Practical Law™
GLOBAL GUIDE 2018
COMMERCIALISATION OF HEALTHCARE

Commercialisation of healthcare in Mexico: overview

Alejandro Luna F, Erwin Cruz and Luz Elena Elías Olivares

global.practicallaw.com/7-618-2972

REGULATORY OVERVIEW

1. What is the regulatory framework for medical products?

Legislation

The regulatory framework for medical products (that is, drugs, medical devices and biological products for human use) is set out in the following federal laws:

- General Health Law (*Ley General de Salud*).
- General Health Law Regulations (*Reglamento de Insumos para la Salud*).
- Official Mexicans Standards (*Normas Oficiales Mexicanas*) (NOMs).

Regulatory authorities

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*).

For more information on the COFEPRIS see box: *The regulatory authority.*

Private parties

The health system in Mexico includes some private parties that are involved in the commercialisation of medical products, including:

- Pharmaceutical companies.
- Distributors.
- Third health institutions (that is, private or public companies authorised to pre-examine regulatory submissions).

2. What types of medical products are regulated?

The medical products that are regulated in Mexico are:

- Drugs.
- Biological products.
- Traditional medicines.
- Homeopathic medicines.
- Medical devices.

DRUGS

3. What are the general requirements for a drug to be manufactured, advertised and sold?

Manufacturing

Companies manufacturing medicinal products must obtain a manufacturing licence/approval (*licencia sanitaria*) from the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

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

- Workforce conditions in the manufacturing facilities (including, 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 General Health Law Regulations set 60 working days as the time frame for reviewing an application for a manufacturing approval. 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 the COFEPRIS to review regulatory submissions).

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

Advertising

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

- General Health Law Regulation regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RLGSMP).
- Opinions issued by the Advertising Council.

The COFEPRIS is responsible for enforcing the provisions above.

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. Although those provisions are not mandatory, failure to comply may result in a suspension of rights as a member of the Chamber or in expulsion from it.

Only over-the-counter drugs can be advertised to the general public, subject to prior approval from the COFEPRIS. Media channels must request certified copies of the corresponding marketing authorisations before releasing the advertisements. Any visual or audio advertisement for over-the-counter drugs must (*Article 43, RLGSMP*):

- Include the message "consult your physician".
- Mention any required precautions when the use of the drug represents a danger in the case of an existing pathology.

It is not possible to advertise prescription medicines 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*).

Sale

To sell any drug, manufacturers must obtain a marketing authorisation from the COFEPRIS. To obtain a marketing authorisation, the 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 type of drug.

The applicable regulations establish a system of co-operation between the COFEPRIS and the Mexican Institute of Industrial Property. The main reason for this is to prevent the granting of marketing authorisations in violation of exclusive rights.

4. Are there different requirements for patented and generic drugs?

There are different requirements for patented and generic drugs.

For patented 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.

The Federal Commission for Protection against Sanitary Risk (COFEPRIS) and the Mexican Institute of Industrial Property (IMPI) will co-operate to prevent the granting of marketing authorisations in violation of exclusive rights.

Under the IP Regulations, 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 the application, the generic applicant must either:

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

5. What authority is responsible for regulating the manufacture, advertising and sale of drugs?

The authority responsible for regulating the manufacture, advertising and sale of drugs is the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

For more information on the COFEPRIS see box: *The regulatory authority*.

6. Are there fewer or different requirements for drugs that have already been licensed or approved in another jurisdiction?

There is a special procedure for drugs to be approved for the first time in Mexico and that 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 the Federal Commission for Protection against Sanitary Risk (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.

Industry participants have welcomed these rules, although they are still being tested.

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

A marketing authorisation issued by the Federal Commission for Protection against Sanitary Risk (COFEPRIS) is required to sell drugs manufactured in other jurisdictions. In Mexico, selling drugs

without a marketing authorisation can be prosecuted as a criminal offence.

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

8. Is it permitted to advertise drugs to consumers? Are there restrictions on advertising?

Only over-the-counter drugs can be advertised to the general public, subject to approval by the Federal Commission for Protection against Sanitary Risk (COFEPRIS). Media channels must require certified copies of the corresponding marketing authorisations for medicines before releasing the advertisements.

An advertisement must be limited to indicating the general characteristics of the product, its therapeutic properties and use.

Any visual or audio advertisement for over-the-counter drugs must (*Article 43, Regulation of the General Law of Health regarding Advertising (Reglamento de la Ley General de Salud en Materia de Publicidad)* (RLGSMP)):

- Include the message "consult your physician".
- Mention any required precautions when the use of the drug represents a danger in the case of an existing pathology.

Advertising prescription medicines to the general public is prohibited (*Article 310, General Health Law*). Prescription medicines can be advertised to health professionals. However, advertisements directed to health professionals can only be published in specialised media and must be based on medical prescription information (*Article 42, RLGSMP*).

The RLGSMP grants COFEPRIS strong powers to:

- Request media channels to remove any suspected illegal advertisement within 24 hours.
- Impose a fine of up to 16,000 times the minimum wage (about US$72,000) on entities that publish illegal advertisements.

Electronic advertisement is governed by the general rules on advertising in Article 2 of the RLGSMP. The COFEPRIS is currently increasing its monitoring of internet advertisements for medical products, which had been less strict than for television or radio advertisements.

MEDICAL DEVICES

9. What is the definition of medical device in your jurisdiction?

The official website of the Federal Commission for Protection against Sanitary Risk (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 instrument's proper use or application) that is:

- Used alone or in combination with other medical devices to:
  - diagnose, monitor and prevent human diseases;
  - 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 to the definition for drugs, which only includes substances or a mixture of substances with therapeutic, preventive or rehabilitative effects.

Where there is doubt as to whether a product is a drug or a medical device, a writ can be filed with the COFEPRIS, requesting their decision on the category to which the product belongs.

10. What are the general requirements for a medical device to be manufactured, advertised and sold?

Manufacturing

Companies manufacturing medical devices must file an operation notice with the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

The requirements for manufacturing approval are set out mainly in the General Health Law, its regulations and Official Mexican Standards (NOMs) setting good manufacturing practices for medical devices (NOM-241-SSA1-2012).

Medical devices are classified as follows:

- **Class I.** Well-known devices with proven safety and efficacy, which are not commonly introduced in the human body.
- **Class II.** Devices which 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.

Advertising

The advertising of medical devices must be authorised by the COFEPRIS. The authorisation must state whether the product can be advertised to the general public or to health professionals only.

Advertising to the general public must:

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

Sale

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 certificate of good manufacturing practices (GMP).
- 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 the 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 truthful and communicated in a way that does not mislead consumers (*Consumer Law*).

11. What authority is responsible for regulating the manufacture, advertising and sale of medical devices?

The authority responsible for enforcing rules relating to medical devices is the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

For more information on the COFEPRIS see box: *The regulatory authority.*

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

The Federal Commission for Protection against Sanitary Risk (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.

13. 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.

Exempted devices must still comply with good manufacturing practices and with the labelling standards set out in the applicable provisions, such as the Consumer Protection Regulations, since regulatory authorities have wide powers to verify any potential health risk at any time.

In addition, under the Consumer Law, information provided on products must be truthful and communicated in a way that does not mislead consumers.

14. Is it permitted to advertise medical devices to consumers? Are there restrictions on advertising?

It is permitted to advertise medical devices to consumers. However, advertising must be authorised by the Federal Commission for Protection against Sanitary Risk (COFEPRIS). Advertising to the general public must:

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

BIOLOGICAL PRODUCTS

15. What are the general requirements for a biological product to be manufactured, advertised and sold?

Manufacturing

Companies manufacturing biological products must obtain a manufacturing authorisation from the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

The General Health Law and its regulations were recently amended to include provisions on the approval of biologics and biocomparables (biosiomilars). Rules on the approval of biological innovators and biocomparables give the Assessment Sub-Committee on Biotech Products (*Subcomité de Evaluación de Productos Biotecnológicos*) (SEPB) powers to:

- Assess technical and scientific data in connection with clinical trials, approval or renewal of innovator biologics or follow-on biologics (biocomparables).
- Issue opinions on the characterisation of biologics as innovators, reference products or biocomparables.

The new rules also include transitional provisions for the renewal of marketing authorisations of biologics granted before the amendments to the General Health Law Regulations for Biologics came into force. These provisions establish that:

- COFEPRIS will assess whether the renewal of biologics applications refer to innovators or biocomparables.
- Renewal applications for innovators will not require assessment by the SEPB.
- Renewal applications for biocomparables will require prior assessment by SEPB to identify the product of reference in order for applicants to submit the corresponding tests.

The transitional provisions only apply to renewal applications submitted before 31 December 2015.

Advertising

The advertising of biological products must be authorised by the COFEPRIS. The authorisation must state whether the product can be advertised to the general public or to health professionals only. However, due to the nature of this type of products, advertising is likely to be authorised in relation to health professionals only.

Sale

A marketing authorisation by the COFEPRIS is required to sell any biological product. Generally, an applicant for a marketing authorisation of an innovator 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.
- Include monographs and technical details of the master cell bank, product and manufacturing process.
- Provide scientific information on the quality, safety and efficacy of the product (clinical and pre-clinical trials).
- Include stability, identity and purity tests.
- Have an intensive pharmacovigilance programme.
- Provide prescribing information.
- File a draft label.
- Pay government fees.

Clinical trials for innovator biological products must take place in Mexico where the product is to be manufactured in Mexico. For products manufactured abroad, the Ministry of Health can request that a clinical trial takes place in Mexico when the Sub-Committee on Evaluation of Biotechnological Products of COFEPRIS considers that this is necessary.

Applicants for biocomparables must comply with the above requirements. However, their pre-clinical and clinical tests must be based on a biological reference drug, which must be used to perform physico-chemical comparative studies. For this purpose, the applicant must submit the following:

- *In vitro* studies, although the Ministry of Health can exempt an applicant from this requirement.
- A report of comparative pharmacokinetic test, if required by the Ministry of Health, to demonstrate pharmacokinetic comparability on key parameters between the biocomparable and the reference biological product.
- Pharmacodynamics test reports.
- A comparative efficacy and safety clinical test to show the similarity between the biocomparable and the reference biological product.

The requirements above may vary. The Ministry of Health can impose specific requirements for any biological product on a case-by-case basis, taking into account the opinion of the COFEPRIS Committee of New Molecules, which will have consulted its Sub-Committee on Evaluation of Biotechnological Products.

16. What authority is responsible for regulating the manufacture, advertising and sale of biological products?

The authority responsible for enforcing the rules relating to biological products is the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

For more information on the COFEPRIS see box: *The regulatory authority.*

17. Are there fewer or different requirements for biological products that have already been licensed/approved in another jurisdiction?

Research and development companies can benefit from a special procedure for biological drugs to be approved for the first time in Mexico which have already been approved by the following regulatory agencies:

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

The Federal Commission for Protection against Sanitary Risk (COFEPRIS) recently issued rules to set up this new procedure. The procedure is essentially based on the dossier filed with the foreign regulatory agency, to reduce approval time frames. Industry participants have welcomed these new rules, although they are still being tested.

18. Is it possible to sell biological products to or buy biological devices from other jurisdictions?

A marketing authorisation from the Federal Commission for Protection against Sanitary Risk (COFEPRIS) is required to sell biological products manufactured in other jurisdictions. Selling biological products without a marketing authorisation can be prosecuted as a criminal offence.

19. Is it permitted to advertise biological products to consumers? Are there restrictions on advertising?

The advertising of any biological product must be authorised by the Federal Commission for Protection against Sanitary Risk (COFEPRIS). As biological products are complex medicines, advertisement relating to these products cannot:

- Mention non-analysed properties.
- State that a product is indispensable.
- State that being a biological product is an advantage over other products.

NATURAL HEALTH PRODUCTS

20. Is there a category for natural health products (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.

21. What are the general requirements for natural health products to be manufactured, advertised and sold?

Manufacturing

Companies manufacturing natural health products must file an operation notice with the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

Advertising

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

- General Health Law Regulation regarding Advertising (*Reglamento de la Ley General de Salud en Materia de Publicidad*) (RLGSMP).
- Opinions issued by the Advertising Council.

The 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 for this category of product, 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 the 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, nor hold preventive indications, rehabilitative or therapeutics.
- 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.

Sale

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

- Herbal, homeopathic and vitamin medicines require a marketing authorisation from the COFEPRIS.
- Herbal remedies require recordal (*clave alfanumérica*) (that is, a type of approval) with the COFEPRIS.
- Distributors of dietary supplements must give notice (*aviso de suplemento alimenticio*) to the 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 certificate of good manufacturing practices (GMP).
- 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 certificate of GMP.
- Provide a certificate of free sales, 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 certificate of GMP.
- A draft label.

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

22. What authority is responsible for regulating the manufacture, advertising and sale of natural health products?

The authority responsible for enforcing the rules relating to health products is the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

For more information on the COFEPRIS see box: *The regulatory authority.*

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

The holder of 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, approval in another jurisdiction is not recognised by the Federal Commission for Protection against Sanitary Risk (COFEPRIS).

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

A marketing authorisation issued by the Federal Commission for Protection against Sanitary Risk (COFEPRIS) is required to sell herbal, homeopathic and vitamin medicines manufactured in other jurisdictions. A 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 good manufacturing practices 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 truthful and communicated in a way that does not mislead consumers.

25. Is it permitted to advertise natural health products to consumers? Are there restrictions on advertising?

Natural health products approved as over-the-counter medicines and herbal medicines can be advertised to the general public, subject to approval by the Federal Commission for Protection against Sanitary Risk (COFEPRIS). Before releasing advertisements, media channels must require certified copies of the marketing authorisation for the product.

Advertisements must be limited to indicating the general characteristics of the product, its therapeutic properties and use.

Any visual or audio advertisement of natural health products must:

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

REFORM

26. Are there any plans to reform the rules on the development, manufacture, advertising and sale of medical products?

Mexico is taking part in negotiations for the North American Free Trade Agreement (NAFTA). This will have an impact on all areas relating to intellectual property, including pharmaceutical patents and the regulation of healthcare.

There is also a proposal for the introduction of a regulation for the medical use of marijuana.

THE REGULATORY AUTHORITY

Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS)

W *www.cofepris.gob.mx*

Principal responsibilities. COFEPRIS is part of the Ministry of Health (*Secretaria de Salud*) and is responsible for enforcing the regulatory framework relating to medical products.

COFEPRIS is in charge of protecting public health by ensuring the safety, efficacy and security of human drugs, biological products, medical devices, health services, food and beverages, tobacco, cosmetics, pesticides, fertilisers and any other substance that can be a risk to the population. Specifically, COFEPRIS' responsibility is to exercise sanitary regulation, control and promotion through the:

- Control and supervision of health institutions.
- Prevention and control of environmental factors that can harm the population.
- Control of basic occupational health and hygiene.
- Sanitary control of medical products and services (including their import and export) and of establishments that process such products.
- Sanitary control of the process, use, maintenance, import, export, and final disposal of medical equipment, prosthetics, orthesis, functional aids, diagnostic agents, orthodontic goods and services, surgical and health materials, and of the establishments that process these products.
- Sanitary control of the publicity for health activities, products and services.
- Sanitary control of the disposal of organs, tissue and their components, and human cells.
- International public health system.
- Sanitary control of organ, tissue, and human cell donation and transplant.

ONLINE RESOURCES

Federal Commission for Protection against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS)

W *www.cofepris.gob.mx* (for translation, use the browser's translation option)

Description. The official website of the COFEPRIS provides information related to chemical drugs, biological products, medical devices, including the corresponding legal framework, lists of marketing authorisations and official forms. Translation is for guidance only. The website of the COFEPRIS is not 100% reliable as it is not frequently updated.

Practical Law **Contributor profiles**

Alejandro Luna, Partner

Olivares

T +52 55 53 22 30 00
F +52 55 53 22 30 01
E alf@olivares.com.mx
W www.olivares.com.mx/En

Professional qualifications. Bachelor Degree, Universidad Latinoamericana, Mexico, 1996; four diplomas, Universidad Panamericana.; LLM in intellectual property law, Franklin Pierce Law Center, US.

Areas of practice. Biotechnology/pharmaceutical law; intellectual property litigation; anti-piracy; anti-counterfeiting; alternative dispute resolution; IP enforcement.

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.

Languages. English, Spanish

Professional associations/memberships. Member of the Mexican Association for IP Protection (AMPPI); member of the International Trademark Association (INTA).

Luz Elena Elías, Associate

Olivares

T +52 55 53 22 30 00
F +52 55 53 22 30 01
E iom@olivares.com.mx
W www.olivares.com.mx/En

Professional qualifications. LLM on Patents, Trademarks and Copyrights, University of Alicante 2002; LLM on International Law, University of Ottawa 1996, National Autonomous University of Mexico (UNAM) 1994

Areas of practice. IP litigation; pharmaceutical law; regulatory advisory.

Recent transactions. Dealt with the unconstitutionality of the injunctions provision of the Intellectual Property Law.

Languages. Spanish, English, French

Professional associations/memberships. Mexican Association for IP Protection (AMPPI).

Erwin Cruz, Associate

Olivares

T +52 55 53 22 30 00
F +52 55 53 22 30 01
E ecs@olivares.com.mx
W www.olivares.com.mx/En

Professional qualifications. LLM on Biotech Law and Ethics (first), University of Sheffield, 2014; postgraduate IP specialisation (first), National Autonomous University of Mexico (UNAM), 2009; LLB (first), UNAM, 2006

Areas of practice. Biotech/pharmaceutical law, patent law, IP rights litigation, enforcement and regulatory compliance.

Recent transactions

- Awarding of damages and lost profits regarding a patented blockbuster drug.
- Achieving court's decisions revoking regulatory approvals for follow-on products of patented blockbuster drugs.
- Awarding the first court's precedent in Mexico over patentability of computer-implemented inventions (Microsoft).
- McDonalds: several litigation proceedings against formative trade marks.

Languages. English, Spanish

Professional associations/memberships. Mexican Association for IP Protection (AMPPI).