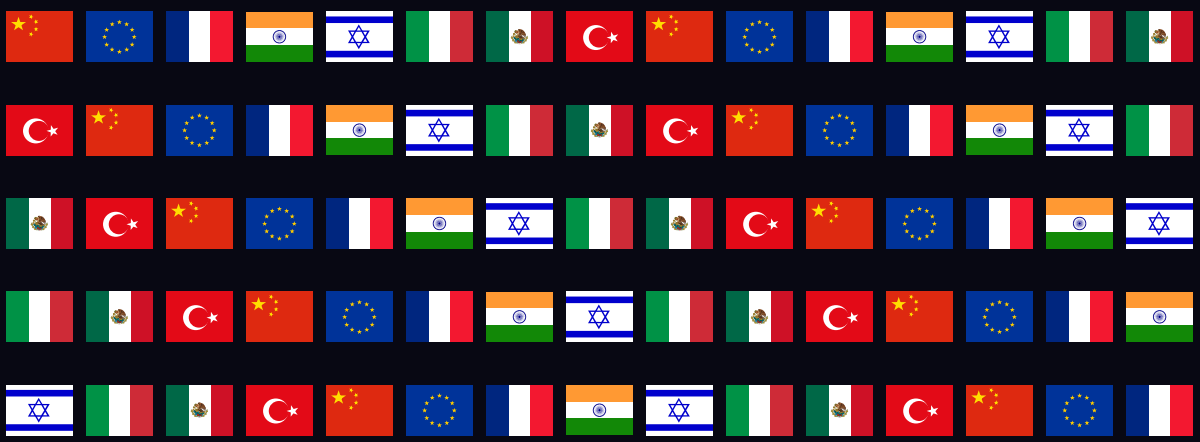
PHARMACEUTICAL TRADEMARKS

Mexico



LEXOLOGY
Getting The Deal Through

Pharmaceutical Trademarks

Quick reference guide enabling side-by-side comparison of local insights, including into key legislation, agencies and regulators; parallel imports; anti-counterfeiting and enforcement; advertising; generic substitution; and recent trends / prospects for future development.

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OVERVIEW

Legislation

What is the primary law governing trademarks in your jurisdiction?

The Federal Law for the Protection of Industrial Property Law (IP Law) and its Regulations govern trademarks practice in Mexico. Likewise, Mexico has acceded to the following international and multilateral treaties relevant to trademark protection:

- the Paris Convention for the Protection of Industrial Property Rights;
- the United States-Mexico-Canada Free Trade Agreement (NAFTA);
- the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS);
- the Madrid Protocol for trademark registration; and
- The United States-Mexico-Canada Agreement (USMCA).

On 1 July 2020, and as a result of the entry into force of the United States–Mexico–Canada Agreement (USMCA), which replaces the North American Free Trade Agreement (NAFTA), the new Federal Law for Protection of the Industrial Property was enacted and came into force on 5 November 2020.

Law stated - 31 October 2022

Agencies

Which agency is responsible for the grant and registration of pharmaceutical trademarks?

The exclusive right to a trademark is obtained through registration with the Mexican Institute of Industrial Property (IMPI), which is an administrative authority depending on the Ministry of Economy. All traditional and non-traditional trademarks (eg, scent, sound marks, holograms, etc), as well as trade dress can be protected, provided that they are sufficiently distinctive and can distinguish the goods or services to which they apply from others in the same class (article 172 of the new IP Law).

However, anyone applying for pharmaceutical trademarks must bear in mind that pharmaceutical products require market authorisation granted by another regulatory agency, depending on the Ministry of Health and the Federal Commission for Protection against Sanitary Risks (COFEPRIS), and therefore, the clearance work for choosing a pharmaceutical trademark must be conducted bearing in mind these two authorities.

Law stated - 31 October 2022

Regulators

What are the relevant national and international regulatory bodies and requirements that need to be considered when clearing a pharmaceutical trademark?

Manufacturers must obtain marketing authorisation to sell any medicine or certain medical devices. The relevant authority is COFEPRIS, which approves the names of medicines, referred to as ‘distinctive names’ in the Health Law and its regulations. To apply for marketing authorisation, the distinctive name of the product must be pre-approved by COFEPRIS (article 2, section IV of the Health Supplies Regulation).

The Health Law and the Health Supplies Regulation specify the requirements for distinctive names. The principal rules for the names of medicines are as follows:

- 'Distinctive name' means the name or trademark assigned to a pharmaceutical product in order to distinguish it from other similar products (article 2, section IV of the Health Supplies Regulations).
- In use and marketing, medicines must be identified by their distinctive and generic names (article 225 of the Health Law).
- The distinctive name must not refer to the composition of the product or its therapeutic action. Vaccines and biological products excepted, no indications may relate to diseases, syndromes, symptoms, anatomical data or physiological phenomena (article 225 of the Health Law).
- A proposed distinctive name will be rejected if it is identical to the previous name of another approved medicine (article 23 of the Health Supplies Regulation).
- Under the 'three-letters rule', the difference between the proposed name and the previous name should be at least three letters in each word to prove dissimilarity (article 23 of the Health Supplies Regulations).
- A distinctive name can be used for pharmaceutical products that have the same active ingredient and have been approved by the same laboratory but have different pharmaceutical forms or doses (article 23 of the Health Supplies Regulation).

There is no clear link between the IP Law and the Health Law and their regulations regarding conflicts between registered trademarks and marketing authorisations or distinctive names.

IMPI examiners usually consider the three-letter rule when analysing the similarity of pharmaceutical trademarks, although it is not binding on them. However, the Health Supplies Regulation do not require COFEPRIS to consider senior trademark registrations (for pharmaceutical products) when examining the similarity of distinctive names using its own software developed to apply the three-letter rule. This inconsistency has had unfortunate consequences, including contradictory decisions by IMPI and COFEPRIS regarding the likelihood of confusion of trademarks and distinctive names.

Further, IMPI and COFEPRIS have different databases. IMPI's database comprises all trademark applications and registrations that have been filed with the agency or its predecessors, while COFEPRIS' database contains only the distinctive names allowed for medicinal products, regardless of whether they are in use.

COFEPRIS' system enables pharmaceutical companies to obtain a pre-approval certificate for distinctive names, valid for 90 days, which is useful for any marketing authorisation. However, the system allows only 10 certificates to be granted per company and such certificates do not bind COFEPRIS, which can still reject marketing authorisation for a pre-approved distinctive name that COFEPRIS may ultimately consider is unacceptable. This rejection may be contested before the federal courts.

Confusion with INNs

Including international non-proprietary names (INNs) or their stems as part of pharmaceutical product trademarks creates conflicting situations.

The Health Law (article 225) expressly forbids the use of pharmaceutical trademarks that clearly resemble INNs, and the IP Law (article 173) prohibits registration of generic names. Accordingly, IMPI has no legal basis for refusal of a trademark that comprises a stem or an INN and additional distinctive elements that make the trademark registrable as

a whole.

INNs are generic and cannot be treated otherwise, which makes it impossible for IMPI to assess the likelihood of confusion between pharmaceutical trademarks and INNs.

IMPI thus faces a challenge in following the World Health Organisation's recommendations to safeguard the proper use of INNs and to avoid the registration of trademarks derived therefrom.

Law stated - 31 October 2022

Non-traditional trademarks

What non-traditional trademarks are available in your jurisdiction and how are they registered?

Pursuant to the IP Law amendments effective from 10 August 2018, trademark protection for non-traditional trademarks (eg, scent and sound marks, certain animated marks such as holograms and trade dress) have been incorporated for the first time in Mexico. Likewise, acquired distinctiveness will be recognised as an exception to the absolute grounds for refusal established in law.

The IP Law establishes that a trademark should be understood as 'any sign perceptible by the senses'. The only condition for the protection of such signs is that these are 'susceptible of being represented in a way that allows to determine the clear and precise object of protection'. No specific requirements have been issued at present for non-traditional trademarks, since said requirements are supposed to be included in the Regulations of the new IP Law; however, these regulations are yet to be published.

Law stated - 31 October 2022

Cannabis-derived products

Does your jurisdiction allow the registration of cannabis-derived products?

Yes, the Health Law and the Health Supplies Regulation provide the use of cannabis for pharmaceutical purposes. Additionally, on 12 January 2021, the Regulation on sanitary control for the production, research and medicinal use of cannabis and pharmacological derivative uses, was published in the Federal Official Gazette and entered into force one day after its publication.

Law stated - 31 October 2022

PARALLEL IMPORTS

Regulation

What are the rules governing parallel imports of pharmaceutical goods?

Any import of medicines, health or pharmaceutical products, or raw materials for such products, must be approved by COFEPRIS. Medicines must have marketing authorisation. Under certain circumstances (eg, clinical trials and orphan drugs), the import of a minimal quantity of products without marketing authorisation can be approved.

In relation to trademarks, parallel imports are allowed, provided that the product was legally introduced in the country of origin. The packaging and labelling of pharmaceuticals are governed by the Health Law and its Regulations and require approval by COFEPRIS. Altering or modifying the authorised packaging or labelling of approved pharmaceutical products can be considered a criminal offence.

Law stated - 31 October 2022

Strategies against parallel imports

What strategies are available to police and enforce against parallel imports?

In accordance with the IP Law, and subject to the analysis of the particular circumstances of the case, there is the possibility to file infringement actions on the grounds of unfair competition. However, the parallel importations (grey market goods) are not limited regarding trademarks and copyrights.

Another option to be explored is to file a complaint with the General Administration of Foreign Commerce Audit (AGACE), which is another regulatory agency related to the Tax Administration Service (SAT) in charge of verifying the compliance of the correct payment of all taxes and duties derived from the importation of goods into Mexico.

Once again, depending on the circumstances of the particular case, some grey market goods may evade the payment of taxes, which may open the door for AGACE to seize the imported goods, based on the lack of compliance of tax obligations. This action may be started through the filing of a complaint by any person, but the legal standing is then transferred to AGACE, which means that the person or company who filed the complaint will not have control over the activities that AGACE conducts and the resolution that it gets to adopt in connection with the grey market goods detected.

In the case of pharmaceutical products a complaint may also be filed with COFEPRIS, based on the lack of compliance to Health Law provisions, which may endanger consumer's health. However, as in the case of the complaints filed with AGACE, the legal standing is then transferred to COFEPRIS, which means that the person or company who filed the complaint will not have control over the activities that COFEPRIS gets to conducts and the resolution that it gets to adopt in connection with the infringing pharmaceutical products identified in Mexican market.

Law stated - 31 October 2022

ANTI-COUNTERFEITING AND ENFORCEMENT

Types of proceedings

What types of legal or administrative proceedings are available to enforce against infringing products?

A Trademark Enforcement database has been created, managed by Customs in coordination with IMPI, which contains the registered trademarks of owners interested in monitoring their rights at the 50 Customs checkpoints at the country's borders, ports, bus and train stations, and airports.

Regarding medicines, pharmaceutical substances, chemicals and active pharmaceutical ingredients (APIs), Customs' efforts are limited to detecting prohibited drugs and narcotics. The next step is to strengthen IP protection for patents within Mexico, particularly for those that protect pharmaceutical products.

Customs may collaborate with rights holders to detect and seize APIs based on IMPI-ordered border measures, initiated by the right holder. Thanks to cooperation between Customs and IMPI, bulk border seizures of patented APIs have taken place.

A trademark registration can be enforced against alleged infringers in two ways:

- if the infringer uses a confusingly similar or identical trademark for identical or similar goods or services, an infringement action can be brought before IMPI; and
- if the counterfeiter uses an identical trademark for identical goods or services, a criminal action can be brought before the Attorney General's Office.

Law stated - 31 October 2022

Remedies

What are the available remedies for infringement?

Infringement actions are filed before IMPI, which is an administrative authority rather than a court. Once admitted for prosecution, IMPI serves notice of the infringement action on the alleged infringer, granting it 10 working days to reply.

On request, IMPI can impose provisional injunctions before the filing of an infringement claim or during the prosecution of the case. For requesting the implementation of preliminary injunctions, a bond has to be posted and a prima facie case has to be presented before IMPI in order to show good appearance of law.

If the right holder decides to proceed with a provisional injunction, it will have 20 days after imposing these, to formally file the administrative infringement action.

The claimant and the alleged infringer must both submit evidence at the time of filing or responding to the claim. Subsequently, IMPI grants the parties a common term to file closing allegations. IMPI's decision is subject to appeal before the Federal Court for Administrative Affairs, whose decision can be further appealed before the Circuit Courts.

Infringers can incur penalties ranging from a fine of up to 250,000 units of measurement and updating (UMAs), in force at the time the offence is committed per infringement conduct, to closure of their businesses (article 388 of the IP Law).

The IP Law establishes that the damages awarded to the owner of an infringed IP right should not be less than 40 per cent of the sales of the infringing product at the consumer retail price.

Damages may be claimed at the choice of the affected titleholder once the administrative procedure has been completed, with:

- the Mexican Institute of Industrial Property (IMPI) through a special proceeding. Once IMPI has declared an administrative infringement and this decision is enforceable, the affected titleholder may file a damages claim as well as the corresponding quantification, exhibiting relevant evidence; and
- the civil courts, in accordance with the provisions of common legislation and without the need for prior declaration of infringement by IMPI.

Furthermore, The Federal Prosecutor at the Attorney General's Office also investigates IP crimes and can implement several injunctions, such as the implementation of raids related to IP rights crimes.

However, the right holder must file a criminal complaint to initiate a criminal action, so that the Federal Prosecutor may request the raid order from a criminal judge only in cases involving the counterfeiting of goods for which IP rights are held.

The criminal complaint filed by the right holder can be in the context of an investigation and, in certain cases, counterfeit goods can be seized without the implementation of a raid, but through a street seizure if they are publicly available. However, if they are stored on private property, a search or warrant order must be obtained from the criminal judge.

A raid may take place within 20 to 45 days, depending on the type of premises to be raided and its distance from the Attorney General's Office in which the right holder initiated the criminal action.

Indictments may be issued within 48 hours of execution of a search or warrant order if a person that is considered as the responsible of the commission of the crime is arrested. If during the raid, the federal prosecutor or the police did not identify any responsible party, the criminal investigation will continue until the authority obtains all the elements to indict the case. This could take between two months and two years. During all this time, the seized goods are stored in government warehouses.

Once the criminal investigation is indicted, the criminal judge will proceed with the first revision of the file to identify if all the elements are present and confirm that the case may move forward with a criminal trial.

Additionally, some administrative complaints may also be filed with COFERPIS and AGACE, on a case by case basis.

Law stated - 31 October 2022

Border enforcement

What border enforcement measures are available to halt the import and export of infringing goods?

We can implement criminal actions or administrative actions.

Mexican Customs are not empowered to proceed with the seizure of products, therefore, they will only initially seize the alleged infringing products during a five-day period, until the authority receives the notification from IMPI or from the Attorney General´s Office that a border measure injunction or a criminal case has been initiated.

In the case of the administrative actions taken with IMPI, they can be grounded on the infringement of trade dress, unfair competition, use of identical or similar trademarks, copyrights, patents, designs, among other IP rights. This will be the most complete action that a right holder can initiate because, we can implement said legal actions based on several IP rights.

However, regarding the criminal cases, we can only proceed when we identify an identical use of trademarks and copyrights. The type of action that the right holder could present will derive from the alert received by Customs and the enforceable rights in Mexico.

Law stated - 31 October 2022

Online pharmacy regulation

What rules are in place to govern online pharmacies?

Under the Health Regulations, medicines must be made available through authorised pharmacies and can only be sold to patients with a physician's prescription, especially antibiotics (except over-the-counter products).

Electronic advertising falls under the general advertising rules in article 2 of the Health Regulations. COFEPRIS has been increasing its monitoring of online ads for medicinal products, which traditionally have been less stringently monitored than television or radio ads.

Pharmacies must obtain permission to operate on health grounds and other stores are forbidden from marketing prescription medicines.

The Code of Good Promotion Practices requires the implementation of measures to ensure that the promotion of prescription medicines on websites is accessible only to healthcare professionals. Such websites must carry a warning, stating that they may be used only by healthcare professionals allowed to prescribe drugs.

Law stated - 31 October 2022

Recent cases

What are the most notable recent cases regarding the enforcement of pharmaceutical marks?

Recently our law firm has started a case on behalf of the holder of a registered pharmaceutical mark, against a manufacturer of non-branded drugs that is using the said registered pharmaceutical mark in its advertising campaign. Instead of correctly making reference to the API, the alleged infringer is stating in its advertising campaign that its product is the first non-branded product of the drug manufactured by our principal, but making reference to the registered pharmaceutical mark, which should be deemed an unfair competition activity, because by comparing trademarks and not APIs, it is taking advantage of the goodwill of the registered pharmaceutical trademark, and may also lead consumers to be mistaken or deceived, by making them believe that there is a relationship between the two products under comparison or that the non-branded product is being manufactured under specifications of the owner of the registered pharmaceutical mark.

This case is ongoing and must remain confidential, but it will be interesting to learn how IMPI interprets some concepts set forth in the provisions of the Mexican Health Law related to the generic and distinctive designation of pharmaceutical products, and their interaction with registered pharmaceutical trademarks.

Law stated - 31 October 2022

ADVERTISING

Regulatory bodies

Which bodies are responsible for oversight of pharmaceutical advertising in your jurisdiction (and what are their powers)?

The primary legislation for the advertising of medicinal products is the General Health Law (HL) and its Regulations (HLR). These norms are supplemented by guidelines published by COFEPRIS. This agency controls the advertising of medicinal products. Industry Codes of Practices complement this regulation. The Council of Ethics and Transparency of the Pharmaceutical Industry (CETIFARMA) has issued some self-regulatory instruments.

The latest versions of these Codes have been in force since 1 April 2013. Affiliate members of the National Chamber of the Pharmaceutical Industry must follow these Codes. CETIFARMA supervises members' and adherents' compliance. Additionally, other general legislation may be relevant for the advertising of medicinal products, particularly, the Federal Law for the Protection of Consumers and the Industrial Property Law. The most important rule to be considered in connection with consumer's protection is that information or advertising relating to pharmaceuticals that is disseminated through any medium must be true, verifiable and free of text, dialogue, sounds, images, trademarks, denominations of origin and other descriptions that induce or may induce an error or confusion because they are deceptive or abusive.

CETIFARMA's codes further require the provision of accurate and objective explanations of the characteristics, functions, advantages and disadvantages of pharmaceutical products and services.

Law stated - 31 October 2022

Advertising rules

What specific rules are in place regarding the advertising of pharmaceutical products?

Non-prescription medicines

According to the Health Law Advertising Regulations, only non-prescription medicines can be advertised to the general public, subject to approval by COFEPRIS. The media must require certified copies of the relevant marketing authorisations for the corresponding medicines before publishing or broadcasting related ads.

According to its internal guidelines, COFEPRIS does not approve ads comparing products with the same therapeutic indication or questioning the quality of products with marketing authorisation.

Prescription medicines

Prescription medicines can be advertised to healthcare professionals. However, this advertising can be done only through specialised media and must be based on medical prescription information.

The Code of Good Promotion Practices requires that the information provided to healthcare professionals be accurate, balanced, fair and objective, and sufficiently complete for them to form their own opinion of the therapeutic value of the corresponding medicine.

Monitoring

COFEPRIS can order the suspension of advertising activity in breach of the legal framework. The responsible party and the media channel must comply within 24 hours.

The penalties for failure to comply with the advertising rules are suspension of advertising activities by the responsible party or the media and a fine of up to 16,000 times the minimum wage (approximately US$76,800).

Law stated - 31 October 2022

GENERIC SUBSTITUTION

Legality

Is generic substitution permitted in your jurisdiction?

Yes, under the Health Regulations, a physician must prescribe medicines and biologics using their INNs and may choose to indicate the preferred distinctive name. Thus, patients may receive from the pharmacist any product with the same active ingredient.

A review of possible mechanisms to prevent automatic switching from biologic innovators to biosimilars in view of potential health issues is pending.

Additionally, promotional activities to consumers should inform the patient or consumer about the properties of the medicines he or she is using, of the importance of concluding the treatment prescribed by the physician, and about the risks of substituting the prescribed medicine for another one without knowledge and proper medical supervision.

Law stated - 31 October 2022

Regulations

Which regulations govern generic substitution by pharmacists of brand-name drugs?

The Health Supplies Regulation establishes the provisions applicable to the prescription of drugs.

Law stated - 31 October 2022

UPDATE AND TRENDS

Key developments and future prospects

What were the key judicial, legislative, regulatory and policy developments of the past year in relation to the protection and enforcement of pharmaceutical trademarks? What are the prospects for future developments?

On 1 July 2020, and as a result of the entry into force of the United States–Mexico–Canada Agreement, which includes favourable amendments related to pharmaceuticals and regulatory matters, the new Federal Law for Protection of the Industrial Property was enacted. The new IP Law represents an important legislative change as it is aimed at matching the domestic law with the standards set by the new trade and cooperation agreements signed by Mexico in recent years, and it came into force on 5 November 2020. Due to the above, amendments to the health laws are expected in the near future.

Law stated - 31 October 2022

Jurisdictions

China	Kangxin Partners PC
European Union	SKW Schwarz
France	Fiducial Legal By Lamy
India	LexOrbis
Israel	Gilat Bareket & Co, Reinhold Cohn Group
Italy	Studio Legale Jacobacci & Associati
Mexico	OLIVARES
Turkey	Moroğlu Arseven