) formulates and co-ordinates the policies of the Federal Public Administration regarding the biosafety of GMOs.

However, this regulatory framework does not apply to the use of GMOs in medicines. Instead, this is governed by the provisions of the General Health Law on biological medicines (*see Question 11*).

## Biological Medicines

11. What is the definition of biological medicines in your jurisdiction and what are the main laws that specifically apply to them (if any)?

The General Health Law (GHL) defines a biological medicine as any substance that:

- Is manufactured by molecular biotechnology.

 

- Has therapeutic, preventive or rehabilitative effects.
- Is provided in dosage form.
- Is identified as such by its pharmacological activity and physical, chemical and biological properties.

The Health Law Regulations set out requirements for the approval of biologics and biosimilars (biocomparables). However, this remains a poorly regulated area (*see Question 4*).

Due to the lack of specialised regulation and industry requirements for biologics, COFEPRIS issued an emergency NOM in 2012 (NOM-257-SSA1-2014). This NOM mainly includes guidelines on good manufacturing practices, safety and efficacy requirements, applicable biocomparability tests, and pharmacovigilance for biologics. However, this NOM does not cater for the differences between biologics and other medicines.

As technological advances are constant in this field, the Mexican Government is still seeking to adopt a suitable regulatory framework for biological medicines.

12. Are there any additional or alternative regulations that apply specifically to biological medicines?

The regulatory framework for biological medicines is generally the same as for other medicines. However, NOM-257-SSA1-2014 specifically applies to biological medicines (*see Question 11*).

The standards to approve biological medicines are essentially the same as for other medicines (that is, they must be safe and effective and have the required quality). However, applications for biological medicines must comply with various additional requirements, in view of their specific characteristics.

## Medical Devices

13. What is the definition of medical device (or equivalent) in your jurisdiction? What is the significance of any legal classifications?

The official website of COFEPRIS defines a medical device as a substance, a mixture of substances, a material, an apparatus, or an instrument (including the computer program that is necessary for the proper use or application of the device) that is either:

- Used alone or in combination with other medical devices to:

 

  - diagnose, monitor and prevent human diseases; or
  - support the treatment of human diseases and disabilities.

- Used in the replacement, correction, restoration or modification of the human anatomy or human physiological processes.

Medical devices include products in the following categories:

- Medical equipment.
- Prostheses.
- Orthoses.
- Functional aids.
- Diagnostic agents.
- Supplies for dental use.
- Surgical and healing materials.
- Hygiene products.

The definition of a medical device differs from the definition of medicine, which only includes substances or a mixture of substances with therapeutic, preventive or rehabilitative effects.

When there is doubt as to whether a product is a medicine or a medical device, a writ can be filed with COFEPRIS requesting a decision on the classification of the product.

Medical devices are classified as follows:

- Class I: well-known devices with proven safety and efficacy that are not commonly introduced in the human body.
- Class II: devices that are introduced in the human body and may have materials or concentrations modifications.
- Class III: devices recently accepted in medical practice which are introduced in the human body for more than 30 days.

14. What authorities are responsible for regulating the manufacture, marketing and advertising of medical devices?

 

COFEPRIS is responsible for enforcing rules relating to medical devices.

PROFECO can verify that information provided on medical devices is true and communicated in a way that does not mislead consumers.

15. What notifications, registrations, approvals and licences are required to manufacture and market medicinal devices?

## Manufacturing

Companies manufacturing medical devices must file an operation notice with COFEPRIS.

The requirements to obtain manufacturing approval are mainly set out in the:

- General Health Law.
- General Health Law Regulations.
- NOM setting good manufacturing practices for medical devices (NOM-241-SSA1-2012).

## Marketing

Selling certain medical devices require a marketing authorisation from the COFEPRIS, in particular those classified in classes II and III. To obtain a marketing authorisation, an applicant must:

- Have an authorised manufacturing facility, either in Mexico or abroad.
- Provide a GMP certificate.
- Provide a certificate of free sale, for products manufactured abroad.
- Appoint a legal representative.
- Have a vigilance unit.
- Have a storage facility.
- Provide information on stability and quality of the device.
- Provide scientific information on non-toxicity, safety and efficacy.
- Provide instructions for use for the device.
- File a draft label.
- Pay government fees.

 

The above requirements can vary depending on the applicant and type of medical device.

Certain medical devices are exempt from marketing authorisation (for example, bandages, immobilisers, pads, and so on).

Exempted devices must still comply with GMP and with labelling standards set out in relevant legislation (for example, the Consumer Protection Regulations), since regulatory authorities have wide powers to verify any potential health risk at any time. In addition, information provided on devices must be true and communicated in a way that does not mislead consumers (*Consumer Law*).

16. Are there fewer or different requirements for medical devices that have already been licensed or approved in another jurisdiction?

COFEPRIS follows a special procedure for medical devices that have already been approved by:

- The US Food and Drug Administration.
- Health Canada.
- The Ministry of Health, Labour and Welfare of Japan.

Approval is essentially based on the dossier filed with the foreign regulatory agency, to reduce approval time frames by up to 30 working days.

17. Is it possible to sell devices to or buy devices from other jurisdictions?

It is possible to sell devices to or buy devices from other jurisdictions. Medical devices can either require or be exempt from a marketing authorisation (*see Question 15, Marketing*).

18. What are the general requirements to advertise medical devices?

 

Medical devices can be advertised to consumers. However, advertising must be authorised by COFEPRIS. Advertising to the general public must:

- Be clear and easily comprehensible.
- Contribute to hygiene education.
- Include cautionary legends if use of the product can involve health risks.

19. What product marking is required for authorised medical devices?

Labels of medical devices must include the marketing authorisation number (if relevant).

## Combination Products

20.Does your jurisdiction recognise combination products? What are the main laws that specifically apply to them (if any)?

There is no law that specifically applies to combination products. However, combination products can obtain a marketing authorisation (for example, implantable insulin pumps).

21. Are there any additional or alternative regulations that apply specifically to combination products?

See *Question 20*.

## Natural Health Products

 

22. Is there a category for natural health products (or equivalent) (including, for example, traditional medicines, homeopathic medicines, supplements, vitamins and minerals)?

There are specific provisions that regulate different types of natural health products, including:

- Herbal, homeopathic and vitamin medicines.
- Herbal remedies.
- Dietary supplements.

23. What authorities are responsible for regulating the manufacture, marketing and advertising of natural health products?

COFEPRIS is responsible for enforcing rules relating to natural health products.

PROFECO can verify that information provided on natural health products is true and communicated in a way that does not mislead consumers.

24. What notifications, registrations, approvals and licences are required to manufacture and market natural health products?

## Manufacturing

Companies manufacturing natural health products must file an operation notice with COFEPRIS.

## Marketing

There are different requirements for the sale of different types of natural health products:

- Herbal, homeopathic and vitamin medicines require a marketing authorisation from COFEPRIS.
- Herbal remedies require recordal (*clave alfanumérica*) (that is, a type of approval) with COFEPRIS.
- Distributors of dietary supplements must give notice (*aviso de suplemento alimenticio*) to COFEPRIS.

 

Applicants for a marketing authorisation relating to herbal, homeopathic and vitamin medicines must:

- Have an authorised manufacturing facility, either in Mexico or abroad.
- Provide a GMP certificate.
- Provide information on the manufacturing process.
- Provide a certificate of free sale, for products manufactured abroad.
- Provide information on stability, identity and purity.
- Provide prescribing information.
- Submit a draft label.
- Include instructions for use, if applicable.
- Pay government fees.

In addition, product monograph and information on storage conditions are required for vitamin medicines.

For recording herbal remedies, applicants must:

- Have an authorised manufacturing facility, either in Mexico or abroad.
- Provide a GMP certificate.
- Provide a certificate of free sale, for products manufactured abroad.
- Provide information on the product and manufacturing process.
- Provide information on identity and purity.
- Submit a draft label.
- Include instructions for use, if applicable.
- Pay government fees.

A notice of marketing for a dietary supplement must include:

- Product information.
- A GMP certificate.
- A draft label.

Some of the requirements above may vary depending on the specific product.

 

25. Are there fewer or different requirements for natural health products that have already been licensed or approved in another jurisdiction?

The holder of an authorisation for a natural health product approved by a recognised foreign regulatory authority can use the dossier filed with this authority when filing a marketing authorisation/recordal application in Mexico. However, COFEPRIS does not automatically recognise approval in another jurisdiction.

26. Is it possible to sell natural health products to or buy natural health products from other jurisdictions and/or electronically?

Selling herbal, homeopathic and vitamin medicines manufactured in other jurisdictions requires a marketing authorisation from COFEPRIS. Recordal with COFEPRIS is required to sell herbal remedies. Selling medicines without a marketing authorisation can be prosecuted as a criminal offence.

Natural health products exempt from marketing authorisation/recordal must still comply with GMP and labelling standards set out in relevant legislation (for example, the Consumer Protection Regulations), as regulatory authorities have wide powers to verify any potential health risk at any time. In addition, information provided on the products must be true and communicated in a way that does not mislead consumers.

There are no specific requirements for the export of natural health products. Therefore, the same requirements apply as for medicines (*see Question 7*).

Natural health products can be sold online.

27. What are the general requirements to advertise natural health products?

The advertising of natural health products in Mexico is permitted and governed by the:

- RLGSMP.
- Opinions issued by the Advertising Council.

COFEPRIS enforces the provisions on advertising.

The advertising of any natural health product is subject to the following restrictions:

 

- Media channels must request certified copies of the relevant marketing authorisation, alphanumeric key (that is, the registration number) or operating notice before publishing related advertisements.
- Any visual or audio advertisement for non-prescription medicines must include the message "consult your physician."
- The advertisement must not present the product as a solution to a disease or symptoms that are different from those included in the marketing authorisation.
- The advertisement must not induce consumers to acquire products through raffles and games of chance, or offer any other product or service in exchange.

Advertisements of herbal medicines must:

- Be limited to one symptomatic effect based on the information contained on the label.
- Not advertise the products as having curative properties.
- Include the message "there is no scientific evidence supporting curative or preventive properties."

Advertisements of dietary supplements must:

- Include the message "there is no scientific evidence supporting curative or preventive properties."
- Not present these products as stimulants or modifiers of the physical or mental state.
- Not induce or promote eating habits that have harmful effects on health.
- Not affirm that a product complies with individual nutritional requirements.
- Not attribute a higher or different nutritional value.
- Not compare or undermine natural food properties.
- Not have confusing, exaggerating or misleading information regarding the composition, origin, effects or other properties of the product, or mention preventive, rehabilitative or therapeutic indications.
- Not include denominations, shapes, statements related to diseases, symptoms, anatomic data, physiological phenomena, or messages that affirm that the product can replace any food or meal.

## Data

28. What data and information laws must be complied with by life sciences businesses that collect, use or otherwise deal in patient data (including through health apps)?

 

Currently, life science businesses that collect, use or otherwise deal in patient data (including through health apps) must comply with the Federal Law for the Protection of Personal Information Held by Private Entities and its Regulations. Mexico does not have a sectoral law dealing with the protection of personal information in the health industry.

## Research

29. What restrictions and regulatory requirements apply to the testing of life sciences products on human and animal subjects?

### Testing on Animals

Under the Regulation of the General Health Law regarding Health Research (RLGMIS), the main requirements that apply to experimental research on animals are as follows:

- Investigations must be designed to minimise animal suffering.
- When it is necessary to euthanise an experimental animal, the procedure used must ensure death without suffering as far as possible.
- Animal research facilities must be adapted to the species, body, habits, postural preferences and characteristics of the animals, to ensure comfort, except when justified by experimental variables.
- Chronic production and maintenance facilities must be supervised by qualified and competent professionals and must allow the growth, maturation, reproduction and normal behaviour of the animals.
- The head of the institution where the investigation is carried out must adopt, and monitor compliance with, safety measures for the care and handling of animals, as well as preventive and vaccination measures necessary for the protection of exposed personnel.

Animal testing must be conducted in official, approved or authorised testing laboratories.

### Testing on Humans

The main legislation on clinical trials is the:

- RLGSMIS.
- NOM for Health Research in Human Beings (*NOM-012-SSA3-2012*).

The Guideline for Good Clinical Practice E6(R1) is taken into account.

This legislation is enforced by the Ministry of Health through COFEPRIS.

 

The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued the following self-regulatory codes:

- Code of Ethics and Transparency of the Pharmaceutical Industry.
- Code of Good Practices of Promotion (GPP Code).
- Code of Good Practices of Interaction of the Pharmaceutical Industry with Patient Organisations (GPI Code).

**Authorisations.** Any research on human beings must be approved by COFEPRIS. This research can include testing new medicinal products or new uses, dosages or administration routes for already approved medicinal products. The main requirements for an application for authorisation from COFEPRIS are as follows:

- Approval by an independent ethics committee registered with the Ministry of Health.
- Approval by the medical institution or institutions where the clinical trials will be conducted. These institutions must be approved by COFEPRIS to conduct clinical trials.
- Clinical trial protocol (including schedule and approximate amount of medicinal products to be imported).
- Written informed consent templates.
- Pre-clinical and clinical data that justifies conducting the research.
- Description of available resources to conduct the research and to address emergencies (including a statement of sponsorship).
- Written letter by the qualified investigator acknowledging their responsibilities, and details of both them and their staff.
- Medical assistance and financial indemnification for damage caused by the clinical trial must be provided to research participants.

**Consent.** Investigators must collect informed consent from research participants in a formal written document, which must also be signed by two witnesses. The requirements for valid consent are that a participant grants it on a voluntary basis, with capacity to do so and sufficient information (knowing potential risks and benefits). Participants have the right to leave the trial at any time. Investigators must ensure post care for them, until it is clarified that there are no damages derived from the research.

**Trial Pre-Conditions.** Pre-clinical data must be collected to justify whether clinical trials can be conducted. The RLGSMIS requires measures to ensure that the investigator does not have conflict of interest, to:

- Protect the rights of research participants.
- Maintain accurate results.
- Allocate resources.

**Procedural Requirements.** The RLGSMIS and the NOM for Health Research in Human Beings set out the guidelines and standards for the clinical trial protocol, including rules concerning documentation, compilation, confidentiality and reports.

 

Essentially, any clinical trial must be conducted following ethical guidelines and must always respect the dignity, rights and welfare of human beings (*NOM for Health Research in Human Beings*).

Clinical trials can specify certain steps or goals to be achieved. The principal researcher must compile a final technical report for the clinical trial. When clinical trials last longer than one year, annual technical reports must be compiled for health authorities. The following NOMs apply for:

- Medicinal products labelling (NOM- 072- SSA1-2012).
- Pharmacovigilance (NOM-220-SSA1-2012).
- Interchangeability and biocomparability tests (NOM-177-SSA1-2013).
- Biological products (NOM-257-SSA1-2014).
- Good manufacturing practices for medicinal products (NOM-059-SSA1-2015).
- Good manufacturing practices for active ingredients (NOM-164-SSA1-2015).

Sponsors and investigators must also comply with privacy and data protection laws (*see Question 28*).

**Transparency and Reporting Requirements.** The sponsor and principal investigator must report all expected and unexpected suspicions, events and adverse reactions of which they are aware directly to the centres or pharmacovigilance units within:

- 15 calendar days from identification, for serious events.
- 30 calendar days from identification, for non-serious events.

When three or more similar cases of suspected adverse reactions occur within 24 hours, with the same drug and at the same location, the cases must be reported within 24 hours or the next business day.

## Reform

30. Are there any plans to reform the rules on the development, manufacture, marketing and advertising of life sciences products and services?

### COFEPRIS

The Decree of incorporation of various administrative units and decentralised bodies of the Ministry of Health was published in the *Official Gazette* on 19 August 2020. The decree incorporates COFEPRIS to the Undersecretary for Prevention and Promotion of Health of the Ministry of Health.

 

Previously, COFEPRIS was a decentralised agency of the Ministry of Health with administrative, technical and operational autonomy, as well as its own legal personality and assets. COFEPRIS and its faculties now depend directly from the Undersecretary for Prevention and Promotion of Health.

This reform raises concerns for the independence and autonomy of COFEPRIS. Additionally, it may give rise to conflicts of interest, as some public policies regarding the acquisition of medicines and medical supplies are drafted by the Undersecretary.

## Proposal for a Law on the Federal Commission for the Prevention and Protection Against Sanitary Risks

This proposal was submitted to Congress on 30 September 2020 and aims to:

- Strengthen the mechanisms to prevent corruption and promote responsible spending within the Commission, without creating costly new structures.
- Promote consolidated purchases of medicines and medical supplies.
- Promote investment in research of effective treatments and the national production of medicines.
- Improve customer service.
- Simplify procedures and increase the use of information technologies in internal procedures.
- Protect priority groups.
- Improve response to sanitary emergencies.

As the proposal is very recent, it is not possible to know when it will be adopted.

## Amendment to the General Health Law Regulations

The General Health Law provides that the packaging of medicines used in the public sector and in the private sector must be differentiated. On 31 May 2021, the Regulation of Health Supplies was amended to provide that the packaging of medicines to be used in the public sector must include the words "Not for Sale" or "Property of the Health Sector."

The amendment entered into force on 1 June 2021.

## Patent Linkage

In 2020, the Lower Chamber of Representatives published two proposals to limit the scope of the patent linkage system. Key proposals include the following:

- The grant of use patents/claims must be expressly prohibited.
- The *Linkage Gazette* must be a list of patents covering reference medicines prepared by COFEPRIS.
- Co-operation between COFEPRIS and the IMPI will be through a gazette in which COFEPRIS will include an active ingredient patent for each reference medicine.

 

- Marketing authorisations should not be denied on the ground of formulation or use patents.

Generally, the proposals conflict with Article 28 of the Constitution and various articles of the Industrial Property Law. Additionally, the initiative contradicts the patent system itself as well as the United States-Mexico-Canada Agreement (USMCA), which entered into force on 1 July 2020.

These proposals are part of various attempts to limit the patent linkage system. The authors consider that it is unlikely to be approved as presented.

## Marketing Authorisations

A proposal to amend Article 376 of the General Health Law was introduced on 3 December 2020. The proposal removes the requirement to renew marketing authorisations every five years. There is also a proposal to insert an Article 376TER into the General Health Law to set out the obligations of holders of marketing authorisations with indefinite validity (such as compliance with pharmacovigilance and other requirements to ensure the safety, efficacy and quality of the product).

The proposal has been submitted to the Health United Commission and Legislative Studies of the Senate.

## Medical Devices

A recent initiative aims to regulate the use of medical devices. This would involve amending both the General Health Law and the General Health Law Regulations. The main features are as follows:

- Introduce more specific regulations on prosthetics, diagnostic agents, and dental devices.
- Replace the terms "essential nutrients for health" with "medical devices."
- Indicate that applicants requesting authorisation for the sale, supply, or importation of medical devices must have a marketing authorisation.
- Provide that the indications for use of medical devices must be detailed in the instructions of the relevant product in printed or electronic form.

The proposal was introduced on 17 June 2020 and has been submitted to the Health United Commission and Legislative Studies of the Senate.

## Telemedicine

A recent initiative aims to implement telemedicine. This would involve making amendments to the General Health Law. The proposals are that:

- Medical prescriptions should be issued in digital form.
- The provision of prescriptions in digital form should be implemented by public and private agencies as well as the National Health System, subject to any COFEPRIS regulations.

The proposal was introduced on 18 March 2021 and has been submitted to the Health United Commission and Legislative Studies of the Senate.

 

## Cannabis Regulation

On 12 January 2021, the General Health Law Regulation on Sanitary Control for the Production, Research and Medicinal Use of Cannabis and its Pharmacological Derivatives (Cannabis Regulation) was published in the *Federal Official Gazette*.

The new Cannabis Regulation aims to regulate, promote, and monitor the use of cannabis and its derivatives for medicinal use. The regulation includes provisions on primary production, research, manufacturing of pharmacological derivatives and medicines, distribution, advertising, prescription, and commercialisation.

The Cannabis Regulation came into force on 13 January 2021.

## Price Regulation

A proposed regulation aims to regulate the price of medicines to ensure proper access. According to the proposal, the price of medicines would be reviewed and evaluated each year (or at any other time, if necessary) based on economic, technical or therapeutic conditions.

The proposal was introduced on 19 February 2019 and has been submitted to the Health United Commission and Legislative Studies of the Senate.

## Government Procurement of Medicines

The Amendment to Article 1 of the Public Sector Procurement, Leasing and Services Law came into force on 12 August 2020. This allows the Mexican Government to buy medicines through intergovernmental organisations.

Following the recent agreement between the Institute of Health for the Welfare of the United Mexican States (INSABI) and the United Nations Office for Project Services (UNOPS), the first information session open to the national and international market was held on 5 October 2020 for the management of the consolidated purchase of medicines and healing materials for the period 2021-2024. The following announcements were made:

- 2,380 codes for medical supplies and patented medicines are planned for tender, including single source and generics. More than 800 national and international companies interested in participating in more than 90% of the codes have already been identified, with an initial investment of about USD4 billion.
- Timelines have been provided for the 2021 procurement process, for patented and generic medicines and critical medical supplies, as well as estimates for the 2022-2024 procurement process.
- The stages of the bidding procedure were briefly explained, emphasising that it will be carried out in accordance with UNOPS regulations, ensuring high standards of transparency and fair prices for quality, safe and effective products.
- All types of vaccines are exempt from this process.
- The procedure applicable to marketing authorisations was explained.

In light of the health emergency caused by the 2019 novel coronavirus disease (COVID-19) pandemic and shortages of various health supplies, the Mexican Congress urgently approved a decree amending the current Procurement Law.

 

The amendment allows the Mexican Government to buy medicines and other health supplies through international organisations without having to comply with the procedures set out in the current regulations on public procurement. The decree aims to increase options to buy medicines at lower prices, through transparent and efficient processes.

This reform has generated controversy by allowing the federal government to buy medicines through international organisations such as UNOPS and the World Health Organization (WHO).

Criticisms of the reform also relate to the ambiguity of the new rules on the acquisition process and whether supplies must comply with domestic regulations and regulatory standards. It appears that the federal government will have discretion to apply this buying process rather than the regular public bidding process.

Within this new legal framework, the government has already signed a first agreement with UNOPS and the WHO to buy medicines through these mechanisms.

Publication of the decree in the *Federal Official Gazette* is pending.

## New Healthcare Strategy

The goal of this scheme, announced in November 2019, is to introduce universal and free coverage of both medicines and medical care in Mexico. The scheme would be implemented in several stages, which require amendments to the current regulations. According to the official strategy outlined by the Mexican President, the key goals are as follows:

- Federalisation of the health system. This would be implemented through the gradual signing of agreements with the 32 Mexican states, which would transfer their power to regulate health matters to the federation.
- The Mexican Social Security Institute (IMSS), the Mexican Civil Service Social Security and Services Institute (ISSSTE) and other State Social Security entities will provide equal and non-discriminatory services to all persons, regardless of social security status.
- The Federal National Formulary will be abolished. The Federal National Formulary lists medicines that can be prescribed and indications authorised by the General Health Council (it includes codes, description, indication, route of administration, dosage, generalities, adverse effects, contraindications, precautions, and risk during pregnancy).
- The UN will observe public bids for acquisitions of medicines, equipment and medical devices.
- There will be a preference for national public bids over international bids (but bids will be open to international companies and products).
- A MXN50 billion increase for the health budget. How this proposal will be applied remains uncertain, and the Mexican Government is currently working on a strategy.

## Self-Medication

Proposals that aim to prevent self-medication were introduced on 30 March 2017 and have been submitted to the Chamber of Deputies. These involve amending Articles 112 and 310 of the General Health Law. The proposals are that:

 

- Health education should provide guidance and training on the dangers and risks of self-medication and self-prescription.
- The advertising of over-the-counter medical products and herbal remedies should:
  - include the legend: "self-medication may aggravate the disease"; and
  - outline or provide details of the general characteristics of secondary reactions (that is, the effects of self-medication).

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**Recent Transactions**

- Participated in cases against the unconstitutionality and inefficiency of certain amendments to the Federal Law of Administrative Proceedings in Mexico, which have affected the venues for challenging resolutions by the Mexican Institute of Industrial Property.
- Sponsor of a proposal to modify the litigation system of industrial property, limiting the Mexican Institute of Industrial Property to an exclusive registration authority, and transferring jurisdiction to civil courts for infringement cases and to administrative courts for cases related to the annulment of trade mark registrations and patents.

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