Life Sciences Commercialisation in Mexico: Overview

by Alejandro Luna F, Armando Arenas, and Karla Paulina Olvera Acevedo, *Olivares*

Country Q&A | Law stated as at 01-Oct-2023 | Mexico

A Q&A guide to life sciences commercialisation in Mexico.

This Q&A provides a high-level overview of key practical issues, including the life sciences sector, pricing and state funding, distribution and sale, importing, advertising, patents, trade marks, competition law, and product liability.

Life Sciences Sector Overview

1. Give a brief overview of the life sciences sector in your jurisdiction.

The Federal Commission for Protection Against Sanitary Risk (*Comisión Federal para la Protección contra Riesgos Sanitarios*) (COFEPRIS). COFEPRIS is certified as a level 4 national regulatory authority that is competent and efficient in the performance of the health regulation functions recommended by the Pan American Health Organization (PAHO) and World Health Organization (WHO) to guarantee the safety, efficacy, and quality of medicines. It is responsible for making drugs and medical devices regulation more efficient, encouraging the use of regulatory decisions from other jurisdictions, and formulating and implementing strategies to strengthen its regulatory system.

In July 2020, the government signed a procurement agreement with the United Nations Office for Project Services (UNOPS). Under this agreement, UNOPS directly purchases medications on behalf of Mexican health institutions, according to UNOPS' procurement policies and procedures. Although the government's intention was for UNOPS to be exclusively responsible for the acquisition of medicines, at the end of 2021 it was announced that two independent consolidated acquisitions would be carried out, one by the Institute of Health for Wellbeing (*Instituto de Salud para el Bienestar*) (INSABI) and another by UNOPS. In December 2021, both INSABI and UNOPS independently announced tenders for medicines to be acquired by the government.

On 30 May 2023, the Decree reforming, adding, and repealing various provisions of the General Health Law, to regulate the Health System for Welfare, came into effect. The regulatory and administrative provisions necessary for the application of this Decree are pending issue. It disestablishes the Institute of Health for Welfare (*Instituto de Salud para el Bienestar*) (INSABI), providing that the functions of INSABI will become part of the Mexican Institute of Social Security for Welfare (*Instituto Mexicano del Seguro Social-Bienestar*) (IMSS-Bienestar). In collaboration with the Ministry of Health, IMSS-Bienestar will be the decentralised entity in charge of providing free health services, medicines, and other supplies to people without social security in Mexico. IMSS-Bienestar will participate in the consolidated contracting procedures for the acquisition and distribution of medicines and other health-related supplies, under the terms provided in the Public Sector Acquisitions, Leasing and Services Law and other applicable provisions.

On 1 July 2020, as a result of the entry into force of the United States-Mexico-Canada Agreement (USMCA), the new Federal Law for Protection of Industrial Property (new IP Law) was enacted. The new IP Law represents an important legislative change, as it aims to align domestic law with the standards set by the trade and cooperation agreements signed by Mexico in recent years. It came into force on 5 November 2020 and amendments to the health laws to reflect this are expected in the near future.

2. Give a brief overview of key life sciences funding issues in your jurisdiction.

The Mexican financial market offers many alternatives for life sciences funding through:

- Financial institutions including banks, savings and loan associations, FinTechs, specialised banks, and credit unions.
- Specialised institutions, for example, leasing, finance, and factoring companies, and non-bank financial institutions.

All types of private funding are available, including venture capital, private equity, incubators, and crowdfunding. Government funds and financing are also available with financial aid, tax incentives, and sponsorship programmes for small and medium-sized companies involved in certain industries and sectors.

The most common sources of life sciences financing in Mexico are:

- **Banks.** Banks are the most important suppliers of funds to business. Banks offer short, medium, or long-term loans. The rate of interest can be fixed or variable. In some cases, short-term bridging loans are available. These loans are often conditional on companies meeting certain requirements, for example, executing notes and formal loan agreements, providing personal guarantees and audited financial statements, or providing mortgages over real estate owned and business assets.

  Banks can also offer foreign investors one of the following options, in financial agreements:

  - credit instalments;
  - leasing; and
  - factoring and invoice discounting.

  Multiple Purpose Financial Companies (*Sociedad Financiera de Objeto Multiple*) (SOFOM) are non-bank financial institutions that provide financing through direct loans, microfinance, payroll discounted loans, financial leasing, and factoring. They do not need to obtain authorisation from the Ministry of Finance to carry out business operations. However, they cannot receive savings funds from the public, as they are not banking institutions.

- **Government.** The government offers finance and funding programmes through the small company investment scheme, which supports small and medium-sized companies (*pequeña y mediana empresa*) (PyMEs), through low-rate financing. To be eligible for these programmes, the company must be incorporated in Mexico, have its taxable income in Mexico and carry out a qualifying trade and purpose.

Pricing, Government Funding, and Reimbursement

National Health Care System

3. What is the structure of the national health care system, and how is it funded? Briefly explain how pharmaceuticals are introduced into that system.

Structure and Funding

The Ministry of Health (*Secretaría de Salud*) governs the health care system in Mexico. The Mexican health care system comprises public and private institutions, insurers, and independent professionals.

The public sector comprises:

- Social security institutions exclusively for officially registered workers, which are funded by contributions from the federal government, employers, and employees, including:
    - the Mexican Institute of Social Security (*Instituto Mexicano del Seguro Social*) (IMSS), which administers social security for the self-employed and employees in private companies;
    - the Institute of Social Security for State Workers (*Instituto de Seguridad y Servicios Sociales de los Trabajadores del Estado*) (ISSSTE);
    - specialised public institutions for members of the military and navy; and
    - PEMEX Medical Services, for Mexican petroleum workers.

- Public institutions exclusively for people not covered by social security, which are funded by the federal government and states (although in certain cases patients may be required to contribute, taking into account their financial means and the cost of services).

The public health sector often faces financial problems and implements measures to limit costs by, for example, pressing for price reductions in consolidated public tenders (involving the most important health institutions) and encouraging competition.

Individuals and private insurers fund the private sector. Private health insurance generally covers professional, executive, and higher levels of the private sector. According to official figures, up to 50% of annual health spending in Mexico comes from out-of-pocket expenses related to private doctors, insurance, and drug acquisitions.

On 30 May 2023, the Decree reforming, adding, and repealing various provisions of the General Health Law, to regulate the Health System for Welfare, came into effect. It disestablishes INSABI, providing that the functions of INSABI will become part of IMSS-Bienestar (see *Question 1*).

Interaction of the Life Sciences Industry with the Health Care System

In the public sector, social security and public institutions provide medicines directly to the public at no cost.

Social security institutions, for example, the IMSS and ISSSTE, are responsible for delivering medicines to their beneficiaries. After a medical appointment, the treating doctor delivers a prescription with a validity period that varies depending on the type of condition. To obtain medication free of charge, the patient must present a valid prescription to the pharmacy of the institution itself or any pharmacy designated by the institution.

Public health institutions for people who do not have social security, aim to deliver free medical care and medicines, although patients may be required to contribute personally under certain conditions.

Price Regulation and Reimbursement

4. How are the prices of medicinal products regulated? When is the cost of a medicinal product funded by the government or reimbursed? How is a pharmacist compensated for dispensing services?

Price Regulation

Price control in the private sector is based on a scheme of self-regulated maximum retail price (MRP) covering patented products, which is overseen by the Ministry of Economy (*Secretaría de Economía*). Pharmaceutical companies' participation is voluntary. Under the price control scheme, each product's MRP must not exceed an international reference price, estimated as the average price in six major markets, plus a market factor. There are no established sanctions for violations of the MRP.

During public tenders, the convening authority conducts market research and submits requests for quotations to private companies and UNOPS (in connection with the international referencing of drug prices).

Reimbursement

Commonly, public insurers dispense medicinal products prescribed by their health care professionals. Products are prescribed from a basic medicinal products list, which public insurers essentially base on the National Compendium of Health Supplies issued by the Ministry of Health. Public insurers acquire those listed products mostly through public tender processes. The IMSS is the largest public sector buyer of drugs.

For direct purchasing of patented products, the Committee for the Negotiation of Drug Prices (CNDP) analyses:

- The effectiveness of the products and relevant therapeutic alternatives.
- The feasibility and implications of an eventual substitution with equivalent medicines.

The CNDP also conducts an economic evaluation of the cost-effectiveness of patented medicines compared with those potential substitutes.

For persons covered by the ISSSTE, a prescribed medicinal product can be dispensed in a private drug store registered with the public insurer, provided that it is not available within ISSSTE facilities and under certain conditions. The ISSSTE reimburses the cost of that product according to previous agreements.

In the private sector, most payments are made on an out-of-pocket basis. Private insurers are currently improving the level of pharmaceutical coverage as the private market in medicines has grown considerably.

Pharmacist Reimbursement

In the public sector, the ISSSTE is the only social security institution that expressly regulates reimbursement of health services. Although reimbursement for medications is not expressly mentioned, depending on the case and circumstances, pharmaceutical products are considered included within the health services for which reimbursement can be requested.

A Request for Reimbursement for Extra-Institutional Medical Expenses is submitted using the format available for these purposes**,** meeting the requirements in the ISSSTE Regulation of Medical Complaints and Reimbursement Requests. The request must be submitted within two years from the date the events occurred. The ISSSTE usually responds within about 115 business days from the filing of the request.

Private health services vary depending on whether or not the patient has private health insurance, the chosen hospital unit, the insurer, and the coverage of the chosen policy.

Distribution and Sale

5. Who is authorised to prescribe and supply medicines to patients or consumers? Who is authorised to distribute prescription medicines and over-the-counter medicines?

Medicines must be made available through authorised pharmacies and can only be sold to patients with a physician's prescription, except for specific over-the-counter products that can be marketed in various types of establishments.

Pharmacies must obtain a sanitary authorisation from COFEPRIS. This certifies that the pharmacy complies with the current sanitary requirements for the commercialisation and dispensing of medicines and health supplies, to preserve the safety, quality, and efficacy of products until they reach patients.

6. How is the wholesale distribution of medicines regulated?

Wholesale distribution is not independently regulated in Mexico. Therefore, any company dedicated to the commercialisation and wholesale distribution of medicines must comply with the main legislation for pharmaceuticals and procurement of medicines:

- The General Health Law (*Ley General de Salud*).
- The General Health Law Regulations (*Reglamentos de la Ley General de Salud*).
- The Health Supplies Regulation (*Reglamento de Insumos para la Salud*).
- The Official Mexican Standards (*Normas Oficiales Mexicanas*) (NOMs).
- The Public Sector Procurement, Leasing, and Services Law (*Ley de Adquisiciones, Arrendamientos y Servicios del Sector Público*).

7. Which regulatory authority supervises the distribution of medicines? What are the consequences of non-compliance with the medicine distribution laws?

Regulatory Authorities

The Ministry of Economy and the Ministry of Health supervise the distribution and commercialisation of pharmaceuticals, and set the maximum prices for the sale of medicines and supplies to the public (General Health Law). In addition, the Ministry of Finance and Public Credit (*Secretaría de Hacienda y Crédito Público*) determines prices for goods produced by the public sector.

COFEPRIS is responsible for the control and surveillance of all aspects related to sanitary regulation, including the distribution and commercialisation of pharmaceuticals. COFEPRIS can make on-site inspection visits of the manufacturing, distribution, or storage facilities, to:

- Verify that their products meet the approved specifications and do not represent a risk for the public health.
- Ensure that good manufacturing practices, stability, pharmacovigilance, and labelling standards are complied with.

Consequences of Non-compliance

COFEPRIS can initiate legal proceedings to sanction non-compliance. COFEPRIS can implement measures such as:

- Seizure of products.
- Ordering partial or total suspension of activities, services, or adverts.
- Under certain conditions, revoke any approval and/or impose sanctions, ranging from a fine of up to 16,000 times the applicable unit of measure (about USD 80,000).

- to closure of the establishment.

The imposition of administrative sanctions does not exclude civil and criminal liability. Repeated infringement is also considered a criminal offence.

Sanctioned parties can appeal COFEPRIS decisions, through the administrative or judicial channels.

Cross-Border Trade and Parallel Imports

8. What are the main requirements to import medicinal products into your jurisdiction? Are parallel imports of medicinal products into your jurisdiction allowed?

Import Requirements

As a rule, all medicines must have a marketing authorisation to be manufactured and commercialised in Mexico (General Health Law and Health Supplies Regulation).

In certain circumstances (for example, in relation to clinical trials and orphan drugs), import of a small quantity of products without a marketing authorisation can be approved. COFEPRIS can also grant permission for the import of finished products that do not have a marketing authorisation in the following cases:

- When required by a contingent event.
- When required by health policy.
- For the purposes of scientific research, registration, or personal use.
- For laboratory tests.

In January 2020, the Ministry of Health published an official administrative decree, establishing an expedited procedure for applications for marketing authorisation and import of medicines into Mexico (Equivalence Decree). The Equivalence Decree confirms that both:

- The requirements and evaluation procedures applied by various foreign regulatory health authorities to allow the sale, distribution, and use of allopathic and biological medicines are equivalent to those under the General Health Law, the Health Supplies Regulation, and other instruments.
- Compliance with these foreign requirements and procedures is sufficient to evidence the levels of quality, safety, and efficacy required to obtain a marketing authorisation in Mexico.

On 22 June 2021, the Ministry of Health published a Decree amending the Equivalence Decree. The Decree includes the following amendments:

- Regardless of the country of origin of a medicine, COFEPRIS must process marketing authorisation applications submitted in accordance with the decree within 45 working days. If COFEPRIS fails to provide a response within that time frame, the application will be presumed to have been denied.
- Mexican authorities can import medicines that do not have a marketing authorisation in Mexico, if this is necessary to guarantee the supply of medicines for the correct and timely provision of health services to the population. In this case, the foreign marketing authorisation holder or its legal representative must initiate the sanitary authorisation process with COFEPRIS within ten working days after import of the product. COFEPRIS must then decide on the application within 45 working days.

Parallel Imports

Patent holders can enforce border measures and the remedies provided by the Federal Law for the Protection of Industrial Property (*Ley Federal de Protección a la Propiedad Industrial*) (IP Law). If a generic application is approved while the corresponding patent is still in force, the patent holder or licensee can bring a court action against marketing approval and a patent infringement action to stop the manufacture and sale of the generic products.

In relation to trade marks, parallel imports are allowed if the product was legally introduced in the country of origin. The packaging and labelling of pharmaceuticals are governed by the General Health Law and the General Health Law Regulations, and require approval by COFEPRIS. Altering or modifying the authorised packaging or labelling of approved pharmaceutical products may be considered a criminal offence. The IP Law does not specifically address patents in this context. However, it is likely that the principle of exhaustion of rights also applies to patents.

Advertising

9. What is the main legislation and what are the regulatory authorities that control pharmaceutical advertising? Does the industry have a system of self-regulation based on industry codes of conduct? What are the main elements of that system?

The primary legislation for the advertising of medicinal products is the General Health Law and its Advertising Regulations (*Reglamento de la LGS en materia de Publicidad*) (RLGSMP). These are supplemented by guidelines published by COFEPRIS, which controls the advertising of medicinal products, and industry codes of practice.

The Council of Ethics and Transparency of the Pharmaceutical Industry (*Consejo de Ética y Transparencia de la Industria Farmacéutica*) (CETIFARMA) has issued the following self-regulatory codes:

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

Affiliate members of the National Chamber of the Pharmaceutical Industry (*Camara Nacional De La Industria Farmacéutica*) (CANIFARMA) must comply with these codes. CETIFARMA supervises members' and adherents' compliance.

There are also opinions issued by the Advertising Council, which includes representatives from the Ministry of Health, the academic and scientific communities, the business sector, the media, and consumer groups.

Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly, the Federal Law for the Protection of Consumers (*Ley Federal de Protección al Consumido*) and the IP Law.

10. Is there a definition of advertising or advertisement in relation to pharmaceuticals? What kinds of activities, channels, and communications meet those definitions (and are therefore subject to restrictions), and what falls outside (and is therefore permitted)?

Advertising is defined as an activity consisting of any process of creation, planning, execution, and circulation of adverts in media channels, to promote the sales or consumption of products and services. An advert is a message directed at the public or a section of the public, to inform them about the existence or characteristics of a product, service, or activity, for its commercialisation and sale or to influence action. (Article 2, General Health Law Regulations.)

In terms of the GPP Code, promotion means any activity undertaken, organised, or sponsored by a pharmaceutical company or under its authority (that is, by subsidiaries, foundations, associations, institutes, and agencies), that supports the prescription, dispensing, sale, and acquisition or administration of its medicines, complying with applicable rules, regulations, and standards.

11. Do companies have to set up internal procedures for managing and approving their advertising of pharmaceuticals?

The Code of Ethics and Transparency of the Pharmaceutical Industry requires CANIFARMA members to act in accordance with sound trading practices and in strict compliance with the prevailing legislation. Members must establish the proper measures and monitoring procedures to verify that their associated members comply with the applicable regulations.

12. Does pharmaceutical advertising have to be approved by a regulator?

Advertisements Directed at the General Public

Advertisements of medicinal products must be approved by COFEPRIS. An application for approval must include all details of the proposed advertisement. Companies can obtain a preliminary opinion on their advertisement from an authorised expert. This opinion can be filed with the approval application to speed up the process.

Only non-prescription medicines can be advertised to the general public, subject to approval by COFEPRIS (Article 310, General Health Law).

Any visual or audio advertisement must bear the words "Consult your physician" (Article 43, General Health Law Regulations). Advertisements must mention applicable precautions and contraindications (Article 43, RLGSMP).

The GPP Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture for the rational and appropriate consumption of medicines, encouraging the guidance of health care professionals authorised to prescribe.

Advertisements Directed at Health Care Professionals

Advertisements directed at health care professionals only need to be notified to COFEPRIS.

Advertisements directed at health care professionals can only be published in specialised media, and must be based on the approved prescription information of the corresponding medicinal product (Article 42, General Health Law Regulations).

13. Are there rules on comparative advertising that apply to pharmaceutical advertising?

Various provisions on comparative advertising apply to pharmaceutical advertising:

- **IP Law.** It is possible to use another company's brand name in advertising, if the comparison is intended to inform the public and is not tendentious, false, or exaggerated (Article 386 (III)).
- **Federal Law for the Protection of Consumers.** Unfair practices in comparative advertisements are penalised, including unfair use of trade marks, and a complaint can be filed before the Consumer's Bureau against these activities (Article 32).
- **Code of Ethics and Transparency of the Pharmaceutical Industry.** This requires members to compete fairly, avoiding unfair practices. Market competition must be fair and respect intellectual rights, or any other members' rights. Members must refrain from discrediting competitors or spreading any false or inaccurate information about their activities or products.
- **GPP Code.** Claims or comparisons must not be included in advertising, unless scientifically tested. All information, claims, or comparisons included in promotional material must be substantiated and fair. In particular, any comparison between different medicines must be scientifically justified and must comply with the regulations of fair competition standards. It must not be denigrating and comparisons must be grounded in equivalent elements and relevant evidence.

There are no specific provisions relating to references to a competitor's product that has not been approved in Mexico (and that does not have a well-known trade mark in Mexico). Therefore, it is advisable to submit the advertisement before COFEPRIS for an opinion or an authorisation.

14. Is it possible to share information about pharmaceuticals or indications that are unlicensed and is there a risk that this could be caught by advertising rules?

Information about an unlicensed product should not be provided to a private institution, as it is likely to be perceived as advertising of an unauthorised medicine.

Similarly, prescribing information for unlicensed products cannot be provided to health care professionals, as the authorisation to provide prescribing information is granted under the general marketing authorisation for the corresponding product.

Where the results of clinical trials are published in specialised or widely distributed magazines, pharmaceutical companies must request the authors to disclose any conflicts of interest (GPP Code).

Off-label information must be strictly limited to a scientific audience, avoiding the promotion, directly, indirectly, or through a third party, of any unauthorised directions of use.

15. Are there particular rules or issues with the use of the internet and social media for advertising pharmaceuticals?

General Health Law Regulations and COFEPRIS Guidelines

The General Health Law Regulations apply to any advertising activity, including advertising through electronic means and other forms of technological media. COFEPRIS monitors advertising on the internet.

COFEPRIS issued guidelines for digital advertising that apply to any product subject to monitoring or approval by COFEPRIS. These guidelines clarify that digital advertising campaigns must be approved by COFEPRIS before being used on any digital media.

It is recommended that companies adopt the proper measures to ensure the promotion of prescription medicines through electronic means is only accessible to health care professionals.

COFEPRIS has not yet regulated mobile medical applications.

CETIFARMA Codes

CANIFARMA member pharmaceutical companies must also comply with the following:

- Online promotion of prescription-only medicines addressed to health care professionals must be duly approved by the corresponding authorities (GPP Code).
- Advertising must be hosted on scientific websites and the sponsor must be clearly identified.
- Sound trading practices and strict compliance with the prevailing legislation (Code of Ethics and Transparency).
- Promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of health care professionals authorised to prescribe (GPP Code).
- Adopt the proper measures to ensure the promotion of prescription medicines on their websites will only be accessible to health care professionals. These websites must include a precaution stating that it is only addressed to health care professionals empowered to prescribe drugs.

16. What are the consequences of non-compliance with the rules on advertising pharmaceuticals? How are the rules enforced and by which authorities or organisations?

In response to non-compliance with the rules of advertising pharmaceuticals, the Ministry of Health, through COFEPRIS, can impose any or all of the following penalties:

- The suspension of any advertising activity. The responsible party and the media channel must comply with the order within 24 hours of issue.
- Warnings to companies to modify advertisements that are suspected to be in breach of the law. If an advertisement is not modified, or the modification is not adequate, COFEPRIS can suspend a company's advertising activities and impose a fine of up to 16,000 times the applicable unit of measure (about USD80,000).
- A fine (on the infringer or the media channel) up to 16,000 times the applicable unit of measure (about USD80,000).

COFEPRIS' decisions and orders can be appealed before COFEPRIS or the federal courts.

COFEPRIS constantly monitors advertising activities and is strict in imposing penalties. COFEPRIS has imposed large fines against specific over-the-counter medication manufacturers for using misleading advertising related to their products, inciting the public to self-medicate.

The General Health Law and the General Health Law Regulations both contemplate the possibility of a "people's action," which is a complaint filed before COFEPRIS regarding a breach of the law.

There is a co-ordinated effort between COFEPRIS and pharmaceutical companies to encourage self-regulation. In addition, CETIFARMA can supervise and impose monetary sanctions on its members in breach of its various codes.

Advertising to the Public

17. Which pharmaceuticals can and cannot be advertised to the public? What information must and must not be included in advertising of pharmaceuticals to the public?

Only non-prescription medicines can be advertised to the general public (Article 310, General Health Law).

The objective of the advertisements must be to inform the public about the products' characteristics, therapeutic properties, and form of use. The GPP Code requires that members' promotional activities directed towards consumers must be undertaken with the aim of generating a new culture with regard to the rational and appropriate consumption of medicines, encouraging the guidance of health care professionals authorised to prescribe.

Any visual or audio advertisement must bear the following message: "Consult your physician." Advertisements should mention applicable precautions, and whether the use of the medicine represents any danger in the event of an existing pathology.

18. Is it permitted to provide free samples to the public? Are there restrictions on special offers and other types of inducements?

General Health Law Regulations

The following rules apply:

- Providing free samples of products does not require approval, provided that the samples meet the requirements of the approved medicinal products (Article 49).
- The samples must be contained in a package with a lesser number of units than the approved product.
- It is not permitted to provide samples of prescription-only medicinal products to the general public.
- Samples must not be given out to minors.
- Samples must contain the wording "Not for sale."
- The sale of medical samples is a crime punishable with one to nine years in prison and a fine equivalent to between USD81,746 and USD204,355 (Article 464 ter).

GPP Code

The GPP Code establishes guidelines for sampling. It prohibits members from offering or supplying samples with the aim of seeking or rewarding prescription practices. It also prohibits any trade of samples.

Those providing samples must have full and up-to-date control over their samples, including in relation to their manufacture, storage, delivery to regional co-ordinators or others, and provision to medical representatives and physicians.

Engagement with Patient Organisations

19. What activities are permitted (or required) in relation to engagement with patient organisations? What restrictions apply?

Collaboration between the pharmaceutical industry and patient organisations must be subject to a written agreement including, at least:

- The activities to be undertaken, and the cost, source, and destination of funding.
- Direct and indirect support and any other relevant non-financial aid.

(GPP Code.)

Pharmaceutical organisations must follow their applicable guidelines, codes of ethics and conduct, transparent practices, and the deontological instruments approved by CETIFARMA and CANIFARMA. They must also provide criteria and procedures for the approval and implementation of these kinds of collaborations.

Advertising to Health Care Professionals and Organisations

20. What are the definitions of a health care professional and a health care organisation? What information must be included in advertising to them?

Health care professionals are defined as personnel who work in health institutions (for example, doctors, dentists, biologists, bacteriologists, nurses, social workers, chemists, psychologists, sanitary engineers, nutritionists, dieticians, and pathologists), who have a professional title or certificate of specialisation that has been legally issued and registered by the competent educational authorities.

Advertisements directed at health care professionals can only be published in specialised media, and they must be based on the approved prescription information relating to the corresponding medicinal product (Article 42, HLR). When promotional material refers to published studies, these must be faithfully reproduced or clear, easily accessible references must be given (GPP Code).

Medical and scientific departments must ensure that the information provided to health care professionals is accurate, balanced, fair and objective, and sufficiently complete to enable the recipients to form their own opinion of the medicine's therapeutic value (GPP Code). The departments have scientific and moral responsibility for the content of the information provided by them, or by others under an outsourcing agreement.

Gifts and Incentives

21. What are the restrictions on marketing practices such as gifts, sponsoring, consultancy agreements or incentive schemes for health care establishments or individual medical practitioners?

Health care professionals in government institutions must not request, accept, or receive any gifts or donations from persons whose commercial or industrial activities are directly linked to, or regulated or supervised by, government officers (Article 47, Federal Law on Responsibilities for Government Officers). This also applies to doctors working for the IMSS or ISSSTE.

The General Health Law and the General Health Law Regulations do not address doctors in private practice, although they specify that private doctors must act according to professional ethics.

Providing free samples of products does not require approval, provided that the samples meet the requirements of the approved medicinal product. These samples must be contained in a package with a smaller number of units than the approved product (Article 49, General Health Law Regulations).

Companies must not provide doctors with goods or incentives of any kind to use, prescribe, purchase, or recommend a medicinal product, or to influence the result of a clinical trial (Article 4.9.1, Code of Good Practices of Advertising of CANIFARMA). The corresponding sanctions range from a warning to a fine.

CETIFARMA-affiliated companies must act responsibly in relation to sponsorships and donations. For example:

- No gifts of significant commercial value or incentives of any kind can be offered to health care professionals as an inducement to use, prescribe, purchase, or recommend a specific product or influence the results of a clinical study.
- No gifts, bonuses, pecuniary advantages, benefits-in-kind, or any sort of incentive can be offered or promised to health care professionals, administrative staff, or government employees involved in the cycle of prescription, purchase, distribution, dispensing, and administration of medicines (except for inexpensive promotional aids related to the practice of medicine or pharmaceutical activities).
- Samples must be provided directly, in fair amounts, and at no cost to health care professionals, so that they can become familiar with the products or to initiate a treatment.

(GPP Code.)

Similarly, the Code of Ethics and Transparency of the Pharmaceutical Industry indicates, in general terms, that companies should act responsibly in relation to sponsorships and donations.

Mexico does not currently have any anti-bribery laws to limit these practices, and there is no domestic legislation to regulate these cases beyond Mexico's jurisdiction. However, Mexico has ratified certain international treaties that regulate, and in some cases prohibit, these practices**.**

Transparency and Disclosure

22. Do pharmaceutical companies have to disclose details of transfers of value to health care professionals or health care organisations?

The General Health Law Regulations do not require pharmaceutical companies to disclose details of transfers of value to health care professionals, health care organisations, or patient organisations.

However, the GPP Code and the GPI Code allow CETIFARMA to require CANIFARMA members to record any valuable support given to health care professionals, institutions, or patient organisations. Members must provide information concerning donations granted, on a yearly basis, to be made available to the public to promote transparency.

The interactions of the pharmaceutical industry with health care professionals (including in relation to supporting studies, invitations to conferences, and other promotional activities), can generate conflicts of interest. In these cases, CETIFARMA should be consulted, to avoid uncertainty.

23. What are the consequences of non-compliance with the rules on marketing to health care professionals?

In the case of non-compliance with the rules on marketing to health care professionals, COFEPRIS can warn companies with approved products to modify advertisements. If not modified, or the modification is considered to not comply with the legal provisions, the Ministry of Health, through COFEPRIS, can impose either or both of the following penalties:

- The suspension of advertising activities. The order can be made to the responsible party or directly to the media.
- A fine up to 16,000 times the applicable unit of measure (about USD80,000).

CETIFARMA can impose monetary sanctions on CANIFARMA members who are in breach of the GPP Code or the GPI Code.

Patents

Conditions for Patentability

24. Provide a brief definition of a patent, the key legal requirements to obtain it and the law that applies.

Conditions and Legislation

Patent applications are regulated by the IP Law and its regulations.

Patentable inventions must meet all of the following requirements:

- Be novel.
- Result from an inventive step.
- Be industrially applicable.

Types of Patent Available

Products and processes can be the subject of patent protection under the IP Law. The Mexican Patent and Trademark Office (*Instituto Mexicano de la Propiedad Industrial*) (IMPI) grants patents protecting compounds, formulations, uses, and manufacturing processes for medicines.

New uses of pharmaceutical or biotechnological compounds or compositions are only patentable if they are not obvious to a person skilled in the art. Purpose-limited product and Swiss-type claims are accepted in practice to claim new uses.

Main Categories Excluded from Patent Protection

The following subject matter is not patentable in Mexico:

- Inventions whose commercial exploitation is contrary to public order or contravenes any legal provision, including those whose exploitation must be prevented to protect the health or life of people, animals, or plants, or to avoid serious damage to the environment. These include:
    - cloning procedures for human beings and their products;
    - procedures for modifying the germinal genetic identity of human beings and their products, when they imply the possibility of creating a human being;
    - uses of human embryos for industrial or commercial purposes; and

    - procedures for modifying the genetic identity of animals that cause suffering without substantial medical or veterinary utility for humans or animals.

- Plant varieties and animal breeds, except micro-organisms.
- Essentially biological processes for obtaining plants or animals, and the products resulting from these processes.

The following are not considered inventions in Mexico:

- Discoveries, scientific theories, and principles.
- Mathematical methods.
- Literary, artistic works, and other aesthetic creations.
- Schemes, plans, rules, and methods for the exercise of intellectual activities, games, commercial activities, or the conduct of business.
- Computer programs.
- Presentations of information.
- Biological and genetic material, as found in nature.
- Medical procedures and therapeutic methods (although a patent can be obtained for a therapeutic method by drafting the claims in a Swiss-style format, that is, claiming the medical use of the compound for the treatment of a specified illness).
- Juxtapositions of known inventions or combinations of known products, or alterations of the use, form, dimensions, or materials of those inventions or products, except where:
    - they are so combined or merged that they cannot function separately; or
    - their particular qualities or functions have been so modified as to produce an industrial result or use that is not obvious to a person skilled in the art.

Specific Provisions for the Life Sciences Industry

Regulations of the new IP Law are pending (see above, *Types of Patent Available*).

Registering a Patent

25. Which authority registers patents? Briefly outline the key stages and timing in obtaining a patent.

Patent Registration Authority

Applications must be filed with the *IMPI*. Details on the application procedure and government fees are available in Spanish on the IMPI's website.

Process and Timing

Generally, it takes three to six years to obtain a patent in Mexico, depending on the field of technology.

Application. A patent application contains a statement that must include all of the following:

- A description of the invention that is sufficiently clear and complete to allow it to be fully understood, and to guide any person knowledgeable in the field.
- The best method known by the applicant for putting the invention into practice.
- Drawings required to understand the description, when necessary.
- A claims chapter, which must be clear and concise, and must describe the concept of the invention without overlapping with the description.

If the application is filed in English, a Spanish translation must be filed within two months from the filing date.

For applications under the Paris Convention for the Protection of Industrial Property 1883 (Paris Convention), a certified copy of the priority right document must be filed within three months from the filing date.

Formal examination and clarifications. The IMPI conducts a formal examination of the documents and can order clarifications or further details, or that an omission be remedied. The IMPI usually issues an official communication to request any outstanding documents four to six months after filing. The applicant has two months (plus two additional months on payment of extra fees) to comply with a request. If the applicant fails to comply, the application is deemed abandoned.

After all the formal documents have been filed, the IMPI issues an official communication that covers any priority claimed, when applicable. An abstract of the application is published in the *Official Gazette* 18 months after filing of the priority claim, or if no priority is claimed, 18 months from the filing date.

Examination on the merits of the invention starts automatically after the corresponding fees are paid on filing of the application.

Within the two months following the publication of the patent application, third parties can file information related to the patentability of the invention with the IMPI. This does not suspend the application process and the IMPI has discretion whether to consider the information filed. A third party is not considered a party to the patent prosecution and does not have access to the patent file or immediate legal standing to challenge a granted patent.

Grant. An official decision on the application is issued about three to six years after the filing date, either requesting amendments to the claims (for example, clarification regarding novelty), or granting the protection sought and requesting payment of the final IMPI fees, together with payment of the first five annual fees.

After a patent is granted, anyone can inform the IMPI of causes of invalidity, including third parties. The IMPI can consider this information to initiate cancellation proceedings.

Patent Prosecution Highway (PPH). The IMPI has implemented PPH pilot programmes to recognise examinations by the:

- United States Patent and Trademark Office (USPTO).
- Japanese Patent Office (JPO).
- Spanish Patent and Trademark Office.
- Korean Intellectual Property Office.
- State Intellectual Property Office of China.

These programmes are an attempt to accelerate pending applications.

Parallel patent grant (PPG). On 7 December 2020, the USPTO and IMPI announced the launch of a PPG initiative. This allows for patents to be granted in Mexico based on published US patents. The aim is to expedite the examination of Mexican applications for which there is a corresponding US patent, and therefore reduce application processing times.

While an applicant must request to benefit from the PPH before the issuance of a first office action, the IMPI will directly invite applicants to participate in the PPG. If the applicant agrees, they must pledge to claim the same matter that is covered by the corresponding US patent. However, the Director of the IMPI has stated that applicants will still be able to request participation in the PPG programme. The specific procedures for requesting and inviting participation in the programme are yet to be determined.

Length of Patent Protection

26. When does patent protection start and how long does it last? Can monopoly rights be extended by other means?

Duration

The term of a Mexican patent is 20 years from the filing date of the patent application in Mexico. For Patent Cooperation Treaty 1970 (PCT) applications, the effective filing date is the date of filing of the international patent application.

Extending Protection

The new IP Law allows patent owners to request an extension of their patent term to compensate for delays during prosecution. This only applies to patents that are filed and granted after 5 November 2020.

Under the new system, a complementary certificate can be granted when both:

- There are unreasonable delays directly attributable to the IMPI.

- The patent was granted more than five years after the application filing date of in Mexico.

The validity of a complementary certificate cannot exceed five years. The IMPI determines the period that corresponds to an unreasonable delay (based on one day for every two days of unreasonable delay). A complementary certificate takes effect the day after the expiration of the original 20-year patent term and confers the same rights as the patent from which it derives.

Under case law, it may be possible to extend the term of patents due to unjustified delays during patent prosecution under the old IP law. However, this only applies to the parties to the case and does not bind the IMPI. Therefore, it is expected that the IMPI will not extend the term of patents for unjustified delays without a court order. The decision is not binding on Mexican courts, but is highly persuasive.

The USMCA provides for the extension of patent protection in cases of unreasonable curtailment of the effective patent term, due to the time taken to obtain marketing approval. However, this mechanism has not been implemented into national law.

Patent Infringement

27. What rights does a patent grant to its owner? On what grounds can a patent infringement action be brought? What are the main defences to a patent infringement action? How is a claim for patent infringement made and what remedies are available?

Rights Granted by a Patent

The IP Law grants patentees the right to the exclusive exploitation of the patented invention and to exclude others from making, using, offering for sale, or importing the protected invention.

Grounds for Patent Infringement

In a patent infringement action, the claimant must prove either of the following:

- Unauthorised production, offer for sale, or import of the patented invention. If a claimant claims infringement of a patented process, the defendant must prove use of a process other than the patented process.
- Unauthorised use of the patented invention. The claimant must prove that the patent claim or claims cover the alleged infringing product or process. The IP Law only recognises literal infringement, meaning that the infringing product or process must fall within the literal scope of the claim(s). There is no doctrine of equivalence. The scope of the claims is determined by their wording, aided by the description and drawings.

The IP Law does not recognise a contributory infringement doctrine.

In November 2016, the First Circuit Court issued a non-binding isolated opinion that peripheral interpretation, based on identity or equivalence, constitutes a method for establishing infringement.

Defences to a Patent Infringement Action

Defences to a patent infringement action include:

- The manufacture, import, or use of the patented invention was for purely experimental, trial, or teaching purposes, or scientific or technological research activities, in the private or academic sphere and for non-commercial purposes.
- The use, manufacture, offer for sale, or import of a patented product, was exclusively to generate the tests, information, and experimental production necessary to obtain marketing authorisation of medicines for human health.
- The invention had already been lawfully introduced into commerce in Mexico.
- The use or manufacture of the invention, or the necessary preparations to carry out its use or manufacture, were initiated before the filing date of the patent application or recognised priority.
- The invention was used in transport vehicles from other countries, when they are in transit in Mexico.
- In the case of patents related to living matter, the patented invention was used as an initial source of variation or propagation to obtain other products (unless the use is made repeatedly).
- In the case of patents related to products consisting of living matter, the patented invention was used, put into circulation, or marketed, for purposes other than multiplication or propagation, after it was lawfully introduced into commerce by the owner of the patent, or the person granted a licence.

International IP Treaties

28. Is your jurisdiction party to international treaties that facilitate the recognition of foreign IPRs in your jurisdiction?

General

WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Patents

Patent Cooperation Treaty 1970 (PCT).

Trade Marks

WIPO Madrid Agreement Concerning the International Registration of Marks 1891.

Paris Convention for the Protection of Industrial Property 1883.

Trade Marks

Legal Requirements to Obtain a Trade Mark

29. Provide a brief definition of a trade mark, the key legal requirements to obtain it, and the law that applies.

The IP Law and its Regulation regulate trade marks in Mexico.

A trade mark is any sign that both:

- Is perceptible by the senses and capable of being represented in a way that allows determination of the clear and precise object of protection.
- Distinguishes products or services from others of the same type or class in the market (Article 172, IP Law).

As long as they meet the above requirements, trade mark protection is also available for:

- Non-visible signs, for example, smell marks and sound marks.
- Certain animated marks, for example, holograms.
- Trade dress.

(IP Law.)

Registering a Trade Mark

30. Which authority registers trade marks? Briefly outline the key stages and timing to obtain a registered trade mark.

Trade Mark Registration Authority

Applications must be submitted to the *IMPI*.

Details on the application procedure and government fees are available in Spanish on the IMPI's website.

Process and Timing

Application. A trade mark application must include the following information:

- The applicant's full name and address.
- A representation of the trade mark (graphic elements that are not part of the mark must be indicated by dashed or dotted lines).
- A description of the goods or services covered.
- Information on use in commerce in Mexico. Non-use applications are allowed, as use in commerce is not a requirement to obtain registration in Mexico. However, if the trade mark is already in use in Mexico, it is recommended the applicant provides the full date of first use of the mark (day, month, and year). This information will enable the applicant to have priority rights over other applicants who intend to challenge the registration based on use of a similar mark covering similar goods or services.
- The applicant's factory address, business address, or commercial establishment (if the mark is in use in Mexico).
- Convention priority (where applicable). If convention priority is claimed, the applicant must indicate the jurisdiction of the priority application, application number, date of filing, and exact description of the goods and services covered.

Formal examination. A formal examination is undertaken, which checks compliance with the formal legal requirements (for example, the official application form must be duly completed and the government fees paid). If any formal information or documents are missing, or if the products or services are not correctly classified, the IMPI will give the applicant two months to remedy the defect(s). (This period can be automatically extended for a further two months.)

Second examination. A second examination of the registrability of the mark (without evidence of use) is undertaken, to establish whether it complies with the legal conditions for registration. The examiner considers both relative grounds for refusal (prior rights) and absolute grounds for refusal (inherent registrability of the mark). If there are any objections to registrability, the IMPI gives the applicant two months to remedy the defect(s). (This period can be automatically extended for a further two months.)

It generally takes four to seven months for the IMPI to conduct both examinations.

Publication and opposition. Filed applications are published for opposition in the *Industrial Property Gazette* within ten working days of receipt of the application. If an opposition is filed, the applicant must file a response within four months of service of the opposition. If no response is filed, the registration application is considered abandoned. The party that filed the opposition cannot later file an invalidity action against the registered trade mark on the same grounds and based on the same evidence.

The deadline to file final arguments in opposition proceedings is five days from notification by the IMPI. If the application filing date changes during the prosecution of a trade mark application for any reason, the application is published again for opposition purposes.

Registration and cost. If there are no requests for further information, and no oppositions or objections to registration, the average cost for obtaining a Mexican non-priority trade mark registration is about USD800.

Competition Law Issues

Competition Authorities and Legislation

31. Briefly outline the competition law framework in your jurisdiction and how it impacts on the pharmaceutical sector.

Competition Law and Main Provisions

The main legislation is:

- The Economic Competition Federal Law (*Ley Federal de Competencia Económica*) (ECL).
- The ECL Regulations (*Reglamento de la Ley Federal de Competencia Económica*).
- The Administrative Rules (*Disposiciones administrativas de carácter general reglamentarias*).

Competition Authority

The *Federal Economic Competition Commission* (*Comisión Federal de Competencia Económica*) (COFECE) enforces the competition legal framework in Mexico. This is an administrative agency with technical and operational autonomy. It is related to the Ministry of Economy (but is not supervised by it).

The COFECE has statutory authority to review practices by pharmaceutical companies. In 2010, the COFECE imposed a fine on six pharmaceutical companies for anti-competitive practices in public tender proceedings organised by the IMSS. The COFECE is currently conducting an investigation into alleged irregularities in the market for the production, distribution, and marketing of medicines.

32. Has pharmaceutical competition case law in your jurisdiction focused on any key areas?

The Ministry of Public Function (SFP), which has the power to impose fines on companies for acts of corruption or bad practices, has prohibited certain drug distributors from participating in public contract tenders for allegedly monopolising purchases from Mexico's social security institutes.

Commercial Contracts and Competition Law

33. Briefly outline the competition issues that can arise in relation to commercial contracts and other business arrangements relating to medicinal products.

Restrictive Agreements and Abuse of Patent Rights

An action can be brought before the COFECE against activities falling outside the scope of a patent, for example:

- Non-compete agreements for products that are not covered by the patent claims.
- Product tying.
- Unfair competition (for example, advertising that a product is better than an alternative for the sole reason of it being covered by a patent).

Actions can also be brought before the COFECE for other forms of abuse of patent rights, for example, clearly unfounded attempts to enforce a patent.

Compulsory Licensing

After three years from the date of grant of the patent or four years from the filing date, whichever is later, any person can request the grant of a compulsory licence from the IMPI when a patent has not been used in Mexico, except where there are justified reasons for non-use.

A compulsory licence will not be granted when either:

- The patent holder or a licensee has been importing the patented product or the product obtained by the patented process.
- A licensee has worked the patent, provided that the licence is recorded with the IMPI.

A party applying for a compulsory licence must have the technical and economic capacity to efficiently work the patented invention.

Before the grant of the first compulsory licence, the IMPI gives the patentee the opportunity to begin working the patent within one year from the date notification. If the patentee does not work the patent within that time frame, the IMPI will decide on the grant of a compulsory licence following a hearing with the parties. If the IMPI decides to grant a compulsory licence, it sets out its duration, conditions, field of application, and amount of royalties to be paid to the patent holder. The royalties are determined by the IMPI after a hearing with the parties. Royalties must be fair and reasonable.

There have not been any compulsory licences granted in recent years.

Licensing Approvals and Formalities

34. Does a patent or trade mark licence and payment of royalties under it to a foreign licensor have to be approved by a government or regulatory body? Are there any formalities or other requirements to make the licence enforceable?

There are no restrictions on licensing or transferring patents to foreign parties. There are no restrictions on intellectual property transfers for inventions funded, or partially funded, by public investment.

There is no requirement for a patent or trade mark licence and payment of royalties under it to a foreign licensor to be approved by a government or regulatory body.

Recording a patent or a trade mark licence is not mandatory and the agreement is enforceable between the parties regardless of recordal. However, to be enforceable against third parties, and to ensure the title holder can use the trade mark or patent, the licence must be recorded with the IMPI (IP Law).

Product Liability

Regulators

35. Outline the key regulators and their powers in relation to medicinal product safety.

COFEPRIS's monitoring is focused, among other things, on:

- Ensuring compliance with good manufacturing practices.
- Ensuring that activities performed do not exceed either authorised limits or differ from authorised activities.
- Ensuring that companies perform validation analyses of their manufacturing processes and systems.

(General Health Law Regulations and NOMs.)

In cases of potential non-compliance, COFEPRIS has statutory authority to:

- Evaluate them *ex officio*, granting procedural rights to those involved.

- Inspect at reasonable times, subject to reasonable limits and in a reasonable manner, any place where products are manufactured, packed, or held for marketing.
- Impose measures to prevent harm, for example, seizure and orders to recall products and adverts.
- Impose fines of up to 16,000 times the applicable unit of measure (about USD80,000).
- Revoke marketing authorisations and other approvals.

The imposition of administrative sanctions does not exclude civil and criminal liability.

In co-ordination with COFEPRIS, the Federal District Attorney's office (FGR) can:

- Investigate and prevent the commercialisation of illegal medicines.
- Implement measures to protect public health, for example, the seizure of products.

The Federal Agency for the Protection of Consumers (*Procuraduría Federal de Protección al Consumidor*) (PROFECO) can start proceedings for violations of NOMs.

COFECE can conduct investigations on many aspects related to the manufacturing and commercialisation of medicines, and carry out inspection visits on requests of individuals or on its own initiative. After conclusion of the investigation stage, COFECE determines whether to close the case or to start administrative proceedings. In both cases, COFECE can impose preliminary injunctions. The affected party can claim damages before a court. Follow-on private litigation against manufacturers is possible, but not common. Additionally, COFECE can file criminal complaints.

Medicinal Product Liability Law

36. Outline the key areas of law applicable to medicinal product liability, including key legislation and recent case law.

Legal Provisions

Generally, liability arises from federal or local civil codes. Liability can also arise from violations of statutory provisions. The NOM for good manufacturing practices of medicinal products (NOM-059-SSA1-2015) also contains provisions regarding liability. The Federal Consumer Protection Law allows class actions.

Substantive Test

Liability claims are mainly regulated by statutes rather than court precedents. Therefore, there is no clear substantive test. The standards to determine damages are high. According to precedents from the federal courts, the causal nexus between actions/omissions and damage must be fully proved.

Liable Parties

37. Who is potentially liable for defective medicinal products?

All persons involved in selling or distributing medicinal products can be liable in civil actions for harm derived from defective medicinal products. The marketing authorisation holder is responsible for the quality of the approved product (NOM-059-SSA1-2015). In addition, when manufacturing through third parties, the marketing authorisation holder must supervise the manufacturing of the product and establish in agreements the liabilities and duties of each party involved (NOM-059-SSA1-2015).

Defences

38. What defences are available to product liability claims? Is it possible to limit liability for defective medicinal products?

Available defences to product liability claims include:

- Statutes of limitations (ranging from two to ten years). Liability for any illicit action (excluding criminal offences) expires after two years (Civil Code).
- Assumption of risk and contributory negligence.

Liability for defective medicinal products cannot be excluded.

Product Liability Claims

39. How can a product liability claim be brought?

Limitation Periods

Depending on the conduct and cause of action, the limitation periods range from:

- Two to ten years for civil actions.
- One to nine years for certain criminal actions.

Class Actions

The federal procedural laws were recently amended to allow class actions before the federal courts. PROFECO, the Attorney General's Office, non-profit associations, and a common representative of a group of at least 30 members can now pursue class actions. These amendments are subject to testing in the courts and there does not appear to be any precedent for class actions for product liability.

In addition, through a "popular action," any individual with or without legal standing can file a complaint with COFEPRIS on the ground that a product on the market poses certain health risks. However, the claimant's procedural rights are limited, and these actions are intended to remove a health risk, not to obtain compensation.

Remedies

40. What remedies are available to the claimant? Are punitive or exemplary damages allowed for product liability claims?

Preliminary injunctions can be ordered to stop the commercialisation and distribution of a product. Monetary compensation is the most common remedy, but equitable remedies are also available.

Punitive damages are not subject to regulation and there are no legal precedents for this.

Contributor Profiles

Alejandro Luna F, Partner

Olivares
T +52 55 5322 3080
E *alejandro.luna@olivares.mx*
W *www.olivares.com.mx*

Professional qualifications. Lawyer, Mexico

Areas of practice. IP litigation; alternative dispute resolution; regulatory law; anti-piracy; anti-counterfeiting; enforcement.

Recent transactions

- Participated in questioning the constitutionality of certain provisions of the Industrial Property Law and the Federal Copyright Law.
- Sponsor of an important proposal to modify the system of litigation and enforcement of intellectual property rights in Mexico.
- Spearheaded a ten-year litigation strategy that has incorporated regulation changes and lobbying, which has resulted in precedent for patent linkage regulations and life terms of pipeline patents in Mexico.

Non-professional qualifications. Universidad Latinoamericana, Juris Doctor, 1996; Franklin Pierce Law Center, LL.M., Intellectual Property Law, 2002; UNAM, Ph.D., 2020

Languages. English, Spanish

Professional associations/memberships. Part-time professor at the National Autonomous University of Mexico (UNAM).

Publications. Author of several articles on patents, litigation, and regulatory issues.

Armando Arenas, Partner

Olivares
T +52 55 5322 3000
E *armando.arenas@olivares.mx*
W *www.olivares.com.mx*

Professional qualifications. Lawyer, Mexico

Areas of practice. Pharmaceutical law; IP litigation; civil and commercial litigation; anti-piracy; anti-counterfeiting; enforcement.

Recent transactions

- Obtaining through litigation the correction of the life term of pharmaceutical patents granted under transitory Article 12 of the Law for the Promotion and Protection of Industrial Property, representing more than seven innovative companies.
- The declaration of infringement of patents that protect active ingredients, medical uses, pharmaceutical formulations, and production processes of biotechnological drugs, to maintain the market exclusivity of their clients.

- Obtained the nullity of marketing authorisations (more than seven successful cases) of generic medicines for violating the Mexican Linkage System for the benefit of patent holders that protect active ingredients, pharmaceutical formulations, and medical uses.
- Secured a judgment declaring the unconstitutionality of Article 167 bis of the Health Supplies Regulation, as it does not provide the right of the titleholder of a patent to be heard during the prosecution of the marketing authorisation.
- Successfully participated in civil actions for damages to obtain the payment of compensation for violating the Industrial Property rights of the clients.

Non-professional qualifications. National Autonomous University of Mexico (UNAM), Bachelor Degree, 1995

Languages. English, Spanish

Karla Paulina Olvera Acevedo, Associate

Olivares
T +52 55 5322 3000
E *karla.olvera@olivares.mx*
W *www.olivares.com.mx*

Professional qualifications. Lawyer, Mexico

Areas of practice. Pharmaceutical law; IP litigation and enforcement.

Recent transactions

- Legal advice to clients from different industries through the preparation and implementation of innovative strategies to protect their intellectual property rights in Mexico.
- Litigation related to patents, trade marks, unfair competition, and regulatory and administrative matters.
- Participated in the first case in Mexico in which it was decided to revoke the granting of a marketing authorisation of a medicine in violation of a formulation patent derived from the non-compliance by the regulatory authority of the existing linkage system between the granting of marketing authorisations and patents in force. Also involved in the first case in which the application of this system was recognised in relation to a use patent and its defence in public tenders.
- Involved in various litigations related to government procurement, data protection of biologics medicines, and in infringement actions involving those products and the granting of marketing authorisations for biocomparable medicines.

Non-professional qualifications. LLM International and European Intellectual Property Law, Trinity College Dublin, Ireland, 2017; Bachelor Degree, Universidad Iberoamericana, Mexico, 2010

END OF DOCUMENT